# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 160407 **Seq:** 1 **Gender:** M
**Reported:** 05/01/2001 **Weight:**
**Hospitalisation:** **Age:** 36Y
**Onset Date:** 05/12/2000 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Visual field defect | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Vision disturb not defec sight
75.0 Milligram Daily
**Batch:** **Started:** 05/12/2000 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

No spilepsy in family ct - no clear problems. astymatic but no other visual defect in history.

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### Report Detail

**Case Number:** 160543 **Seq:** 1
**Reported:** 12/01/2001
**Hospitalisation:**
**Onset Date:** 09/01/2001
**Outcome:** Unknown

**Gender:** M
**Weight:** 73.00
**Age:** 26
**DOB:** 17/10/1974
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea<br>Diplopia<br>Insomnia | | | Required a visit to doctor. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

75.0 Milligram Daily

**Batch:** **Started:** 08/01/2001 **Stopped:** 09/01/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 160623 **Seq:** 1
**Reported:** 15/01/2001
**Hospitalisation:**
**Onset Date:** 10/01/2001
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 77.00
**Age:** 54
**DOB:** 08/07/1946
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor<br>Chills<br>Coordination abnormal<br>Dizziness<br>Nausea<br>Oculogyration | Severe | Persistent shaking of limbs. | Required visit to doctor x 2. |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis

75.0 Milligram 1 time

**Batch:** **Started:** 10/01/2001 **Stopped:** 11/01/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

P/h of severe nausea/vomiting with aropax in 1997/98.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 160771 **Seq:** 1 **Gender:** M
**Reported:** 16/01/2001 **Weight:**
**Hospitalisation:** **Age:** 53Y
**Onset Date:** 16/11/2000 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension | | | Efexor ceased. |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** 19/10/2000 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient also taking tritace, lipex and progout.

## Report Detail

**Case Number:** 160851 **Seq:** 1 **Gender:** F
**Reported:** 22/01/2001 **Weight:**
**Hospitalisation:** **Age:** 22
**Onset Date:** 19/01/2001 **DOB:** 22/11/1978
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fatigue<br>Headache<br>Hyperhidrosis<br>Nausea | | | |

## Medicine Details:

**LOGYNON ED (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** 22/06/1999 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 13/01/2001 **Stopped:** 17/01/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Nil known allergies.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 161144 **Seq:** 1 **Gender:** F
**Reported:** 02/02/2001 **Weight:** 80.00
**Hospitalisation:** **Age:** 51Y
**Onset Date:** 04/01/2001 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cold sweat<br>Diarrhoea<br>Dyspepsia<br>Dysphagia | | Feeling hot and cold. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 02/01/2001 **Stopped:** 05/01/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient also taking betaloc, oxazepam, zoton.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 161205 **Seq:** 1
**Reported:** 05/02/2001
**Hospitalisation:**
**Onset Date:** 31/12/2000
**Outcome:** Recovered

**Gender:** M
**Weight:** 95.00
**Age:** 39
**DOB:** 22/02/1961
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash<br>Pruritus | Severe | Red dots in hair | Efexor ceased. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 01/11/2000 **Stopped:** 13/01/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Immunology | 0 - 140 | | | Ige - 1723 |

### Additional Information:

Efexor xr dose was increased from 1 to 2 df daily in early 12/00 and rash started then. patient hospitalised because of reaction patient also taking olanzapine, panadeine forte, progout. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 161272 **Seq:** 1 **Gender:** F
**Reported:** 07/02/2001 **Weight:**
**Hospitalisation:** **Age:** AD
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Multiple congenital abnormalities | | | |

## Medicine Details:

**EPILIM (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
500.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Mother taking epilim and venlafaxime during pregnancy. baby born with multiple malformations - lobster claw deformity (r) hand (fused 2nd and 3rd digits, fused 4th digit with accessory digits. iugr, low set ears, thin upper lip,micrognathia, micropenis, anteverted nares.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 161525 **Seq:** 1
**Reported:** 13/02/2001
**Hospitalisation:**
**Onset Date:** 29/01/2001
**Outcome:** Not yet recovered

**Gender:** M
**Weight:**
**Age:** 46
**DOB:** 11/03/1954
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Fatigue<br>Polyuria<br>Vertigo | | Following cessation of treatment. | Required a visit to doctor.<br>efexor ceased. |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Tablet 75.0 Milligram Daily Oral

**Batch:** **Started:** 23/02/2000 **Stopped:** 29/01/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Sequelae: symptoms persisting.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 161589 **Seq:** 1 **Gender:** M
**Reported:** 19/02/2001 **Weight:**
**Hospitalisation:** **Age:** 44Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea | | | Efexor ceased. required a visit to doctor. |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** 12/12/2000 **Stopped:** 06/02/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 161590 **Seq:** 1 **Gender:** M
**Reported:** 19/02/2001 **Weight:**
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 08/02/2001 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Confusional state<br>Hyperhidrosis<br>Pallor<br>Tremor | | Severe withdrawal reaction 48hrs post | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** 12/12/2000 **Stopped:** 06/02/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 161602 **Seq:** 1 **Gender:** M
**Reported:** 16/02/2001 **Weight:** 70.00
**Hospitalisation:** **Age:** 53
**Onset Date:** 02/01/2001 **DOB:** 17/04/1947
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br><br>Coordination abnormal<br>Dizziness<br>Drug withdrawal syndrome<br>Inner ear disorder<br>Nystagmus<br>Vertigo | | | Required a visit to doctor. date of recovery 29/01/01. |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
355.0 Milligram Daily
**Batch:** **Started:** 01/01/1999 **Stopped:** 28/12/2000

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

### Report Detail

**Case Number:** 161762 **Seq:** 1 **Gender:** F
**Reported:** 15/02/2001 **Weight:**
**Hospitalisation:** **Age:** 71Y
**Onset Date:** 15/01/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea<br>Vomiting | | | Required a visit to doctor. stemetil - some relief. efexor |

### Medicine Details:

**HYPERICUM PLUS (ST JOHNS WORT WITH GINKGO) (Interaction)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** 01/12/2000 **Stopped:** 14/01/2001

**EFEXOR (Interaction)** **Reason:** Depression
37.5 Milligram Daily
**Batch:** **Started:** 15/01/2001 **Stopped:** 16/01/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient knew to cease st john's wort before starting efexor but only waited on e day pt will now wait two weeks for washout period of st j's wort before commencing efexor.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 161849 **Seq:** 1
**Reported:** 23/02/2001
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 75.00
**Age:** 51
**DOB:** 18/04/1949
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Gynaecomastia | | Unilateral gynaecomastia | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** 01/09/2000 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Previous episode of similar symptoms 3 years ago. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 161932 **Seq:** 1 **Gender:** F
**Reported:** 26/02/2001 **Weight:** 48.00
**Hospitalisation:** **Age:** 49
**Onset Date:** 21/02/2001 **DOB:** 10/01/1952
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Grand mal convulsion | | | Required a visit to doctor. |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 03/01/2001 **Stopped:** 22/02/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient also taking premarin, tegretol, temaze.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 161973 **Seq:** 1 **Gender:** F
**Reported:** 26/02/2001 **Weight:**
**Hospitalisation:** **Age:** 35
**Onset Date:** 20/02/2001 **DOB:** 23/08/1965
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | Agitated, hot feeling. | |
| Hypertonia | | Muscle jerks | |
| Insomnia | | Slept poorly that night. | |
| Tremor | | Tremor that migrated from limb to limb. | |
| Tachycardia | | Woke at 5am with racing pulse (114 bpm). | |
| Hot flush | | | |
| Malaise | | | |
| Serotonin syndrome | | | Required a visit to doctor. advised to discontinue zyban, take periactin. date of recovery: 22/2/2001 |

## Medicine Details:

**EFEXOR-XR (Interaction)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** 17/03/2000 **Stopped:**

**ZYBAN SR (Interaction)** **Reason:**
300.0 Milligram Daily
**Batch:** **Started:** 18/02/2001 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient began zyban 150mg/day on 14/2/2001 - no problems. ? serotonin syndrome.

## Report Detail

**Case Number:** 162245 **Seq:** 1 **Gender:** F
**Reported:** 05/03/2001 **Weight:**
**Hospitalisation:** **Age:** 21Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Anxiety<br>Dizziness<br>Drug withdrawal syndrome<br>Hyperhidrosis<br>Insomnia | | Hallucinations of insects on skin. | |

## Medicine Details:

**CHLORPROMAZINE HYDROCHLORIDE (Suspected)** **Reason:**
50.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**NITRAZEPAM (Suspected)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

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Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 162354 **Seq:** 1
**Reported:** 08/03/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 27/02/2001
**Outcome:** Recovered

**Gender:** F
**Weight:** 50.00
**Age:** 67
**DOB:** 31/12/1933
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Coordination abnormal<br>Dizziness<br><br>Dysarthria<br>Nausea | | | Patient hospitalised. phenergan given. date of recovery 01/03/01 |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 27/02/2001 **Stopped:** 27/02/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 162381 **Seq:** 1
**Reported:** 08/03/2001
**Hospitalisation:**
**Onset Date:** 20/02/2001
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 70.00
**Age:** 20
**DOB:** 17/03/1980
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Stomatitis | | Moderately severe stomatitis oral bleeding. | Required a visit to doctor. |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 19/02/2001 **Stopped:** 27/02/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Previous efexor taken at 75mg on august 2000 to september 2000.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 162402 **Seq:** 1 **Gender:** F
**Reported:** 08/03/2001 **Weight:**
**Hospitalisation:** **Age:** 64Y
**Onset Date:** 18/11/2000 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dehydration<br>Diarrhoea | | | Ceased venlafaxine and |

## Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Oral application 37.5 Milligram Daily Oral

**Batch:** **Started:** 25/10/2000 **Stopped:** 20/11/2000

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient also was taking triazolam, lipitor, norvasc, imdur, karvea.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 162439 **Seq:** 1
**Reported:** 09/03/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 12/02/2001
**Outcome:** Recovered

**Gender:** F
**Weight:** 97.00
**Age:** 43
**DOB:** 24/06/1957
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Renal failure acute | | | Patient was hospitalised. date of recovery 26.2.01. |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 17/01/2001 **Stopped:** 19/02/2001

**AVAPRO (Suspected)** **Reason:** Essential benign hypertension
300.0 Milligram Daily
**Batch:** **Started:** 01/01/2000 **Stopped:** 19/02/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient also taking lithicarb, cardizem cd, diabex, damicron, ogen and provera. no previous history with efexor was on aropax. lithicarb started after onset of symptoms. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 162491 **Seq:** 1 **Gender:** F
**Reported:** 13/03/2001 **Weight:**
**Hospitalisation:** **Age:** 65Y
**Onset Date:** 01/03/2001 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Euphoric mood<br>Nausea | | | Patient ceased efexor for 48hrs and restarted at 75mg bd. |

## Medicine Details:

**DIDROCAL (Other drug)** **Reason:** Osteoporosis
0.0
**Batch:** **Started:** **Stopped:**

**CELECOXIB (Other drug)** **Reason:** Unspecified arthritis
200.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**LIPEX (Other drug)** **Reason:** Othr&unspec metabolic diseases
40.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 162498 **Seq:** 1 **Gender:** F
**Reported:** 14/03/2001 **Weight:** 98.00
**Hospitalisation:** **Age:** 39
**Onset Date:** 19/02/2001 **DOB:** 18/11/1961
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle twitching<br>Diarrhoea<br>Nausea | | Muscle twitching in legs. | Date of recovery: 7/3/2001. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 19/01/2001 **Stopped:** 28/02/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

## Report Detail

**Case Number:** 162776 **Seq:** 1 **Gender:** M
**Reported:** 21/03/2001 **Weight:**
**Hospitalisation:** **Age:** 41Y
**Onset Date:** 17/03/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | Seizure, first ever, brief and generalised. | Settled spontaneously |

## Medicine Details:

**BUPROPION HYDROCHLORIDE (Interaction)** **Reason:** Smoker
300.0 Milligram Daily
**Batch:** **Started:** 09/02/2001 **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 06/12/2000 **Stopped:**

**ALPRAZOLAM (Other drug)** **Reason:** Anxiety neurosis
Tablet 4.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/2001 **Stopped:** 14/03/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 162875 **Seq:** 1
**Reported:** 19/03/2001
**Hospitalisation:**
**Onset Date:** 15/02/2001
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 80.00
**Age:** 50Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urticaria<br>Pruritus | | Rash and welts on trunk. | Zyrtec, referred to doctor asap. |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** 19/04/2000 **Stopped:** CONTIN

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Previously on efexor 75mg bd.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 163044 **Seq:** 1 **Gender:** M
**Reported:** 27/03/2001 **Weight:** 90.00
**Hospitalisation:** **Age:** 60Y
**Onset Date:** 28/02/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension<br><br>Drug withdrawal syndrome | | Bp increased by at least 20 - 30 mn/hg | Required a visit to doctor. recommenced efexor |

### Medicine Details:

**LIPITOR (Other drug)** **Reason:**
40.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**MONOPLUS 20/12.5 (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**XENICAL (Other drug)** **Reason:**
3.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Blood pressure increased by at least 20-30mn hg (both systolic and diastolic) after stopping abruptly. had been on one efexor daily, changed to one on alternate days for 1 week and then stopped. recommenced efexor and bp returned to normal. the date of onset of the reaction is not necessarily accurate but indicates onset sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 163050 **Seq:** 1
**Reported:** 27/03/2001
**Hospitalisation:**
**Onset Date:** 01/07/2000
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 60.00
**Age:** 24
**DOB:** 08/09/1975
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura<br>Coagulopathy | | Bruising<br>Prolonged aptt | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

300.0 Milligram Daily

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was also taking normison, femoden.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 163153 **Seq:** 1 **Gender:** F
**Reported:** 29/03/2001 **Weight:**
**Hospitalisation:** **Age:** 75Y
**Onset Date:** 17/03/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | | Hemicranial headache severe | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** 17/03/2001 **Stopped:** 2D

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 163158 **Seq:** 1 **Gender:** M
**Reported:** 30/03/2001 **Weight:**
**Hospitalisation:** **Age:** 37
**Onset Date:** 03/04/2000 **DOB:** 26/10/1962
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus | | Pruritus all over body | Efexor stopped. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

0.0

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 163319 **Seq:** 1 **Gender:** F
**Reported:** 02/04/2001 **Weight:** 81.00
**Hospitalisation:** **Age:** 55Y
**Onset Date:** 02/03/2001 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | | Front temporal distribution. | Treated with paracetamol. |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** 27/02/2001 **Stopped:** CONTIN

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 163349 **Seq:** 1 **Gender:** F
**Reported:** 29/03/2001 **Weight:** 65.00
**Hospitalisation:** **Age:** 17Y
**Onset Date:** 02/11/2000 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anaphylactoid reaction | | Acute anaphylactic reaction. | Hydrocortisone / vi / |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 02/11/2000 **Stopped:** 02/11/2000

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 163350 **Seq:** 1 **Gender:** F
**Reported:** 29/03/2001 **Weight:** 65.00
**Hospitalisation:** **Age:** 30Y
**Onset Date:** 28/06/2000 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Polyhydramnios | | Polyhydramnios at approx. 28 weeks | Efexor dose decreased back to 37.5mg. |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 01/09/1999 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient had been on efexor in low dose (37.5mg) for early pregnancy. no fetal abnormality. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not necessarily accurate but indicates the drug was started sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 163468 **Seq:** 1 **Gender:** F
**Reported:** 29/03/2001 **Weight:** 63.00
**Hospitalisation:** **Age:** 54Y
**Onset Date:** **DOB:**
**Outcome:** Death **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyspnoea<br>Sudden death | | Breathless. | |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 28/07/1999 **Stopped:** 15/11/2000

**ZYPREXA (Suspected)** **Reason:** Depression
15.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Serum drug level | | | | Blood venlafaxime level = 3.8mg/l (ref <0.5 mg/l) |

## Additional Information:

## Report Detail

**Case Number:** 163500 **Seq:** 1 **Gender:** F
**Reported:** 06/04/2001 **Weight:** 70.00
**Hospitalisation:** **Age:** 57
**Onset Date:** 27/03/2001 **DOB:** 22/04/1943
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia | | Dystonic jaw | |
| Tongue oedema | | Tongue swelled | |

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **PANADOL (Other drug)** | | | **Reason:** | | |
| Capsule | 500.0 | Milligram | As necessary | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **RIVOTRIL (Other drug)** | | | **Reason:** | | |
| Tablet | 2.0 | Milligram | As necessary | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **CELEBREX (Other drug)** | | | **Reason:** | | |
| Capsule | 200.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **OGEN (Other drug)** | | | **Reason:** | | |
| Tablet | 625.0 | Microgram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient experienced symptoms after one cap of efexor.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 163500 **Seq:** 1
**Reported:** 06/04/2001
**Hospitalisation:**
**Onset Date:** 27/03/2001
**Outcome:** Recovered

**Gender:** F
**Weight:** 70.00
**Age:** 57
**DOB:** 22/04/1943
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **PEPCIDINE M (Other drug)** | | | **Reason:** | |
| Tablet | 40.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **EFEXOR (Suspected)** | | | **Reason:** | |
| Capsule | 75.0 | Milligram | 1 time | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |

## Laboratory Investigations:

## Additional Information:

Patient experienced symptoms after one cap of efexor.

## Report Detail

**Case Number:** 163550 **Seq:** 1
**Reported:** 06/04/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 20/02/2001
**Outcome:** Recovered

**Gender:** F
**Weight:** 45.00
**Age:** 35
**DOB:** 13/08/1965
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Grand mal convulsion | | Grand mal seizure | Hospitalised |

## Medicine Details:

**ENDEP (Interaction)** **Reason:** Specific disorders of sleep
25.0 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**ZYBAN SR (Interaction)** **Reason:** Smoker
300.0 Milligram Daily
**Batch:** **Started:** 14/02/2001 **Stopped:** 20/02/2001

**EFEXOR-XR (Interaction)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 16/01/2001 **Stopped:** 11/02/2001

**METHADONE HYDROCHLORIDE (Other drug)** **Reason:** Drug dependence
15.0 Millilitre Daily
**Batch:** **Started:** L TERM **Stopped:** 17/02/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient history of seizures on benzodiazepine withdrawal but with no eeg abnormalities at the time.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 164155 **Seq:** 1
**Reported:** 02/05/2001
**Hospitalisation:**
**Onset Date:** 05/04/2001
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 90.00
**Age:** 80
**DOB:** 21/03/1921
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic function abnormal | | | Ceased venlafaxine and |

## Medicine Details:

**ASPIRIN (Other drug)** **Reason:** Otr&nos disord of heart rhythm
150.0 Milligram Daily
**Batch:** **Started:** 01/01/2001 **Stopped:**

**DIGOXIN (Other drug)** **Reason:** Otr&nos disord of heart rhythm
125.0 Microgram Daily
**Batch:** **Started:** 01/01/2001 **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 30/03/2001 **Stopped:** 06/04/2001

**OLANZAPINE (Suspected)** **Reason:** Depression
5.0 Milligram Daily
**Batch:** **Started:** 30/03/2001 **Stopped:** 06/04/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | | 05/04/2001 | 69 | |
| | AST = SGOT | | 05/04/2001 | 72 | |
| | Bilirubin | | 05/04/2001 | 38 | |
| | GGT = SGGT = | | 05/04/2001 | 263 | |
| | SAP = ALP | | 05/04/2001 | 904 | |

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 164185 **Seq:** 1 **Gender:** F
**Reported:** 03/05/2001 **Weight:** 92.00
**Hospitalisation:** **Age:** 29
**Onset Date:** 26/04/2001 **DOB:** 17/05/1971
**Outcome:** Recovered **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Syncope | | | Therapy ceased. |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 26/04/2001 **Stopped:** 28/04/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient took 1 efexor xr capsule on 2 occasions and collapsed to floor 10 hrs later on both times.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 164204 **Seq:** 1 **Gender:** F
**Reported:** 03/05/2001 **Weight:**
**Hospitalisation:** **Age:** 57
**Onset Date:** 28/10/2000 **DOB:** 03/05/1943
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | Low plasma sodium | |
| Diarrhoea | | Moderate - severe diarrhoea | Vanlafaxime ceased. required a visit to doctor |

## Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
225.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 164395 **Seq:** 1 **Gender:** M
**Reported:** 10/05/2001 **Weight:** 92.00
**Hospitalisation:** **Age:** 54
**Onset Date:** 10/02/2001 **DOB:** 28/11/1946
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Visual disturbance | | Deterioration eyesites | |
| Agitation | | Irritability | |
| Apathy | | Loss of motivation | |
| Dyspnoea | | Respiratory difficulty | |
| Chest pain | | | |
| Headache | | | |
| Myalgia | | | |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** 10/02/2001 **Stopped:** 22/02/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 164485 **Seq:** 1
**Reported:** 14/05/2001
**Hospitalisation:**
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 60.00
**Age:** 74
**DOB:** 07/05/1927
**Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination | | Visiual hallucination | Venlafaxine stopped. |

## Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

75.0 Milligram Daily

**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 164577 **Seq:** 1 **Gender:** F
**Reported:** 16/05/2001 **Weight:**
**Hospitalisation:** **Age:** 38
**Onset Date:** 06/02/2001 **DOB:** 20/04/1962
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash maculo-papular | | | Date of recovery 19/02/2001. required a visit to doctor. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** 15/08/2000 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 164593 **Seq:** 1
**Reported:** 18/05/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 17/03/2001
**Outcome:** Recovered

**Gender:** M
**Weight:** 70.00
**Age:** 41
**DOB:** 12/01/1960
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Grand mal convulsion | | | Patient was hospitalised for 2 days, ct scan and eeg normal. |

### Medicine Details:

**ZYBAN SR (Interaction)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Interaction)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 28/06/1999 **Stopped:**

**KALMA (Other drug)** **Reason:** Anxiety neurosis
3.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 18/04/2001

**VALIUM (Other drug)** **Reason:**
5.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Nil allergies, nor epilepsy. patient hit head x 2 in mba, no loss of consciousness but sounds like concussion, ie. history of head trauma.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 164673 **Seq:** 1 **Gender:** F
**Reported:** 21/05/2001 **Weight:** 55.00
**Hospitalisation:** **Age:** 31
**Onset Date:** 10/05/2001 **DOB:** 08/05/1970
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depersonalisation<br>Dizziness<br>Mydriasis<br>Nausea<br>Visual disturbance | | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 10/05/2001 **Stopped:** 10/05/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient recovered 12/5/01.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 164707 **Seq:** 1 **Gender:** M
**Reported:** 16/05/2001 **Weight:** 108.00
**Hospitalisation:** **Age:** 53
**Onset Date:** 01/09/2000 **DOB:** 09/11/1946
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depression<br><br>Drug level decreased | | Worsening depression. | Required a visit to doctor. date of recovery 1.12.00. |

### Medicine Details:

**EFEXOR (Interaction)** **Reason:** Depression
225.0 Milligram Daily
**Batch:** **Started:** 01/01/1997 **Stopped:**

**TESTOSTERONE IMPLANTS (Interaction)** **Reason:**
600.0 Milligram Daily
**Batch:** **Started:** 25/08/2000 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Biochemistry | | | | Drop in se testosterone. |

### Additional Information:

The dose start date for efexor is not accurate but indicates the drug was started sometime in the year. previously on sustanon injections with no effect on se testosterone. testosterone implant - fall in se testosterone and rise after 4 months to usual borderline levels.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 164852 **Seq:** 1 **Gender:** M
**Reported:** 25/05/2001 **Weight:**
**Hospitalisation:** **Age:** 36Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis<br><br>Libido decreased | | | Efexor has been phased out and zyban was added. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
450.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 165032 **Seq:** 1 **Gender:** F
**Reported:** 01/06/2001 **Weight:** 55.00
**Hospitalisation:** **Age:** 69
**Onset Date:** 28/02/2001 **DOB:** 14/09/1931
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br>Tremor | | | Venlafaxine ceased. required a visit to doctor. |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 01/02/2001 **Stopped:** 15/05/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The date of the onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not necessarily accurate but indicates the drug was started sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 165187 **Seq:** 1 **Gender:** M
**Reported:** 06/06/2001 **Weight:**
**Hospitalisation:** **Age:** 38
**Onset Date:** **DOB:** 25/11/1962
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea<br>Vomiting | | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

Tablet 37.5 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Adverse to 1st dose of efexor 37.5mg - nauseated and vomiting. second dose the same but worse and severe distress.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 165267 **Seq:** 1
**Reported:** 12/06/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 07/05/2001
**Outcome:** Recovered

**Gender:** M
**Weight:**
**Age:** 68
**DOB:** 29/09/1932
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatitis | | | Venlafaxine reduced to 75mg once daily on 7.5.01. patient was hospitalised. |

### Medicine Details:

**CEPHAZOLIN SODIUM (Other drug)** **Reason:**
Injection 6.0 Gram Daily Intravenous
**Batch:** **Started:** 26/03/2001 **Stopped:** CONTIN

**DIAFORMIN (Other drug)** **Reason:**
1.5 Gram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**ISCOVER (Other drug)** **Reason:**
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 26/02/2001 **Stopped:** CONTIN

**ASPIRIN (Other drug)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** 24/02/2001 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | 2-40 | 30/05/2001 | 25 | Alt 543 |
| | AST = SGOT | 2-35 | 30/05/2001 | 31 | Ast 3711. |
| | GGT = SGGT = | 2-45 | 30/05/2001 | 222 | Ggt 335. |
| | SAP = ALP | 20-175 | 30/05/2001 | 173 | Alk phos 221. |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 165267 **Seq:** 1
**Reported:** 12/06/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 07/05/2001
**Outcome:** Recovered

**Gender:** M
**Weight:**
**Age:** 68
**DOB:** 29/09/1932
**Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **RANITIDINE (Other drug)** | | | **Reason:** | | |
| | 300.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **EFEXOR (Suspected)** | | | **Reason:** | | |
| Tablet | 224.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 165280 **Seq:** 1 **Gender:** F
**Reported:** 12/06/2001 **Weight:**
**Hospitalisation:** **Age:** AD
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion neonatal<br>Drug withdrawal syndrome neona | | Jerking movements all 4 limbs lasting 2 | Phenobarbitane |

### Medicine Details:

**EPILIM (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
450.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Mother taking epilim and venlafaxime during pregnancy

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 165476 **Seq:** 1 **Gender:** F
**Reported:** 18/06/2001 **Weight:** 75.00
**Hospitalisation:** **Age:** 29Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia | | Clenching jaw | Drug reduced. |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
225.0 Milligram Daily
**Batch:** **Started:** 13/05/2001 **Stopped:** 15/06/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

## Report Detail

**Case Number:** 165628 **Seq:** 1 **Gender:** M
**Reported:** 20/06/2001 **Weight:** 60.00
**Hospitalisation:** **Age:** 27Y
**Onset Date:** 29/05/2000 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence | | Excessive drowsiness | Required a visit to doctor. |

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **ASCORBIC ACID (Other drug)** | | | **Reason:** | | |
| Oral application | 1.0 | Gram | Daily | Oral | |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | |
| **CALCIUM NOS (Other drug)** | | | **Reason:** | | |
| Oral application | 1.2 | Gram | Daily | Oral | |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | |
| **GARLIC (Other drug)** | | | **Reason:** | | |
| Oral application | 1.0 | Gram | Daily | Oral | |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | |
| **ECHINACEA (Other drug)** | | | **Reason:** | | |
| Oral application | 1.6 | Gram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

## Report Detail

**Case Number:** 165628 **Seq:** 1
**Reported:** 20/06/2001
**Hospitalisation:**
**Onset Date:** 29/05/2000
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 60.00
**Age:** 27Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **PROZAC (Suspected)** | | | **Reason:** | Depression | | |
| Oral application | 40.0 | Milligram | Daily | Oral | | |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | | CONTIN |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression | | |
| Capsule | 37.5 | Milligram | Daily | Oral | | |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | | CONTIN |
| **PROPRANOLOL HYDROCHLORIDE (Suspected)** | | | **Reason:** | Anxiety neurosis | | |
| Tablet | 160.0 | Milligram | Daily | Oral | | |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | | CONTIN |

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 165643 **Seq:** 1 **Gender:** F
**Reported:** 20/06/2001 **Weight:**
**Hospitalisation:** **Age:** 72Y
**Onset Date:** 30/05/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Oculogyration<br>Muscle twitching<br>Vomiting | | Eyes rolled back | Required a visit to doctor, ceased efexor xr. |

## Medicine Details:

**ARIMIDEX (Other drug)** **Reason:** Malignant neoplasm of breast
1.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**TIMOLOL MALEATE (Other drug)** **Reason:**
Eye Drops 2.0 Dose Unspecified Daily Ophthalmic
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**PANAMAX (Other drug)** **Reason:**
Tablet 2.0 Dose Unspecified Daily Oral
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**ASTRIX 100 (Other drug)** **Reason:**
Capsule 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** L TERM **Stopped:** CONTIN

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient recovered 30/5/01.

## Report Detail

**Case Number:** 165643 **Seq:** 1 **Gender:** F
**Reported:** 20/06/2001 **Weight:**
**Hospitalisation:** **Age:** 72Y
**Onset Date:** 30/05/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **OXAZEPAM (Other drug)** | | | **Reason:** | | | |
| | 15.0 | Milligram | Daily | | | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | CONTIN | | |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression | | |
| Capsule | 150.0 | Milligram | Daily | Oral | | |
| **Batch:** | **Started:** | 30/05/2001 | **Stopped:** | 30/05/2001 | | |

## Laboratory Investigations:

## Additional Information:

Patient recovered 30/5/01.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 165747 **Seq:** 1
**Reported:** 25/06/2001
**Hospitalisation:**
**Onset Date:** 30/05/2001
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 50.00
**Age:** 17
**DOB:** 25/04/1984
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mydriasis | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 29/05/2001 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 166002 **Seq:** 1
**Reported:** 02/07/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 12/05/2001
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 32
**DOB:** 23/01/1969
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Supraventricular tachycardia | | | Patient hospitalised overnight in the a & e department. |

## Medicine Details:

**TEGRETOL (Other drug)** **Reason:** Depression
200.0 Milligram Daily
**Batch:** **Started:** 23/04/2001 **Stopped:** CONTIN

**EFEXOR (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 02/05/2001 **Stopped:** CONTIN

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient recovered on the 12/5/2001, continuing efexor at a reduced dose. patient has had brief episodes before exfexor lasting a minute or so, and every 6 months or so.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 166032 **Seq:** 1 **Gender:** F
**Reported:** 02/07/2001 **Weight:**
**Hospitalisation:** **Age:** 53
**Onset Date:** 19/11/2000 **DOB:** 19/05/1947
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Neutropenia | | | Olanzapine ceased. |

### Medicine Details:

**CELECOXIB (Other drug)** **Reason:** Unspecified arthritis
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:** CONTIN

**RANITIDINE (Other drug)** **Reason:**
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:** CONTIN

**OLANZAPINE (Suspected)** **Reason:** Unspecified schizophrenia
7.5 Milligram Daily
**Batch:** **Started:** 22/06/2000 **Stopped:** 01/12/2000

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 01/05/2000 **Stopped:** 01/12/2000

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Neutrophils | | 10/05/2000 | 3.64 | |
| | Neutrophils | | 19/11/2000 | 0.9 | |
| | Neutrophils | | 01/12/2000 | 1.25 | |
| | Neutrophils | | 18/12/2000 | 2.76 | |
| | Neutrophils | | 13/12/2000 | 1.58 | |
| | Neutrophils | | 04/12/2000 | 1.69 | |
| | White blood cells | | 10/05/2000 | 5.58 | |

### Additional Information:

The dose start dates for venlafaxine and valproate are not necessarily accurate but indicate the drugs were started sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 166032 **Seq:** 1 **Gender:** F
**Reported:** 02/07/2001 **Weight:**
**Hospitalisation:** **Age:** 53
**Onset Date:** 19/11/2000 **DOB:** 19/05/1947
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**SODIUM VALPROATE (Suspected)** **Reason:**
1.0 Gram Daily
**Batch:** **Started:** 01/05/2000 **Stopped:** 01/12/2000

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | White blood cells | | 19/11/2000 | 3.40 | |
| | White blood cells | | 01/12/2000 | 3.21 | |
| | White blood cells | | 04/12/2000 | 4.10 | |
| | White blood cells | | 13/12/2000 | 3.90 | |
| | White blood cells | | 18/12/2000 | 4.98 | |

## Additional Information:

The dose start dates for venlafaxine and valproate are not necessarily accurate but indicate the drugs were started sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 166144 **Seq:** 1 **Gender:** F
**Reported:** 05/07/2001 **Weight:**
**Hospitalisation:** **Age:** 83Y
**Onset Date:** 28/03/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br>Inappropriate antidiuretic hormon | | | Efexor xr withheld. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

0.0

**Batch:** **Started:** 26/03/2001 **Stopped:** 02/04/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium<br>Urine osmolality | | | | Previous na (normal) - 135. na while on efexor - 116.<br>Urine osmolality - 554. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 166376 **Seq:** 1 **Gender:** F
**Reported:** 12/07/2001 **Weight:**
**Hospitalisation:** **Age:** 48Y
**Onset Date:** 09/07/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea<br>Tachycardia<br><br><br>Vomiting | | | Required a visit to doctor, ceased efexor, dr prescribed dothiepin 25mg nocte after washout period |

### Medicine Details:

**OXAZEPAM (Other drug)** **Reason:**
15.0 Milligram As necessary
**Batch:** **Started:** 01/05/2001 **Stopped:**

**ZYPREXA (Other drug)** **Reason:**
2.5 Milligram Daily
**Batch:** **Started:** 01/05/2001 **Stopped:**

**ZINC (Other drug)** **Reason:**
Oral application 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 166880 **Seq:** 1 **Gender:** M
**Reported:** 26/07/2001 **Weight:** 60.00
**Hospitalisation:** **Age:** 24
**Onset Date:** 12/07/2001 **DOB:** 30/04/1977
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Micturition disorder | | Uninary obstruction. | Patient required a vistit to a doctor. efexor xr ceased. |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
75.0 Milligram Daily
**Batch:** **Started:** 10/07/2001 **Stopped:** 12/07/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient recovered on the 14/7/2001.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 167149 **Seq:** 1 **Gender:** F
**Reported:** 01/08/2001 **Weight:**
**Hospitalisation:** **Age:** 79
**Onset Date:** **DOB:** 14/05/1922
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache<br>Nausea | Severe | | Efexor xr ceased. |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** 13/07/2001 **Stopped:** 16/07/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient also taking somac, adalat, caltrate, frusemide and lipitor. patient recovered on the 19/7/2001.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 167155 **Seq:** 1 **Gender:** M
**Reported:** 16/07/2001 **Weight:** 110.00
**Hospitalisation:** **Age:**
**Onset Date:** 25/04/2001 **DOB:**
**Outcome:** Death, maybe drug **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

0.0

**Batch:** **Started:** 12/03/2001 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 167331 **Seq:** 1 **Gender:** F
**Reported:** 08/08/2001 **Weight:**
**Hospitalisation:** **Age:** 65Y
**Onset Date:** 10/07/2001 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Constipation | | | Self treatment with increased fibre in diet and laxatives. |

### Medicine Details:

**NORMISON (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**MULTIVITAMINS (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**CALTRATE (Other drug)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
112.5 Milligram Daily
**Batch:** **Started:** 07/07/2001 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 167503 **Seq:** 1 **Gender:** F
**Reported:** 13/08/2001 **Weight:**
**Hospitalisation:** **Age:** 83Y
**Onset Date:** 15/06/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary retention | | | Efexor ceased. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

0.0

**Batch:** **Started:** 02/05/2001 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the middle of the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 167861 **Seq:** 1
**Reported:** 27/08/2001
**Hospitalisation:**
**Onset Date:** 14/07/2001
**Outcome:** Not yet recovered

**Gender:** M
**Weight:**
**Age:** 34
**DOB:** 20/10/1966
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Thrombocytopenia | | | Required a visit to doctor. efexor xr ceased. |

## Medicine Details:

**LOSEC (Other drug)** **Reason:** Other diseases of esophagus
20.0 Milligram Daily
**Batch:** **Started:** 01/02/2001 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 02/03/2001 **Stopped:** 03/08/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Platelets | | | | Low platelets (59) increased to 129 in 2 weeks after stopping |

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 168213 **Seq:** 1 **Gender:** F
**Reported:** 06/09/2001 **Weight:**
**Hospitalisation:** **Age:** 31
**Onset Date:** **DOB:** 06/11/1969
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | | Opiate withdrawal | Required a visit to doctor. |

## Medicine Details:

**EFEXOR (Interaction)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**METHADONE HYDROCHLORIDE (Interaction)** **Reason:**
90.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 168367 **Seq:** 1
**Reported:** 12/09/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 31/08/2001
**Outcome:** Recovered

**Gender:** F
**Weight:** 60.00
**Age:** 50
**DOB:** 11/02/1951
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br><br>Renal impairment | | | Cessation of venlafaxine. admitted to hospital. date of recovery 05/09/2001 |

### Medicine Details:

**DIGOXIN (Other drug)** **Reason:** Acute heart failure,undefined
125.0 Microgram Daily
**Batch:** **Started:** L TERM **Stopped:**

**MS CONTIN (Other drug)** **Reason:** Pain
20.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**AZATHIOPRINE (Other drug)** **Reason:**
50.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**CARVEDILOL HYDROCHLORIDE (Other drug)** **Reason:** Acute heart failure,undefined
6.2 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electrolytes | | 02/09/2001 | 129 | |
| | Electrolytes | | 03/09/2001 | 127 | |

### Additional Information:

Relevant medical history - renal transplant in 1981, mrsa tve and chronic osteoyelitis.

## Report Detail

**Case Number:** 168367 **Seq:** 1
**Reported:** 12/09/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 31/08/2001
**Outcome:** Recovered

**Gender:** F
**Weight:** 60.00
**Age:** 50
**DOB:** 11/02/1951
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **CAPTOPRIL (Other drug)** | | | **Reason:** | Acute heart failure,undefined |
| | 12.5 | Milligram | Daily | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | |
| **PREDNISOLONE (Other drug)** | | | **Reason:** | |
| | 5.0 | Milligram | Daily | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | |
| **FRUSEMIDE (Other drug)** | | | **Reason:** | Acute heart failure,undefined |
| | 375.0 | Milligram | Daily | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | |
| **EFEXOR (Suspected)** | | | **Reason:** | Depression |
| | 300.0 | Milligram | Daily | |
| **Batch:** | **Started:** | 13/07/2001 | **Stopped:** | 03/09/2001 |

## Laboratory Investigations:

## Additional Information:

Relevant medical history - renal transplant in 1981, mrsa tve and chronic osteoyelitis.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 168401 **Seq:** 1 **Gender:** F
**Reported:** 14/09/2001 **Weight:** 72.00
**Hospitalisation:** **Age:** 31
**Onset Date:** 08/09/2001 **DOB:** 09/11/1969
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash<br><br>Urticaria | | Skin rash on limbs, spared the trunk. | Required a visit to doctor. treated with prednisone 25md bd |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 06/09/2001 **Stopped:** 08/09/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

No previous allergies.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 168421 **Seq:** 1 **Gender:** F
**Reported:** 14/09/2001 **Weight:**
**Hospitalisation:** **Age:** 83
**Onset Date:** 01/01/2001 **DOB:** 20/03/1917
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion<br>Apnoea<br>Muscle twitching | | First epileptic seizure<br>Stopped breathing | Phenytoin. |

### Medicine Details:

**MORPHINE NOS (Other drug)** **Reason:** Pain
Injection 60.0 Milligram Daily Intramuscular
**Batch:** **Started:** 24/12/2000 **Stopped:**

**ATROVENT (Other drug)** **Reason:**
2.0 Milligram Daily
**Batch:** **Started:** 24/12/2000 **Stopped:**

**VENTOLIN (Other drug)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 24/12/2000 **Stopped:**

**CELECOXIB (Other drug)** **Reason:** Pain
200.0 Milligram Daily
**Batch:** **Started:** 24/12/2000 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 168421 **Seq:** 1 **Gender:** F
**Reported:** 14/09/2001 **Weight:**
**Hospitalisation:** **Age:** 83
**Onset Date:** 01/01/2001 **DOB:** 20/03/1917
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **PARACETAMOL (Other drug)** | | | **Reason:** Pain | |
| | 4.0 Gram | | Daily | |
| **Batch:** | **Started:** 24/12/2000 | | | **Stopped:** |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** Depression | |
| Oral application | 37.5 Milligram | | Daily | Oral |
| **Batch:** | **Started:** 28/12/2000 | | | **Stopped:** 01/01/2001 |

## Laboratory Investigations:

## Additional Information:

## Report Detail

**Case Number:** 168805 **Seq:** 1
**Reported:** 04/10/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 19/09/2001
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 60
**DOB:** 28/07/1941
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Leukoplakia<br>Lymphopenia<br>Neutropenia | | Eosinophil counts decreased. | Stopped epilim, efexor, zyprexa, rocephin iv 2gm commenced, changed psychotics to serenace 2.5mg bd then increase to 5mg. |

## Medicine Details:

**WARFARIN SODIUM (Other drug)** **Reason:**
3.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Unspecified psychosis
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 19/09/2001

**EPILIM (Suspected)** **Reason:** Other&unspecified epilepsy
600.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 19/09/2001

**ZYPREXA (Suspected)** **Reason:** Unspecified psychosis
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 19/09/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient recovered 26/9/01.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 168805 **Seq:** 1
**Reported:** 04/10/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 19/09/2001
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 60
**DOB:** 28/07/1941
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**TARGOCID (Suspected)** **Reason:** Cellul&absc otr,mult&nos sites
400.0 Milligram Daily
**Batch:** **Started:** 11/09/2001 **Stopped:**

### Laboratory Investigations:

### Additional Information:
Patient recovered 26/9/01.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 168869 **Seq:** 1
**Reported:** 04/10/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 08/09/2001
**Outcome:** Not yet recovered

**Gender:** M
**Weight:**
**Age:** 51
**DOB:** 26/12/1949
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Blood creatine phosphokinase in | | | Patient was hospitalised. seroquel ceased. |

### Medicine Details:

**SEROQUEL (Suspected)** **Reason:** Unspecified neurosis
900.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 22/06/2001

**EFEXOR-XR (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 30/07/2001 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Creatine | | 12/09/2001 | 1050 | |

### Additional Information:

Efexor xr was initiated at 75mg daily on 4.7.01 increasing by 75mg increments to 300mg daily on 30.7.01.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 169003 **Seq:** 1 **Gender:** F
**Reported:** 05/10/2001 **Weight:**
**Hospitalisation:** **Age:** 80Y
**Onset Date:** 24/09/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state<br>Dehydration<br>Dizziness<br>Nausea<br><br>Orthostatic hypotension | | | Required a visit to doctor. efexor was ceased. |

## Medicine Details:

**LANOXIN PG (Other drug)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 27/09/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient has acute brain syndrome. patient recovered 27/9/01.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 169095 **Seq:** 1 **Gender:** M
**Reported:** 10/10/2001 **Weight:** 95.00
**Hospitalisation:** **Age:** 49
**Onset Date:** 27/08/2001 **DOB:** 13/04/1952
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic function abnormal | | | |

## Medicine Details:

**OLANZAPINE (Suspected)** **Reason:** Depression
10.0 Milligram Daily
**Batch:** **Started:** 21/08/2001 **Stopped:** 27/08/2001

**DIAZEPAM (Suspected)** **Reason:** Depression
30.0 Milligram Daily
**Batch:** **Started:** 21/08/2001 **Stopped:** 27/08/2001

**QUILONUM SR (Suspected)** **Reason:** Depression
3.0 Dose Unspecified Daily
**Batch:** **Started:** 10/05/2001 **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 25/08/2001 **Stopped:** 27/08/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | | 27/08/2001 | 646 | |
| | AST = SGOT | | 27/08/2001 | 249 | |
| | Albumin | | 27/08/2001 | 35 | |
| | Bilirubin | | 27/08/2001 | 12 | |
| | GGT = SGGT = | | 27/08/2001 | 277 | |
| | GGT = SGGT = | | 27/08/2001 | 277 | |
| | Protein | | 27/08/2001 | 73 | |

## Additional Information:

## Report Detail

**Case Number:** 169095 **Seq:** 1
**Reported:** 10/10/2001
**Hospitalisation:**
**Onset Date:** 27/08/2001
**Outcome:** Recovered

**Gender:** M
**Weight:** 95.00
**Age:** 49
**DOB:** 13/04/1952
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **OLANZAPINE (Suspected)** | | | **Reason:** Depression | |
| | 10.0 Milligram | Daily | | |
| **Batch:** | **Started:** 21/08/2001 | | **Stopped:** 27/08/2001 | |
| **DIAZEPAM (Suspected)** | | | **Reason:** Depression | |
| | 30.0 Milligram | Daily | | |
| **Batch:** | **Started:** 21/08/2001 | | **Stopped:** 27/08/2001 | |
| **QUILONUM SR (Suspected)** | | | **Reason:** Depression | |
| | 3.0 Dose Unspecified | Daily | | |
| **Batch:** | **Started:** 10/05/2001 | | **Stopped:** | |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** Depression | |
| | 75.0 Milligram | Daily | | |
| **Batch:** | **Started:** 25/08/2001 | | **Stopped:** 27/08/2001 | |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | SAP = ALP | | 27/08/2001 | 198 | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 169524 **Seq:** 1
**Reported:** 29/10/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 17/09/2001
**Outcome:** Recovered

**Gender:** M
**Weight:** 65.00
**Age:** 62
**DOB:** 11/07/1939
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash maculo-papular<br>Pruritus | | Rash with minor erythema over whole | Promethazine 75mg daily, prednisolone 20mg daily, bethamethasone cream 0.05%. patient hospitalised. date of recovery 22/10/01. |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 17/09/2001 **Stopped:** 10/10/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Rash appeared within hours of taking first dose of venlafaxine. the patient had previously experienced rash on his hand and forearms after taking paroxetine.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 169689 **Seq:** 1 **Gender:** F
**Reported:** 01/11/2001 **Weight:** 60.00
**Hospitalisation:** **Age:** 47
**Onset Date:** 31/12/2000 **DOB:** 08/01/1953
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anaemia | | | Required a visit to doctor. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

0.0

**Batch:** **Started:** 01/10/2000 L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Ferritin | | | | Low fe - lower s. ferrintin. |

### Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not necessarily accurate but indicates the drug efexor- xr was started sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 169981 **Seq:** 1 **Gender:** M
**Reported:** 19/11/2001 **Weight:**
**Hospitalisation:** **Age:** 49
**Onset Date:** **DOB:** 29/05/1952
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension | | Bp = 200/140 | Efexor stopped. required a visit to doctor. |
| Tachycardia | | Pulse = 130 | |
| Headache | | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

0.0

**Batch:** **Started:** **Stopped:** 11/10/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 170139 **Seq:** 1
**Reported:** 21/11/2001
**Hospitalisation:** Hospitalisation prolonged
**Onset Date:** 02/11/2001
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 37
**DOB:** 26/06/1964
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tachycardia<br>Psychotic disorder<br>Electrocardiogram abnormal<br>Orthostatic hypotension | Severe | 135 beats per minute.<br>Severely psychotic | Ceased effexor |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 27/10/2001 **Stopped:** 02/11/2001

**CLOZARIL (Suspected)** **Reason:** Schizophrenia
Tablet 850.0 Milligram Daily Oral
**Batch:** **Started:** 13/11/1999 **Stopped:** CONTIN

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 170240 **Seq:** 1
**Reported:** 22/11/2001
**Hospitalisation:**
**Onset Date:** 14/11/2001
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 55.00
**Age:** 22
**DOB:** 28/07/1979
**Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br><br>Hyperhidrosis<br>Muscle twitching<br>Vomiting | | | Required a visit to doctor. patient was hospitalised. |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 01/07/1999 **Stopped:** 11/11/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

The dose start date is not necessarily accurate but indicates the drug was started sometime in the month. similar reaction when attempted reduction in late 2000.

## Report Detail

**Case Number:** 170379 **Seq:** 1
**Reported:** 27/11/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 05/08/2001
**Outcome:** Recovered

**Gender:** U
**Weight:**
**Age:** 81Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fatigue<br>Hyponatraemia | | | Patient was hospitalised. date of recovery 30.8.01. evexor xr |

## Medicine Details:

**OXIS TURBUHALER (Other drug)** **Reason:** Asthma
0.0
**Batch:** **Started:** L TERM **Stopped:**

**SERETIDE ACCUHALER NOS (Other drug)** **Reason:** Asthma
0.0
**Batch:** **Started:** L TERM **Stopped:**

**VENTOLIN NEBULES (Other drug)** **Reason:** Asthma
0.0
**Batch:** **Started:** L TERM **Stopped:**

**ATROVENT (Other drug)** **Reason:** Asthma
0.0
**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | 06/08/2001 | 114 | |

## Additional Information:

Patient felt weird - tired, decreased energy, couldn't opent eyes, breathing changes and barely able to life arm.

## Report Detail

**Case Number:** 170379 **Seq:** 1
**Reported:** 27/11/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 05/08/2001
**Outcome:** Recovered

**Gender:** U
**Weight:**
**Age:** 81Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | |
|---|---|---|---|
| **PREDNISOLONE (Other drug)** | | **Reason:** | |
| | 0.0 | | |
| **Batch:** | **Started:** | | **Stopped:** |
| **NORMISON (Other drug)** | | **Reason:** | |
| | 0.0 | | |
| **Batch:** | **Started:** | | **Stopped:** |
| **RENITEC (Other drug)** | | **Reason:** | Essential benign hypertension |
| | 1.0 Dose Unspecified | Daily | |
| **Batch:** | **Started:** L TERM | | **Stopped:** |
| **EFEXOR-XR (Suspected)** | | **Reason:** | Depression |
| | 75.0 Milligram | Daily | |
| **Batch:** | **Started:** 01/08/2001 | | **Stopped:** 06/08/2001 |

## Laboratory Investigations:

## Additional Information:

Patient felt weird - tired, decreased energy, couldn't opent eyes, breathing changes and barely able to life arm.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 170565 **Seq:** 1
**Reported:** 29/11/2001
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 70.00
**Age:** 45
**DOB:** 08/04/1956
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nightmare | | | Required a visit to doctor. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 26/04/2001 **Stopped:** 19/11/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 170878 **Seq:** 1
**Reported:** 07/12/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 02/12/2001
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 66
**DOB:** 27/09/1935
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state<br>Hyponatraemia | | Acute brain syndrome. | Fluid restriction. patient |

### Medicine Details:

**OROXINE (Other drug)** **Reason:**
50.0 Microgram Daily
**Batch:** **Started:** L TERM **Stopped:**

**MS CONTIN (Other drug)** **Reason:** Otr&unsp vertebrogen pain synd
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**CELEBREX (Other drug)** **Reason:** Otr&unsp vertebrogen pain synd
200.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | | | Na = 114 |

### Additional Information:

## Report Detail

**Case Number:** 171036 **Seq:** 1
**Reported:** 17/12/2001
**Hospitalisation:** Hospitalisation prolonged
**Onset Date:** 07/12/2001
**Outcome:** Recovered

**Gender:** F
**Weight:** 167.00
**Age:** 25
**DOB:** 02/12/1976
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyspnoea | | | Patient was hospitalised. date of recovery 10.12.01. rapid retitration of efexor over 36 hours to usual dose, reinitiation of valproate and titration of quetapine. |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 01/06/2001 **Stopped:** 05/12/2001

**QUETIAPINE (Suspected)** **Reason:** Depression
800.0 Milligram Daily
**Batch:** **Started:** 01/06/2001 **Stopped:** 05/12/2001

**SODIUM VALPROATE (Suspected)** **Reason:**
3.0 Gram Daily
**Batch:** **Started:** 01/06/2001 **Stopped:** 05/12/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

The dose start dates for efexor and quetiapine are not necessarily accurate but indicates the drug was started sometime in the month. patient history of borderline personality disorder and major depression.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 171037 **Seq:** 1
**Reported:** 17/12/2001
**Hospitalisation:** Hospitalisation prolonged
**Onset Date:** 07/12/2001
**Outcome:** Recovered

**Gender:** F
**Weight:** 167.00
**Age:** 25
**DOB:** 02/12/1976
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety<br><br><br><br>Depersonalisation<br>Drug withdrawal syndrome<br>Hallucination<br>Sleep disorder | | | Patient was hospitalised. date of recovery 10.12.01. rapid retitration of efexor over 36 hours to usual dose, reinitiation of valproate and titration of quetiapine. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 01/06/2001 **Stopped:** 05/12/2001

**QUETIAPINE (Suspected)** **Reason:** Depression
800.0 Milligram Daily
**Batch:** **Started:** 01/06/2001 **Stopped:** 05/12/2001

**SODIUM VALPROATE (Suspected)** **Reason:**
3.0 Gram Daily
**Batch:** **Started:** **Stopped:** 05/12/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The dose start dates for efexor and quetiapine are not necessarily accurate but indicates the drugs were started sometime in the month. foices within her own head saying she is a bad person and should kill herself.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 171417 **Seq:** 1
**Reported:** 19/12/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 03/12/2001
**Outcome:** Recovered

**Gender:** F
**Weight:** 139.00
**Age:** 25
**DOB:** 02/12/1976
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Chest pain<br>Dyspnoea<br>Oedema peripheral | | | Patient was admitted to hospital and commenced on frusemide 80mg daily and slow k 2 daily |

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **SEROQUEL (Suspected)** | | | **Reason:** | |
| Tablet | 50.0 Milligram | | As necessary | Oral |
| **Batch:** | **Started:** 01/08/2001 | | | **Stopped:** |
| **SEROQUEL (Suspected)** | | | **Reason:** | Unspecified psychosis |
| Tablet | 800.0 Milligram | | Daily | Oral |
| **Batch:** | **Started:** 01/08/2001 | | | **Stopped:** |
| **EPILIM (Suspected)** | | | **Reason:** | |
| Tablet | 3.0 Gram | | Daily | Oral |
| **Batch:** | **Started:** 01/08/2001 | | | **Stopped:** |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression |
| Capsule | 300.0 Milligram | | Daily | Oral |
| **Batch:** | **Started:** 01/08/2001 | | | **Stopped:** |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The dose start dates are not necessarily accurate but indicates seroquel, epilim, efexor xr, diazepam, were started sometime in the month. patient's father has ischaemic heart disease.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 171417 **Seq:** 1
**Reported:** 19/12/2001
**Hospitalisation:** Admitted to hospital
**Onset Date:** 03/12/2001
**Outcome:** Recovered

**Gender:** F
**Weight:** 139.00
**Age:** 25
**DOB:** 02/12/1976
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**DIAZEPAM (Suspected)** **Reason:**

Tablet 15.0 Milligram Daily Oral

**Batch:** **Started:** 01/11/2001 **Stopped:**

## Laboratory Investigations:

## Additional Information:

The dose start dates are not necessarily accurate but indicates seroquel, epilim, efexor xr, diazepam, were started sometime in the month. patient's father has ischaemic heart disease.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 171503 **Seq:** 1
**Reported:** 02/01/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/12/2001
**Outcome:** Recovered

**Gender:** M
**Weight:**
**Age:**
**DOB:**
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | | Patient hospitalised. no medication given. date of [illegible] 15/12/2001 |

### Medicine Details:

**VALIUM (Other drug)** **Reason:**

Tablet 5.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** CONTIN

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 171507 **Seq:** 1
**Reported:** 02/01/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 69
**DOB:** 21/08/1932
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyskinesia | | Marked ero - facial. | Patient hospitalised. required a visit to doctor. venlafaxine and lithium ceased. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
375.0 Milligram Daily
**Batch:** **Started:** 28/08/1998 **Stopped:** 01/12/2001

**LITHIUM CARBONATE (Suspected)** **Reason:** Depression
1.0 Gram Daily
**Batch:** **Started:** L TERM **Stopped:** 16/12/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

## Report Detail

**Case Number:** 171920 **Seq:** 1 **Gender:** F
**Reported:** 14/01/2002 **Weight:** 53.00
**Hospitalisation:** **Age:** 18
**Onset Date:** 08/01/2002 **DOB:** 23/01/1983
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Syncope | | | Required a visit to doctor. |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 08/01/2002 **Stopped:** CONTIN

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 171993 **Seq:** 1 **Gender:** F
**Reported:** 18/01/2002 **Weight:**
**Hospitalisation:** **Age:** 41Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug ineffective<br>Suicide attempt | | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 172025 **Seq:** 1
**Reported:** 21/01/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 11/10/2001
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 57
**DOB:** 24/03/1944
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Serotonin syndrome | | | Patient hospitalised. date of recovery 23/10/2001. |

## Medicine Details:

**NARAMIG (Interaction)** **Reason:** Migraine
2.5 Milligram As necessary
**Batch:** **Started:** 12/02/2001 **Stopped:** 28/10/2001

**ENDONE (Interaction)** **Reason:** Osteoarthritis
20.0 Milligram As necessary
**Batch:** **Started:** 15/12/2000 **Stopped:** 15/10/2001

**EFEXOR (Interaction)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 05/03/2001 **Stopped:** 28/10/2001

**DESERIL (Interaction)** **Reason:** Osteoporosis
2.0 Milligram Daily
**Batch:** **Started:** 09/05/2001 **Stopped:** 28/10/2001

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Reaction description - mental state change - hallucination + delirium + agitation + sweating + tremor and shivering. the dose stop dates for the drugs efexor, fosamax, naramig and deseril are not necessarily accurate but indicates the drugs were stopped sometime in the month.

## Report Detail

**Case Number:** 172025 **Seq:** 1
**Reported:** 21/01/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 11/10/2001
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 57
**DOB:** 24/03/1944
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **TRAMADOL HYDROCHLORIDE (Interaction)** | | | **Reason:** Migraine | |
| | 400.0 Milligram | Daily | | |
| **Batch:** | **Started:** 05/08/2001 | | **Stopped:** 29/08/2001 | |
| **FOSAMAX (Other drug)** | | | **Reason:** Other diseases of bone | |
| | 10.0 Milligram | Daily | | |
| **Batch:** | **Started:** 27/02/2001 | | **Stopped:** 28/10/2001 | |
| **CELEBREX (Other drug)** | | | **Reason:** Osteoarthritis | |
| | 200.0 Milligram | Daily | | |
| **Batch:** | **Started:** L TERM | | **Stopped:** 27/02/2001 | |
| **VIOXX (Other drug)** | | | **Reason:** Osteoarthritis | |
| | 2.5 Milligram | Daily | | |
| **Batch:** | **Started:** 05/03/2001 | | **Stopped:** 17/09/2001 | |

## Laboratory Investigations:

## Additional Information:

Reaction description - mental state change - hallucination + delirium + agitation + sweating + tremor and shivering. the dose stop dates for the drugs efexor, fosamax, naramig and deseril are not necessarily accurate but indicates the drugs were stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 172073 **Seq:** 1 **Gender:** M
**Reported:** 18/01/2002 **Weight:**
**Hospitalisation:** **Age:** 40
**Onset Date:** 22/12/2000 **DOB:** 11/04/1960
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vertigo | | Giddiness. | |
| Cognitive disorder | | Impaired cognition. | |
| Agitation | | Night and day agitation. | |
| Headache | Severe | Severe headache. | |
| Drug withdrawal syndrome | | | Efexor xr discontinued. |
| Paraesthesia | | | |
| Visual disturbance | | | |

## Medicine Details:

**NOTEN (Other drug)** **Reason:**
25.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 15/06/1998 **Stopped:** 21/12/2000

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Relevant history - hypertension nos.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 172203 **Seq:** 1
**Reported:** 29/01/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 23/01/2002
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 70.00
**Age:** 31
**DOB:** 11/03/1970
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyskinesia | | Oro-pharyngeal dystonia tongue and | Benztropine iv, diazepam por. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
75.0 Milligram Fortnightly
**Batch:** **Started:** 22/01/2002 **Stopped:** 22/01/2002

**ZYBAN SR (Suspected)** **Reason:** Smoker
150.0 Milligram Daily
**Batch:** **Started:** 21/01/2002 **Stopped:** 22/01/2002

**VERMOX (Suspected)** **Reason:**
100.0 Milligram Daily
**Batch:** **Started:** 22/01/2002 **Stopped:** 22/01/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 172307 **Seq:** 1
**Reported:** 21/01/2002
**Hospitalisation:**
**Onset Date:** 16/01/2002
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 68.00
**Age:** 67
**DOB:** 21/04/1934
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash maculo-papular | | Fine rash on trunk and limbs. | Venlafaxine ceased. patient already hospitalised. |

### Medicine Details:

**PANADOL (Other drug)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**HYDROXOCOBALAMIN (Other drug)** **Reason:** Unspec vitamin deficien states
1.0 Microgram Daily
**Batch:** **Started:** **Stopped:**

**ASASANTIN SR (Other drug)** **Reason:**
Capsule 2.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

**IMODIUM (Other drug)** **Reason:**
Tablet 3.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 09/01/2002 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Allergy to penicillin.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 172307 **Seq:** 1
**Reported:** 21/01/2002
**Hospitalisation:**
**Onset Date:** 16/01/2002
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 68.00
**Age:** 67
**DOB:** 21/04/1934
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **UREA (Other drug)** | | | | **Reason:** | | |
| Ointment | | 2.0 | Dose Unspecified | Daily | | Topical |
| **Batch:** | **Started:** | 16/01/2002 | | | **Stopped:** | |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | | **Reason:** | | |
| | | 0.0 | | | | |
| **Batch:** | **Started:** | | | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

Allergy to penicillin.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 172381 **Seq:** 1
**Reported:** 01/02/2002
**Hospitalisation:**
**Onset Date:** 28/11/2001
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 100.00
**Age:** 44
**DOB:** 09/10/1957
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Genital candidiasis | | Penile moniliasis. | |

### Medicine Details:

**KALMA (Other drug)** **Reason:**
3.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 01/08/2001 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The date of onset is not necessarily accurate but indciates onset sometime in the month. the dose start date if not necessarily accurate but indicates the drug was started sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 172641 **Seq:** 1 **Gender:** F
**Reported:** 13/02/2002 **Weight:**
**Hospitalisation:** **Age:** 44
**Onset Date:** 22/04/2001 **DOB:** 27/12/1956
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delirium<br>Leukopenia<br>Neutropenia | | | Quetiapine ceased. |

### Medicine Details:

**PREMIA 5 (Other drug)** **Reason:** Menopausal symptoms
5.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**ASPIRIN (Other drug)** **Reason:**
600.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**LORAZEPAM (Suspected)** **Reason:**
2.5 Milligram As necessary
**Batch:** **Started:** 19/04/2001 **Stopped:**

**SEROQUEL (Suspected)** **Reason:** Unspecified schizophrenia
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 2W

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Neutrophils | | 22/04/2001 | 2.46 | |
| | Neutrophils | | 23/04/2001 | 1.9 | |
| | White blood cells | | 22/04/2001 | 4.14 | |
| | White blood cells | | 23/04/2001 | 3.27 | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 172641 **Seq:** 1 **Gender:** F
**Reported:** 13/02/2002 **Weight:**
**Hospitalisation:** **Age:** 44
**Onset Date:** 22/04/2001 **DOB:** 27/12/1956
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **OLANZAPINE (Suspected)** | | | **Reason:** | |
| | 20.0 Milligram | Daily | | |
| **Batch:** | **Started:** 21/04/2001 | | **Stopped:** | |
| **ZUCLOPENTHIXOL ACETATE (Suspected)** | | | **Reason:** | |
| | 20.0 Milligram | Daily | | |
| **Batch:** | **Started:** | | **Stopped:** | 18/04/2001 |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | |
| | 300.0 Milligram | Daily | | |
| **Batch:** | **Started:** | | **Stopped:** | 20/04/2001 |

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 172875 **Seq:** 1
**Reported:** 18/02/2002
**Hospitalisation:**
**Onset Date:** 17/01/2002
**Outcome:** Recovered

**Gender:** M
**Weight:** 70.00
**Age:** 76
**DOB:** 25/12/1925
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | | Required a visit to doctor. date of recovery 31.1.02. |

## Medicine Details:

**EFEXOR (Interaction)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**DICHLOTRIDE (Interaction)** **Reason:**
0.5 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Chloride | | | | Cl - 85. |
| | Potassium | | | | K decreased to 4.3. |
| | Sodium | | | | Na - 121 mmol/l. |

## Additional Information:

Patient history of anxiety, depressaion and hypertension.

## Report Detail

**Case Number:** 173085 **Seq:** 1
**Reported:** 25/02/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 08/10/2001
**Outcome:** Recovered

**Gender:** F
**Weight:** 70.00
**Age:** 53
**DOB:** 06/09/1948
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mania | | Hypomanic behaviour. | |
| Serotonin syndrome | | Serotonin like syndrome. | Patient was admitted to psychiatric ward. |
| Hyperhidrosis | | | |
| Hypertension | | | |
| Tachycardia | | | |

## Medicine Details:

**EFEXOR-XR (Interaction)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 20/06/2001 **Stopped:** 08/10/2001

**TRAMAL SR (Interaction)** **Reason:** Otr&unsp vertebrogen pain synd
300.0 Milligram Daily
**Batch:** **Started:** 02/09/2001 **Stopped:** 08/10/2001

**DIAZEPAM (Other drug)** **Reason:**
5.0 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**HYPNODORM (Other drug)** **Reason:**
2.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 173086 **Seq:** 1 **Gender:** M
**Reported:** 25/02/2002 **Weight:** 90.00
**Hospitalisation:** **Age:** 43
**Onset Date:** **DOB:** 20/07/1958
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Syncope | | Eight episodes of loss of consciousness. | Patient will see a cardiologist. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** 01/11/2001 **Stopped:** 21/02/2002

**ALCOHOL (Suspected)** **Reason:**
8.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient had 8 stubbies of light beer a day for over 1 year. the dose start date for efexor is not necessarily accurate but indicates efexor was started sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 173214 **Seq:** 1
**Reported:** 28/02/2002
**Hospitalisation:**
**Onset Date:** 11/02/2002
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 124.00
**Age:** 60
**DOB:** 11/02/1942
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia | | Aches and pain. | |
| Tremor | | In hand. | |
| Anorexia | | | |
| Anxiety | | | |
| Diarrhoea | | | |
| Hyperhidrosis | | | Given murelax 30mg/bd. required a visit to doctor. |
| Insomnia | | | |
| Micturition disorder | | | |

### Medicine Details:

**DIAMICRON (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**NORVASC (Other drug)** **Reason:** Essential benign hypertension
5.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**NOTEN (Other drug)** **Reason:** Otr&nos disord of heart rhythm
50.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**TRANSIDERM-NITRO (Other drug)** **Reason:** Angina pectoris w/o hyperten
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Allergy to tetracycline multiple medications.

## Report Detail

**Case Number:** 173214 **Seq:** 1
**Reported:** 28/02/2002
**Hospitalisation:**
**Onset Date:** 11/02/2002
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 124.00
**Age:** 60
**DOB:** 11/02/1942
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | |
|---|---|---|---|
| **LIPITOR (Other drug)** | | **Reason:** | Othr&unspec metabolic diseases |
| | 10.0 Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** |
| **DIAFORMIN (Other drug)** | | **Reason:** | Diabetes mellitus |
| | 500.0 Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** |
| **EFEXOR-XR (Suspected)** | | **Reason:** | Anxiety neurosis |
| | 75.0 Milligram | Daily | |
| **Batch:** | **Started:** 11/02/2002 | | **Stopped:** 18/02/2002 |

## Laboratory Investigations:

## Additional Information:

Allergy to tetracycline multiple medications.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 173251 **Seq:** 1 **Gender:** F
**Reported:** 25/02/2002 **Weight:**
**Hospitalisation:** **Age:** AD
**Onset Date:** 31/12/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Feeding disorder neonatal<br>Drug withdrawal syndrome neona<br>Tremor | | Slow to feed. | Observation. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Mother commenced efexor xr 375mg daily prior to conception. decreased to 150mg daily at 16/40. baby aged 3 days following elective caesarean at 39/40 was admitted to special care baby unit - slow to feed and tremors. biochemically normal. tremors were generalised with no impairment of consciousness. resolved over 8 weeks.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 173261 **Seq:** 1 **Gender:** F
**Reported:** 25/02/2002 **Weight:** 38.00
**Hospitalisation:** **Age:** 98Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Increased appetite | | Carbohydrate cravings | Required a visit to doctor. |

### Medicine Details:

**COVERSYL (Other drug)** **Reason:**
2.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**TRANSIDERM-NITRO (Other drug)** **Reason:**
50.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**EFEXOR (Suspected)** **Reason:**
37.5 Milligram Daily
**Batch:** **Started:** **Stopped:**

**SEREPAX (Suspected)** **Reason:**
7.5 Milligram Daily
**Batch:** **Started:** **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 173364 **Seq:** 1 **Gender:** F
**Reported:** 01/03/2002 **Weight:** 84.00
**Hospitalisation:** **Age:** 56
**Onset Date:** 18/02/2002 **DOB:** 24/09/1945
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia | | | |
| Chills | | | |
| Diarrhoea | | | |
| Headache | | | |
| Vomiting | | | Required a visit to doctor. |
| Yawning | | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

Tablet 37.5 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 173513 **Seq:** 1
**Reported:** 11/03/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 28/02/2002
**Outcome:** Recovered

**Gender:** F
**Weight:** 58.00
**Age:** 33
**DOB:** 19/10/1968
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br><br>Agitation<br>Nausea<br>Vertigo<br>Visual disturbance<br>Vomiting | Severe | Severe discontinuation symptoms. | Patient was hospitalised. required im stemetil / maxolon. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

375.0 Milligram Daily

**Batch:** **Started:** 01/11/2001 **Stopped:** 28/01/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for efexor xr is not necessarily accurate but indicates efexor xr was started sometime in the month. the dose stop date for efexor xr is not necessarily accurate but indicates efexor xr was stopped sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 173579 **Seq:** 1 **Gender:** M
**Reported:** 13/03/2002 **Weight:** 68.00
**Hospitalisation:** **Age:** 66
**Onset Date:** 16/02/2002 **DOB:** 21/05/1935
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion<br><br>Diarrhoea<br>Faecal incontinence<br>Urinary incontinence<br>Vomiting | | | Patient already in hospital required doctor's visit. efexor ceased |

### Medicine Details:

**AVANZA (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**ATIVAN (Other drug)** **Reason:** Anxiety neurosis
1.0 Milligram As necessary
**Batch:** **Started:** 12/02/2002 **Stopped:** 27/02/2002

**MIRTAZAPINE (Other drug)** **Reason:** Depression
45.0 Milligram Daily
**Batch:** **Started:** 12/02/2002 **Stopped:**

**ZANTAC (Other drug)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** 10/02/2002 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 173579 **Seq:** 1
**Reported:** 13/03/2002
**Hospitalisation:**
**Onset Date:** 16/02/2002
**Outcome:** Recovered

**Gender:** M
**Weight:** 68.00
**Age:** 66
**DOB:** 21/05/1935
**Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | |
|---|---|---|---|
| **ISCOVER (Other drug)** | | **Reason:** | |
| | 75.0 Milligram | Daily | |
| **Batch:** | **Started:** 10/02/2002 | | **Stopped:** |
| **EFEXOR (Suspected)** | | **Reason:** | Depression |
| | 37.5 Milligram | Daily | |
| **Batch:** | **Started:** 14/02/2002 | | **Stopped:** 17/02/2002 |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 173625 **Seq:** 1 **Gender:** F
**Reported:** 05/02/2002 **Weight:** 60.00
**Hospitalisation:** **Age:** 38
**Onset Date:** **DOB:** 11/11/1963
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Chromosome abnormality | | Edward's syndrome. | Patient underwent an elective abortion. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 300.0 Milligram Daily Oral
**Batch:** **Started:** 13/04/2000 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The mother became pregnant while taking efexor xr. her fetus was diagnosed with trisomy 18 (via chorionic villus sampling) in the first trimester ( at approximately week 12). the patient underwent an elective abortion.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 173739 **Seq:** 1
**Reported:** 20/03/2002
**Hospitalisation:**
**Onset Date:** 28/02/2002
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 96.00
**Age:** 44
**DOB:** 19/09/1957
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Salivary hypersecretion | | Excessive salivation. | Required a visit to doctor. |

## Medicine Details:

**THYROXINE SODIUM (Other drug)** **Reason:** Myxedema
200.0 Microgram Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
225.0 Milligram Daily
**Batch:** **Started:** 01/11/2001 **Stopped:** 28/03/2002

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Efexor dose has been increasing. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for efexor is not necessarily accurate but indicates efexor was started sometime in the month. the dose stop date for efexor is not necessarily accurate but indicates efexor was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 173809 **Seq:** 1
**Reported:** 22/03/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:**
**Age:** 65
**DOB:** 14/12/1936
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthritis | Required Specialist Consultation | Mild arthritis. | Patient hospitalised. |

## Medicine Details:

**ISOPTIN (Other drug)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:**

**ASPIRIN (Other drug)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:**

**ZOCOR (Other drug)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:**

**VENTOLIN (Other drug)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Efexor xr was also taken at 150mg/daily.

## Report Detail

**Case Number:** 173809 **Seq:** 1
**Reported:** 22/03/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:**
**Age:** 65
**DOB:** 14/12/1936
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **ATROVENT (Other drug)** | | | **Reason:** | |
| | 0.0 | | | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | |
| **SERETIDE ACCUHALER NOS (Other drug)** | | | **Reason:** | |
| Inhalation | 0.0 | | | Inhalation |
| **Batch:** | **Started:** | L TERM | **Stopped:** | |
| **OROXINE (Other drug)** | | | **Reason:** | |
| | 0.0 | | | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression |
| | 225.0 Milligram | Daily | | |
| **Batch:** | **Started:** | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

Efexor xr was also taken at 150mg/daily.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 173823 **Seq:** 1 **Gender:** M
**Reported:** 19/03/2002 **Weight:**
**Hospitalisation:** **Age:** 80
**Onset Date:** 02/12/2001 **DOB:** 19/05/1921
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination<br>Confusional state | | Hallucinations for about 6 hours overnight. | Patient already in hospital. |

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **SOMAC (Other drug)** | | | **Reason:** | Ulcer of duodenum w/o ment perf | |
| Tablet | 40.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | CONTIN |
| **STEMETIL (Other drug)** | | | **Reason:** | | |
| Tablet | 15.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | 02/12/2001 |
| **TRIPRIM (Other drug)** | | | **Reason:** | | |
| | 300.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | CONTIN |
| **PETHIDINE HYDROCHLORIDE (Other drug)** | | | **Reason:** | Pain | |
| Injection | 600.0 | Milligram | Daily | Intramuscular | |
| **Batch:** | **Started:** | 01/02/2001 | | **Stopped:** | 02/12/2001 |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

## Report Detail

**Case Number:** 173823 **Seq:** 1 **Gender:** M
**Reported:** 19/03/2002 **Weight:**
**Hospitalisation:** **Age:** 80
**Onset Date:** 02/12/2001 **DOB:** 19/05/1921
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **MAXOLON (Other drug)** | | | **Reason:** | | |
| Injection | 20.0 | Milligram | Daily | | Intramuscular |
| **Batch:** | **Started:** | 01/02/2001 | | **Stopped:** | 01/02/2001 |
| **PARACETAMOL (Other drug)** | | | **Reason:** | | |
| Oral application | 1.0 | Gram | Daily | | Oral |
| **Batch:** | **Started:** | 01/02/2001 | | **Stopped:** | 02/02/2001 |
| **STILNOX (Suspected)** | | | **Reason:** | | |
| Tablet | 1.0 | Dose Unspecified | 1 time | | Oral |
| **Batch:** | **Started:** | 02/12/2001 | | **Stopped:** | |
| **CAPADEX (Suspected)** | | | **Reason:** | Pain | |
| Capsule | 2.0 | Dose Unspecified | 1 time | | Oral |
| **Batch:** | **Started:** | 02/12/2001 | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 173823 **Seq:** 1 **Gender:** M
**Reported:** 19/03/2002 **Weight:**
**Hospitalisation:** **Age:** 80
**Onset Date:** 02/12/2001 **DOB:** 19/05/1921
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **EFEXOR-XR (Suspected)** | | | **Reason:** | |
| Capsule | 150.0 Milligram | Daily | Oral | |
| **Batch:** | **Started:** 07/02/2001 | | **Stopped:** | CONTIN |

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 173908 **Seq:** 1
**Reported:** 25/03/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 19/12/2001
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 77
**DOB:** 28/01/1924
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delirium<br><br>Psychotic disorder | | | Patient admitted to rehabilitation ward. efexor xr and tramal ceased |

## Medicine Details:

**VERAPAMIL HYDROCHLORIDE (Other drug)** **Reason:**
Tablet 120.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**RALOXIFENE (Other drug)** **Reason:**
Tablet 60.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**PIZOTIFEN MALATE (Other drug)** **Reason:**
Tablet 1.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**FRUSEMIDE (Other drug)** **Reason:**
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient also taking clonazepam, loperamide, codeine & paracemtamol, metoclopramide and aspirin.

## Report Detail

**Case Number:** 173908 **Seq:** 1
**Reported:** 25/03/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 19/12/2001
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 77
**DOB:** 28/01/1924
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **POTASSIUM CHLORIDE (Other drug)** | | | **Reason:** | | |
| Tablet | 600.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **OMEPRAZOLE (Other drug)** | | | **Reason:** | | |
| Capsule | 20.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression | |
| Capsule | 75.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | |
| **TRAMAL (Suspected)** | | | **Reason:** | Unspecified arthritis | |
| Capsule | 100.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | S TERM | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

Patient also taking clonazepam, loperamide, codeine & paracemtamol, metoclopramide and aspirin.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 174423 **Seq:** 1 **Gender:** F
**Reported:** 05/04/2002 **Weight:**
**Hospitalisation:** **Age:** 32Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | | Generalised shaking. | |
| Muscle twitching | | Twitching of the jaw. | |
| Hypokinesia | | Unresponsiveness. | |
| Agitation | | | |
| Confusional state | | | |
| Hyperhidrosis | | | |
| Hypertension | | | |
| Pyrexia | | | |
| Respiratory disorder | | | |
| Serotonin syndrome | | | Diazepam iv 5mg. |
| Tachycardia | | | |

### Medicine Details:

**METOCLOPRAMIDE HYDROCHLORIDE (Interaction)** **Reason:** Nausea and vomiting
Injection 10.0 Milligram 2 times Intravenous
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:** Depression
225.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**MORPHINE SULPHATE (Other drug)** **Reason:**
Injection 5.0 Milligram As necessary Intravenous
**Batch:** **Started:** **Stopped:**

**INDOMETHACIN (Other drug)** **Reason:**
200.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Fisher aa, davis mw. serontonin syndrome caused by selective serotonin reupta- ke-inhibitors-metoclopramide interaction. ann pharmacother.2002 jan;jan 36(1) :67-71.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 174439 **Seq:** 1 **Gender:** F
**Reported:** 11/04/2002 **Weight:**
**Hospitalisation:** **Age:** 61
**Onset Date:** 18/12/2001 **DOB:** 08/11/1940
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Encephalopathy<br>Hepatic failure<br>Jaundice | | | Liver transplantation 5/4/02. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

0.0

**Batch:** **Started:** 01/09/2001 **Stopped:** 13/02/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Biochemistry<br>International | | | | Bilirubin 591, ast 1625, alt 2215, alk phos 342, ggt 682.<br>Max int 7.0. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 174563 **Seq:** 1 **Gender:** M
**Reported:** 15/04/2002 **Weight:** 70.00
**Hospitalisation:** **Age:** 70
**Onset Date:** 22/03/2002 **DOB:** 02/04/1931
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Prostatic disorder | Severe | Severe aggravation of prostatism. | Required a visit to doctor. date of recovery 5.4.02. |

### Medicine Details:

**SAW PALMETTO (Other drug)** **Reason:**
1.6 Gram Daily
**Batch:** **Started:** L TERM **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 22/03/2002 **Stopped:** 04/04/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Cipramil ceased prior to starting efexor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 174567 **Seq:** 1 **Gender:** F
**Reported:** 15/04/2002 **Weight:** 80.00
**Hospitalisation:** **Age:** 27
**Onset Date:** 25/02/2002 **DOB:** 23/05/1974
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Nightmare<br><br>Somnolence | | Immediate dizziness. | Required a visit to doctor. date of recovery 5.4.02. |

### Medicine Details:

**TERIL (Other drug)** **Reason:**
600.0 Milligram Daily
**Batch:** **Started:** **Stopped:** CONTIN

**EFEXOR (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 21/01/2002 **Stopped:** 26/03/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 174746 **Seq:** 1 **Gender:** F
**Reported:** 23/04/2002 **Weight:**
**Hospitalisation:** **Age:** 79Y
**Onset Date:** 19/12/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state<br>Delirium<br>Hyponatraemia | | | Date of recovery 24.12.02. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
0.0
**Batch:** **Started:** **Stopped:**

**IRBESARTAN (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 19/12/2001

**GENTAMICIN SULPHATE (Suspected)** **Reason:**
Injection 240.0 Milligram Daily Intravenous
**Batch:** **Started:** **Stopped:** 19/12/2001

**AMPICILLIN (Suspected)** **Reason:**
Injection 1.0 Gram Daily Intravenous
**Batch:** **Started:** **Stopped:** 19/12/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Creatinine | | 21/10/2001 | 65 | |
| | Creatinine | | 18/12/2001 | 46 | |
| | Creatinine | | 19/12/2001 | 53 | |
| | Creatinine | | 20/12/2001 | 44 | |
| | Creatinine | | 24/12/2001 | 62 | |
| | Creatinine | | 22/12/2001 | 56 | |
| | Potassium | | 21/10/2001 | 4.7 | |

### Additional Information:

## Report Detail

**Case Number:** 174746 **Seq:** 1 **Gender:** F
**Reported:** 23/04/2002 **Weight:**
**Hospitalisation:** **Age:** 79Y
**Onset Date:** 19/12/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**CEPHAZOLIN SODIUM (Suspected)** **Reason:**

Injection 1.0 Gram Daily Intravenous

**Batch:** **Started:** 19/12/2001 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Potassium | | 18/12/2001 | 4.0 | |
| | Potassium | | 19/12/2001 | 4.0 | |
| | Potassium | | 22/12/2001 | 4.4 | |
| | Potassium | | 24/12/2001 | 4.6 | |
| | Potassium | | 28/12/2001 | 4.2 | |
| | Potassium | | 20/12/2001 | 4.3 | |
| | Sodium | | 21/10/2001 | 142 | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 174746 **Seq:** 1 **Gender:** F
**Reported:** 23/04/2002 **Weight:**
**Hospitalisation:** **Age:** 79Y
**Onset Date:** 19/12/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **EFEXOR (Suspected)** | | | **Reason:** | Depression | |
| | 0.0 | | | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **IRBESARTAN (Suspected)** | | | **Reason:** | | |
| | 75.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | 19/12/2001 |
| **GENTAMICIN SULPHATE (Suspected)** | | | **Reason:** | | |
| Injection | 240.0 | Milligram | Daily | | Intravenous |
| **Batch:** | **Started:** | | | **Stopped:** | 19/12/2001 |
| **AMPICILLIN (Suspected)** | | | **Reason:** | | |
| Injection | 1.0 | Gram | Daily | | Intravenous |
| **Batch:** | **Started:** | | | **Stopped:** | 19/12/2001 |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | 18/12/2001 | 110 | |
| | Sodium | | 19/12/2001 | 115 | |
| | Sodium | | 20/12/2001 | 114 | |
| | Sodium | | 22/12/2001 | 127 | |
| | Sodium | | 28/12/2001 | 135 | |
| | Sodium | | 24/12/2001 | 138 | |
| | Urea | | 21/10/2001 | 3.3 | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 174746 **Seq:** 1 **Gender:** F
**Reported:** 23/04/2002 **Weight:**
**Hospitalisation:** **Age:** 79Y
**Onset Date:** 19/12/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**CEPHAZOLIN SODIUM (Suspected)** **Reason:**

Injection 1.0 Gram Daily Intravenous

**Batch:** **Started:** 19/12/2001 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Urea | | 18/12/2001 | 2.9 | |
| | Urea | | 19/12/2001 | 2.4 | |
| | Urea | | 20/12/2001 | 2.3 | |
| | Urea | | 22/12/2001 | 2.8 | |
| | Urea | | 28/12/2001 | 3.2 | |
| | Urea | | 24/12/2001 | 4.6 | |

## Additional Information:

## Report Detail

**Case Number:** 174752 **Seq:** 1 **Gender:** U
**Reported:** 23/04/2002 **Weight:**
**Hospitalisation:** **Age:** 59
**Onset Date:** 30/01/2002 **DOB:** 29/03/1942
**Outcome:** Not yet recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Inappropriate antidiuretic hormon | | | Venlafaxine ceased. patient already in hospital. |

## Medicine Details:

**DIAZEPAM (Other drug)** **Reason:** Anxiety neurosis
20.0 Milligram Daily
**Batch:** **Started:** S TERM **Stopped:** 25/01/2002

**TEMAZEPAM (Other drug)** **Reason:** Specific disorders of sleep
10.0 Milligram Daily
**Batch:** **Started:** 14/01/2002 **Stopped:**

**TRAMADOL HYDROCHLORIDE (Other drug)** **Reason:** Pain
50.0 Milligram Daily
**Batch:** **Started:** S TERM **Stopped:** 25/01/2002

**SODIUM VALPROATE (Other drug)** **Reason:**
1.0 Gram Daily
**Batch:** **Started:** 15/01/2002 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electrolytes | | | | The se na and urine osmolality were within normal limits at start of venlafaxine. |

## Additional Information:

Sodium levels dropped significantly, urine osmolality increased over one week. both returned to normal after ceasing drug venlafaxine. has had many different antidepressants prior to admission to hospital.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 174752 **Seq:** 1
**Reported:** 23/04/2002
**Hospitalisation:**
**Onset Date:** 30/01/2002
**Outcome:** Not yet recovered

**Gender:** U
**Weight:**
**Age:** 59
**DOB:** 29/03/1942
**Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **CIPRAMIL (Other drug)** | | | **Reason:** | Depression | |
| Tablet | 20.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 31/12/2001 | | **Stopped:** | 14/01/2002 |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | | |
| | 0.0 | | | | |
| **Batch:** | **Started:** | | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

Sodium levels dropped significantly, urine osmolality increased over one week. both returned to normal after ceasing drug venlafaxine. has had many different antidepressants prior to admission to hospital.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 174828 **Seq:** 1
**Reported:** 26/04/2002
**Hospitalisation:**
**Onset Date:** 09/04/2002
**Outcome:** Recovered

**Gender:** F
**Weight:** 74.00
**Age:** 45
**DOB:** 18/08/1956
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | | Cns hypersensitivity / disturbance. | Required a visit to doctor. date of recovery: 22/4/2002. |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 01/12/2001 **Stopped:** 08/04/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Marked cns symptoms on withdrawal of venlafaxine despite having slowly reduced the dose from 150mg sr daily to 25mg od over 6 weeks. the dose start date for venlafaxine is not necessarily accurate but indicates vanlafaxine was started sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 174931 **Seq:** 1 **Gender:** M
**Reported:** 29/04/2002 **Weight:** 72.00
**Hospitalisation:** **Age:** 41
**Onset Date:** 28/03/2002 **DOB:** 08/01/1961
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | Tonic clonic seizures. | Required a visit to doctor. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 01/05/2000 **Stopped:** 28/03/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for efexor xr is not necessarily accurate but indicates efexor xr was started sometime in the month. the dose stop date for efexor xr is not necessarily accurate but indicates efexor xr was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 174932 **Seq:** 1
**Reported:** 26/04/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 32Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | | |
| Confusional state | | | |
| Convulsion | | | |
| Dyskinesia | | | |
| Hyperhidrosis | | | |
| Hyperreflexia | | | |
| Hypertension | | | |
| Hypertonia | | | |
| Muscle twitching | | | |
| Mydriasis | | | |
| Nystagmus | | | |

## Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:**
225.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**METOCLOPRAMIDE HYDROCHLORIDE (Interaction)** **Reason:** Nausea and vomiting
10.0 Milligram Daily Intravenous
**Batch:** **Started:** **Stopped:**

**MORPHINE NOS (Other drug)** **Reason:**
2.5 Milligram As necessary Intravenous
**Batch:** **Started:** **Stopped:**

**INDOMETHACIN (Other drug)** **Reason:**
200.0 Milligram Daily Rectal
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

The annals of pharmacotherapy 2002 january vol 36, p68.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 174932 **Seq:** 1
**Reported:** 26/04/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 32Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pyrexia<br>Serotonin syndrome<br>Tachycardia | | | |

## Medicine Details:

**ACETAMINOPHEN (Other drug)** **Reason:**

4.0 Gram Daily Oral

**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

The annals of pharmacotherapy 2002 january vol 36, p68.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 174970 **Seq:** 1
**Reported:** 30/04/2002
**Hospitalisation:**
**Onset Date:** 19/03/2002
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 75Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatocellular damage | | | Omeprazole, metoprolol, isorbide, ramipril, venlafaxine, temazepam were ceased |

## Medicine Details:

**ASPIRIN (Other drug)** **Reason:**
100.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**TEMAZEPAM (Suspected)** **Reason:** Specific disorders of sleep
10.0 Milligram As necessary
**Batch:** **Started:** 18/03/2002 **Stopped:** 20/03/2002

**OMEPRAZOLE (Suspected)** **Reason:** Abdominal pain
40.0 Milligram Daily
**Batch:** **Started:** 18/03/2002 **Stopped:** 20/03/2002

**METOPROLOL TARTRATE (Suspected)** **Reason:**
50.0 Milligram Daily
**Batch:** **Started:** 18/03/2002 **Stopped:** 20/03/2002

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | | 19/03/2002 | 923 | |
| | ALT = SGPT | | 09/04/2002 | 65 | |
| | Bilirubin | | 19/03/2002 | 29 | |
| | Bilirubin | | 09/04/2002 | 10 | |
| | Ferritin | | 19/03/2002 | 5400 | |
| | GGT = SGGT = | | 19/03/2002 | 734 | |
| | GGT = SGGT = | | 09/04/2002 | 337 | |

## Additional Information:

Patient was transferred to older persons psychiatric unit from a general hospital with increasing depressive symptoms post acute mi. was commenced on venlafaxine 37.5mg, which was increased to 75mg on admission. routine blood test indicated hepatic failure. was transfered back to hospital, where all current meds were ceased.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 174970 **Seq:** 1
**Reported:** 30/04/2002
**Hospitalisation:**
**Onset Date:** 19/03/2002
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 75Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **ISOSORBIDE MONONITRATE (Suspected)** | | | **Reason:** | Angina pectoris w/o hyperten |
| | 30.0 Milligram | Daily | | |
| **Batch:** | **Started:** 18/03/2002 | | **Stopped:** | 20/03/2002 |
| **RAMIPRIL (Suspected)** | | | **Reason:** | |
| | 1.2 Milligram | Daily | | |
| **Batch:** | **Started:** 18/03/2002 | | **Stopped:** | 20/03/2002 |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | Depression |
| | 75.0 Milligram | Daily | | |
| **Batch:** | **Started:** 18/03/2002 | | **Stopped:** | 20/03/2002 |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | SAP = ALP | | 19/03/2002 | 710 | |
| | SAP = ALP | | 09/04/2002 | 334 | |

### Additional Information:

Patient was transferred to older persons psychiatric unit from a general hospital with increasing depressive symptoms post acute mi. was commenced on venlafaxine 37.5mg, which was increased to 75mg on admission. routine blood test indicated hepatic failure. was transfered back to hospital, where all current meds were ceased.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 174984 **Seq:** 1
**Reported:** 02/05/2002
**Hospitalisation:**
**Onset Date:** 08/02/2002
**Outcome:** Not yet recovered

**Gender:** M
**Weight:**
**Age:** 19
**DOB:** 27/04/1982
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Galactorrhoea<br>Gynaecomastia | | | Required a visit to doctor.<br>discontinuation of efexor. |

## Medicine Details:

**ZYPREXA (Other drug)** **Reason:** Unspecified schizophrenia
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:** CONTIN

**ZANTAC (Other drug)** **Reason:** Other diseases of esophagus
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 24/12/2001 **Stopped:** 27/03/2002

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 175084 **Seq:** 1
**Reported:** 06/05/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 14/03/2002
**Outcome:** Recovered

**Gender:** M
**Weight:** 60.00
**Age:** 46
**DOB:** 28/10/1955
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br><br>Delirium | | Life threatening reaction. | Normal saline infusion. patient was hospitalised. date of recovery: 12/04/02. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 21/12/2001 **Stopped:** 04/04/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | 14/03/2002 | 125 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 175252 **Seq:** 1
**Reported:** 08/05/2002
**Hospitalisation:** Treated in outpatient department only.
**Onset Date:** 28/03/2002
**Outcome:** Not yet recovered

**Gender:** M
**Weight:**
**Age:** 55Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pain<br>Thirst | | | Patient went to hospital and had ultrasound all was normal. at this time patient was asked to stop efexor. dose was gradually reduced from 75mg to 37. 5mg to 1/2 37.5mg |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

75.0 Milligram Daily

**Batch:** **Started:** 01/01/2002 **Stopped:** 28/04/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The onset date is not necessarily accurate but indicates onset sometime in the month. the dose start and stop dates are not necessarily accurate but indicates efexor was started and stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 175253 **Seq:** 1
**Reported:** 08/05/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 28/03/2002
**Outcome:** Not yet recovered

**Gender:** M
**Weight:**
**Age:** 55Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state<br><br>Disturbance in attention<br>Drug withdrawal syndrome | | | Recently patient stopped efexor altogether and experienced symptoms patient was admitted to hospital for 4 days. patient went back on efexor and symptoms went away. |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
18.7 Milligram Daily
**Batch:** **Started:** 01/01/2002 **Stopped:** 28/04/2002

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

The onset date is not necessarily accurate but indicates onset sometime in the month. the dose start and stop dates are not necessarily accurate but indicates efexor was started and stopped sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 175254 **Seq:** 1 **Gender:** F
**Reported:** 08/05/2002 **Weight:** 95.00
**Hospitalisation:** **Age:** 31Y
**Onset Date:** 17/01/2002 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Heart disease congenital<br><br>Multiple congenital abnormalities | | | Baby admitted for investigation 22/2/02, surgery 4/3/02. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
75.0 Milligram Daily
**Batch:** **Started:** 01/01/2001 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Miscarriage jan 2001. second cousin born with congenital heart defects. transitional av canal-balanced. large osteum primum asd,l-r shunt. 2 av valves, grade 2 mitral regurgitation, grade 2 tricuspid regurgitation. goose neck deformity of aorta. small 2mm pda. baby girl born with heart defects. the dose start date is not necessarily accurate but indicates the drug was started sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 175380 **Seq:** 1 **Gender:** F
**Reported:** 13/05/2002 **Weight:** 61.00
**Hospitalisation:** **Age:** 58
**Onset Date:** 07/05/2002 **DOB:** 24/04/1944
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depression<br>Drug withdrawal syndrome<br>Headache<br>Nausea<br><br>Suicide attempt | | | Required a visit to doctor. date of recovery 08/05/02. |

### Medicine Details:

**TAMOXIFEN CITRATE (Other drug)** **Reason:** Malignant neoplasm of breast
20.0 Milligram Daily
**Batch:** **Started:** 19/12/2001 **Stopped:** CONTIN

**ANPEC (Other drug)** **Reason:**
240.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**TEMAZE (Other drug)** **Reason:** Specific disorders of sleep
10.0 Milligram Daily
**Batch:** **Started:** 04/04/2002 **Stopped:** CONTIN

**EFEXOR (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** 21/02/2002 **Stopped:** 05/05/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 175597 **Seq:** 1
**Reported:** 20/05/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 23/04/2002
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 43
**DOB:** 14/05/1958
**Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Coordination abnormal<br>Anorexia<br>Gait disturbance | | Hot burning sensation all over her body.<br>Unstable and unteady when walking. | Patient hospitalised. |

## Medicine Details:

**PARLODEL (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**SOMAC (Other drug)** **Reason:**
40.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**AVAPRO HCT 300/12.5 (Other drug)** **Reason:** Essential benign hypertension
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 175676 **Seq:** 1 **Gender:** F
**Reported:** 27/05/2002 **Weight:** 80.00
**Hospitalisation:** **Age:** 53
**Onset Date:** 13/05/2002 **DOB:** 12/01/1949
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash<br><br>Face oedema | | Generalised rash. | Required a visit to doctor. telfast, prednisolone tab. date of recovery: 18/05/2002. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 01/04/2002 **Stopped:**

**REMIFEMIN (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 01/04/2002 **Stopped:**

**ZYBAN SR (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 01/05/2002 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The dose start date for efexor is not necessarily accurate but indicates efexor was started sometime in the month. the dose start date for remifemin is not necessarily accurate but indicates remifemin was started sometime in the month. the dose start date for zyban sr is not necessarily accurate but indicates zyban sr was started sometime in the month. no known history of allergies.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 175698 **Seq:** 1 **Gender:** F
**Reported:** 27/05/2002 **Weight:** 80.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 28/04/2002 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delirium<br>Depersonalisation<br>Drug withdrawal syndrome<br>Hallucination | | Patient became accutely and severely | Date of recovery 23.4.02. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 01/03/2002 **Stopped:** 28/04/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start and stop dates for efexor xr are not necessarily accurate but indicates the drug was started and stopped sometime in the month. specialist says that expereince was life threatening because patient had to resist urge to leave room throught window which was on the 4th floor.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 175700 **Seq:** 1 **Gender:** F
**Reported:** 27/05/2002 **Weight:** 60.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** 24/04/2002 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | Seizure most likely grand mal. | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
37.5 Milligram Daily
**Batch:** **Started:** **Stopped:** 26/04/2002

**BUPROPION HYDROCHLORIDE (Suspected)** **Reason:** Depression
200.0 Milligram Daily
**Batch:** **Started:** 01/10/2001 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

The dose start date for bupropion is not necessarily accurate but indicates the drug was started sometime in the month. intense physical activity prior to the seizure. possibly was mildly dehydrated.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 175753 **Seq:** 1 **Gender:** F
**Reported:** 27/05/2002 **Weight:**
**Hospitalisation:** **Age:** 60Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia | | Couldn't sleep. | |
| Nausea | | Nausea with first tablet at midday. | |
| Pollakiuria | | Need to urinate. | |

## Medicine Details:

**PREMARIN (Other drug)** **Reason:** Menopausal symptoms
Tablet 0.3 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**PROVERA (Other drug)** **Reason:** Menopausal symptoms
Tablet 2.5 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram 1 time Oral
**Batch:** **Started:** 15/04/2002 **Stopped:** 15/04/2002

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Sequelae: hit head - pain from injuries.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 175786 **Seq:** 1
**Reported:** 30/05/2002
**Hospitalisation:**
**Onset Date:** 22/05/2002
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 114.00
**Age:** 61
**DOB:** 22/05/1940
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cardiac failure<br><br>Tremor | | | Patient was required to visit doctor. dose was reduced from 150gm |

### Medicine Details:

**XALATAN (Other drug)** **Reason:**
Eye Drops 1.0 Dose Unspecified Daily Ophthalmic
**Batch:** **Started:** **Stopped:** CONTIN

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 01/04/2002 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The dose start date for efexor is not necessarily accurate but indicates the drug was started sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 175802 **Seq:** 1 **Gender:** M
**Reported:** 27/05/2002 **Weight:**
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 14/04/2002 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Dizziness<br>Headache<br>Tremor | | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** 09/04/2002 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Biochemistry<br>Protein | | | | Mononuclear cells.<br>Lumbar pucture revealed raised csf proteins. |

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 175816 **Seq:** 1 **Gender:** F
**Reported:** 31/05/2002 **Weight:** 88.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 28/03/2002 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysgeusia | | | |

## Medicine Details:

**STILNOX (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**DIAMICRON (Other drug)** **Reason:** Diabetes mellitus
Oral application 180.0 Milligram Daily Oral
**Batch:** **Started:** 23/10/2001 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 0.0 Daily Oral
**Batch:** **Started:** 01/02/2002 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for the drug efexor is not necessarily accurate but indicates the drug was started sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 175927 **Seq:** 1 **Gender:** F
**Reported:** 04/06/2002 **Weight:**
**Hospitalisation:** **Age:** AD
**Onset Date:** 14/03/2002 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Talipes<br>Convulsion<br>Drug withdrawal syndrome neona<br>Neonatal disorder<br>Nervousness | | Mild bilateral talipes. | Observation only. |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 11/03/2002

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Female patient took efexor xr during pregnancy. baby male born on 11/3/02 weight 2.5kg.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 175934 **Seq:** 1 **Gender:** F
**Reported:** 04/06/2002 **Weight:**
**Hospitalisation:** **Age:** 30Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Neonatal disorder<br>Congenital hand malformation | | Hypoplastic small digits on both hands. | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 01/01/1999 **Stopped:** CONTIN

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

The dose start date is not accurate but indicates the drug was started sometime in the year. pregnant - ultrasound at 18 weeks "hypoplastic small didits on both hands.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 176258 **Seq:** 1 **Gender:** F
**Reported:** 14/06/2002 **Weight:**
**Hospitalisation:** **Age:** 29
**Onset Date:** 15/05/2002 **DOB:** 13/11/1972
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia | | | Date of recovery 16.5.02. required a visit to doctor. |

### Medicine Details:

**BENZTROPINE MESYLATE (Suspected)** **Reason:**
Tablet 0.0 Oral
**Batch:** **Started:** 13/05/2002 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
225.0 Milligram Daily
**Batch:** **Started:** 11/05/2002 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Began 15-30 minutes after salt & vinegar chips. no previous symptoms on lower dose and no recurrence on lower dose. tongue curled up, difficulty speaking, found it hard to breathe, neck stiff (looking upwards).

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 176287 **Seq:** 1 **Gender:** F
**Reported:** 14/06/2002 **Weight:** 65.00
**Hospitalisation:** **Age:** 19Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anaphylactoid reaction | | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
37.5 Milligram Daily
**Batch:** **Started:** 02/11/2000 **Stopped:** 02/11/2000

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 176288 **Seq:** 1 **Gender:** F
**Reported:** 14/06/2002 **Weight:** 58.00
**Hospitalisation:** **Age:** 57Y
**Onset Date:** 28/10/2001 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cardiomyopathy | | Ejection fraction 10%. | |

### Medicine Details:

**MERSYNDOL (Other drug)** **Reason:**
Tablet 2.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 01/05/1999 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for efexor-xr is not necessarily accurate but indicates the drug was started sometime in the month. the patient has a smoking history of 37 years.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 176289 **Seq:** 1
**Reported:** 14/06/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 28/03/2002
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:**
**DOB:**
**Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Weight decreased<br>Abdominal pain<br>Diarrhoea<br>Vomiting | | Weight loss of 45kg | Patient was hospitalised. |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** 01/01/1998 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Shortly before exploratory surgery, patient took herself off all therapy and symptoms disappeared (no withdrawal symptoms) then rechallenged with elfexor, symptoms reappeared for 28 hours. the date of onset is not necessarily accurate but indicates onset was sometime in the month. the dose start date is not necessarily accurate but indicates efexor was started sometime in the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 176291 **Seq:** 1 **Gender:** F
**Reported:** 14/06/2002 **Weight:** 50.00
**Hospitalisation:** **Age:**
**Onset Date:** 19/10/2001 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cardiomyopathy | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** 01/10/2000 **Stopped:** 26/10/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The dose start date is not necessarily accurate but indicates the drug was started sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 176292 **Seq:** 1
**Reported:** 14/06/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:**
**Age:** 44Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pancytopenia | | | |

### Medicine Details:

**MORPHINE MIXTURE, GOVERNMENT STORES (Other drug)** **Reason:**
50.0 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**LACTULOSE (Other drug)** **Reason:**
0.0 As necessary
**Batch:** **Started:** **Stopped:**

**SENOKOT (Other drug)** **Reason:**
Tablet 0.0 As necessary Oral
**Batch:** **Started:** **Stopped:**

**MS CONTIN (Other drug)** **Reason:** Pain
Tablet 320.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Primary reason for hospitalisation was assessment for suitability for ect. he has severe intractible depression. chronic liver disease due to alcohol.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 176292 **Seq:** 1
**Reported:** 14/06/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:**
**Age:** 44Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **DIAZEPAM (Other drug)** | | | **Reason:** | |
| | 15.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression |
| | 600.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |

## Laboratory Investigations:

## Additional Information:

Primary reason for hospitalisation was assessment for suitability for ect. he has severe intractible depression. chronic liver disease due to alcohol.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 176293 **Seq:** 1 **Gender:** F
**Reported:** 14/06/2002 **Weight:**
**Hospitalisation:** **Age:** 15Y
**Onset Date:** 15/10/2000 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Serotonin syndrome<br>Suicide attempt | | | Patient treated with |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:**
750.0 Milligram Total
**Batch:** **Started:** **Stopped:**

**MOCLOBEMIDE (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

History of depression and past overdoses. serotonin toxicity characterised by sustained ankle clonus, ocular clonus, tachycardia, low-grade fever, hyperreflexia, tremor, myoclonic spasms and agitation.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 176393 **Seq:** 1 **Gender:** F
**Reported:** 17/06/2002 **Weight:**
**Hospitalisation:** **Age:** 42Y
**Onset Date:** 29/12/2001 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Constipation<br><br>Flatulence | | | Patient tried increasing fluid, fibre and exercise, but no benefit. required a visit to doctor |

### Medicine Details:

**LIPITOR (Other drug)** **Reason:** Othr&unspec metabolic diseases
20.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**EFEXOR (Suspected)** **Reason:** Depression
225.0 Milligram Daily
**Batch:** **Started:** 23/12/2001 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Hx of ibs and had laparoscopic removal of ovarian cyst in august 2001.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 176522 **Seq:** 1 **Gender:** F
**Reported:** 21/06/2002 **Weight:** 54.00
**Hospitalisation:** **Age:**
**Onset Date:** 02/06/2002 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthralgia<br>Myalgia | | | Patient required a visit to doctor. date of recovery: [illegible] |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 09/05/2002 **Stopped:** 02/06/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Past history of arthralgia and lupus like disorder.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 176637 **Seq:** 1 **Gender:** F
**Reported:** 24/06/2002 **Weight:** 67.00
**Hospitalisation:** **Age:** 64Y
**Onset Date:** 28/09/2001 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | | Treated with anti-epileptic medication. ongoing epilim. |

### Medicine Details:

**ASPIRIN (Other drug)** **Reason:** Essential benign hypertension
0.0
**Batch:** **Started:** **Stopped:**

**CARDIZEM (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**COVERSYL (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 01/11/2001

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. patient is also using inhalers for asthma. patient had never experienced a fit previously and was drowsy for two days after fitting.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 176665 **Seq:** 1 **Gender:** F
**Reported:** 26/06/2002 **Weight:**
**Hospitalisation:** **Age:** 83Y
**Onset Date:** 25/02/2002 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cold sweat | Life | Life threatening. | Given phenergan and largactil. |
| Hyperhidrosis | Life | Life threatening. | |
| Medication error | Life | Life threatening. | |
| Serotonin syndrome | Life | Life threatening. | |
| Syncope | Life | Life threatening. | |
| Consciousness fluctuating | Life | Threatening. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**LASIX (Suspected)** **Reason:**
40.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**SLOW-K (Suspected)** **Reason:**
1.2 Gram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Past history - depression, mild angina and impaired glucose intolerence.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 176674 **Seq:** 1 **Gender:** F
**Reported:** 20/06/2002 **Weight:**
**Hospitalisation:** **Age:** 53Y
**Onset Date:** 20/01/2002 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia | | In hands | |
| Myalgia | | Myalgia in legs | |
| Anxiety | | | |
| Convulsion | | | |
| Dry mouth | | | |
| Hyponatraemia | | | Patient was hospitalised. patient was treated with phenytoin |
| Nausea | | | |

## Medicine Details:

**ATACAND (Suspected)** **Reason:** Essential benign hypertension
4.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 20/01/2002

**VERAPAMIL HYDROCHLORIDE (Suspected)** **Reason:** Essential benign hypertension
40.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 20/01/2002

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 19/01/2002 **Stopped:** 20/01/2002

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 176737 **Seq:** 1 **Gender:** F
**Reported:** 28/06/2002 **Weight:** 70.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Acne | | Cystic acne - exacerbation | Efexor ceased |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 01/03/2002 **Stopped:** 30/05/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Recurrence of acne with recent return to efexor therapy. the dose start date is not accurate but indicates that the drug was started sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 176763 **Seq:** 1 **Gender:** F
**Reported:** 03/07/2002 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cellulitis<br>Confusional state | | Right forearm | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 176853 **Seq:** 1 **Gender:** F
**Reported:** 04/07/2002 **Weight:** 71.00
**Hospitalisation:** **Age:** 26
**Onset Date:** 17/06/2002 **DOB:** 08/09/1975
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertonia<br>Tremor | | | Diazepam, required a visit to |

### Medicine Details:

**MICROGYNON 50 (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**PANAMAX (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**RHINOCORT (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 100.0 Milligram Daily Oral
**Batch:** **Started:** 24/03/2002 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 176854 **Seq:** 1 **Gender:** F
**Reported:** 04/07/2002 **Weight:** 137.00
**Hospitalisation:** **Age:** 31
**Onset Date:** 02/06/2002 **DOB:** 19/11/1970
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Disturbance in attention<br>Myalgia<br>Nausea<br>Pyrexia<br>Serotonin syndrome<br><br>Tremor | | | Ceased efexor and avanza. given cyproheptadine. required a visit to doctor. patient recovered 10/6/02 |

### Medicine Details:

**EFEXOR (Interaction)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 22/09/2001 **Stopped:** 31/05/2002

**AVANZA (Interaction)** **Reason:** Depression
30.0 Milligram Daily
**Batch:** **Started:** 01/06/2002 **Stopped:** 03/06/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 177172 **Seq:** 1
**Reported:** 15/07/2002
**Hospitalisation:**
**Onset Date:** 08/05/2002
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 70.00
**Age:** 75
**DOB:** 09/12/1926
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion<br>Hyponatraemia | Severe | | Venlafaxine and carbamazepine ceased. treated |

## Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**CARBAMAZEPINE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Insetting of vomiting, diarrhoea and dehydration. fitted before day na was administered.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 177333 **Seq:** 1 **Gender:** F
**Reported:** 22/07/2002 **Weight:**
**Hospitalisation:** **Age:** 52
**Onset Date:** 12/07/2002 **DOB:** 29/11/1949
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | | |

### Medicine Details:

**SERETIDE ACCUHALER NOS (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**VENTOLIN (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** 09/07/2002 **Stopped:**

**AVAPRO HCT 150/12.5 (Suspected)** **Reason:** Essential benign hypertension
Tablet 0.0 Daily Oral
**Batch:** **Started:** L TERM **Stopped:** 16/07/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | 12/07/2002 | 120 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 177333 **Seq:** 1
**Reported:** 22/07/2002
**Hospitalisation:**
**Onset Date:** 12/07/2002
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 52
**DOB:** 29/11/1949
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**CELEBREX (Suspected)** **Reason:** Unspecified arthritis
200.0 Milligram Daily
**Batch:** **Started:** S TERM **Stopped:** 12/07/2002

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 177369 **Seq:** 1 **Gender:** F
**Reported:** 29/07/2002 **Weight:** 60.00
**Hospitalisation:** **Age:** 56
**Onset Date:** 05/07/2002 **DOB:** 14/07/1945
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash erythematous | | | Required a visit to doctor, ceased efexor. patient |

### Medicine Details:

**CYANOCOBALAMIN (Other drug)** **Reason:**
Injection 0.0 Intravenous
**Batch:** **Started:** **Stopped:**

**THYROXINE SODIUM (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** 01/06/2002 **Stopped:** 28/07/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The dose start and stop dates are not necessarily accurate but indicates efexor was started and stopped sometime in the month.

## Report Detail

**Case Number:** 177435 **Seq:** 1 **Gender:** F
**Reported:** 25/07/2002 **Weight:**
**Hospitalisation:** **Age:** 90
**Onset Date:** 15/07/2002 **DOB:** 17/08/1911
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Hallucination | | | |

## Medicine Details:

**TRAMAL (Interaction)** **Reason:**
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** 12/07/2002 **Stopped:** 17/07/2002

**EFEXOR-XR (Interaction)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**FOSAMAX (Other drug)** **Reason:** Other diseases of bone
70.0 Milligram Weekly
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 177448 **Seq:** 1 **Gender:** M
**Reported:** 25/07/2002 **Weight:** 0.00
**Hospitalisation:** **Age:** 74
**Onset Date:** 21/06/2002 **DOB:** 26/03/1928
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | | |

### Medicine Details:

**SODIUM VALPROATE (Other drug)** **Reason:**
Oral application 800.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**ADALAT (Other drug)** **Reason:** Essential benign hypertension
Oral application 30.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**TEMAZEPAM (Other drug)** **Reason:**
Oral application 20.0 Milligram Daily Oral
**Batch:** **Started:** 11/06/2002 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** 14/06/2002 **Stopped:** 27/06/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 16/12/2002 | Sodium | | | | Na decreased to 126mmol/l |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 177487 **Seq:** 1 **Gender:** M
**Reported:** 26/07/2002 **Weight:**
**Hospitalisation:** **Age:** 36
**Onset Date:** 01/06/2002 **DOB:** 22/01/1966
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | | |

### Medicine Details:

**SUSTANON 250 (Other drug)** **Reason:** Menopausal symptoms
Injection 750.0 Milligram Weekly Intramuscular
**Batch:** **Started:** L TERM **Stopped:**

**MINIRIN (Other drug)** **Reason:** Menopausal symptoms
Inhalation 50.0 Microgram Daily Inhalation
**Batch:** **Started:** L TERM **Stopped:**

**PREDNISONE (Other drug)** **Reason:** Menopausal symptoms
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**EPILIM (Other drug)** **Reason:** Other&unspecified epilepsy
Tablet 2.0 Gram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 177487 **Seq:** 1 **Gender:** M
**Reported:** 26/07/2002 **Weight:**
**Hospitalisation:** **Age:** 36
**Onset Date:** 01/06/2002 **DOB:** 22/01/1966
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 12/02/2002 **Stopped:** CONTIN

### Laboratory Investigations:

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 177528 **Seq:** 1
**Reported:** 29/07/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 21/06/2002
**Outcome:** Recovered

**Gender:** M
**Weight:**
**Age:** 77
**DOB:** 15/08/1924
**Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination | | | Patient was hospitalised and efexor dose redueced. |

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **ALLOPURINOL (Other drug)** | | | **Reason:** | |
| Tablet | 100.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **AMIODARONE HYDROCHLORIDE (Other drug)** | | | **Reason:** | |
| Tablet | 200.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **ASPIRIN (Other drug)** | | | **Reason:** | |
| Tablet | 100.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **ATORVASTATIN (Other drug)** | | | **Reason:** | |
| Tablet | 10.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient also taking midodrine, docusate & senna, temazepam and paracetamol.

## Report Detail

**Case Number:** 177528 **Seq:** 1
**Reported:** 29/07/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 21/06/2002
**Outcome:** Recovered

**Gender:** M
**Weight:**
**Age:** 77
**DOB:** 15/08/1924
**Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **POTASSIUM CHLORIDE (Other drug)** | | | **Reason:** | | |
| Tablet | 600.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **CLOPIDOGREL (Other drug)** | | | **Reason:** | | |
| Tablet | 75.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **EFEXOR (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 75.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | S TERM | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

Patient also taking midodrine, docusate & senna, temazepam and paracetamol.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 177580 **Seq:** 1 **Gender:** F
**Reported:** 01/08/2002 **Weight:** 97.00
**Hospitalisation:** **Age:** 41
**Onset Date:** 24/07/2002 **DOB:** 19/07/1961
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Coordination abnormal<br>Dysarthria<br>Fatigue<br>Somnolence<br><br>Stupor | | Unsteady on feet. | Efexor xr ceased. required a visit to doctor. |

### Medicine Details:

**DUROLAX (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

**DIAZEPAM (Other drug)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:** CONTIN

**DUPHALAC (Other drug)** **Reason:**
40.0 Millilitre Daily
**Batch:** **Started:** **Stopped:**

**KAPANOL (Other drug)** **Reason:**
90.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient also taking - erythropoietin and thyroine.

## Report Detail

**Case Number:** 177580 **Seq:** 1
**Reported:** 01/08/2002
**Hospitalisation:**
**Onset Date:** 24/07/2002
**Outcome:** Recovered

**Gender:** F
**Weight:** 97.00
**Age:** 41
**DOB:** 19/07/1961
**Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **LOSEC (Other drug)** | | **Reason:** | | |
| | 40.0 Milligram | Daily | | |
| **Batch:** | **Started:** | | **Stopped:** | CONTIN |
| **VIOXX (Other drug)** | | **Reason:** | | |
| | 25.0 Milligram | Daily | | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **EFEXOR-XR (Suspected)** | | **Reason:** | | |
| Capsule | 75.0 Milligram | Daily | Oral | |
| **Batch:** | **Started:** 24/07/2002 | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:
Patient also taking - erythropoietin and thyroine.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 177767 **Seq:** 1 **Gender:** F
**Reported:** 02/08/2002 **Weight:** 71.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Chills<br>Flushing<br>Headache<br>Hyperhidrosis | | Occurred on 1st & 2nd day after stopping. | |

### Medicine Details:

**FIORINAL (Other drug)** **Reason:** Headache
Oral application 2.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 28/07/2002 **Stopped:**

**SWISSE WOMENS ULTIVITE MULTI-VITAMIN, MINERAL (Other drug)** **Reason:**
Oral application 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

**LEVLEN ED (Other drug)** **Reason:** Contraception
Oral application 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 450.0 Milligram Daily Oral
**Batch:** **Started:** 01/08/2000 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 177936 **Seq:** 1
**Reported:** 07/08/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 83Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br><br>Inappropriate antidiuretic hormon | | | A trial of fluid restriction (900 ml per day). moclobemide, aspirin & heparin given demeclocycline 300mg four times daily. |

### Medicine Details:

**ASPIRIN (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**HEPARIN SODIUM (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**RANITIDINE (Other drug)** **Reason:**
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**MOCLOBEMIDE (Other drug)** **Reason:**
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electrolytes | 135-145 MMOL/L | | | Serum sodium fluctuating between 126 and 129 mmol/l. on day 40 of admission (approximately three weeks after the reintroduction of venlafaxine). serum sodium had declined to 125 mmol/l, urine sodium concent- ration was 60 mmol/l and urine osmolality was 441 mosmol/kg |

### Additional Information:

Medical history - gastroesophageal reflux disease, pernicious anaemia and uriary tract infection. recent history of weight loss 5kg over four months.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 177936 **Seq:** 1
**Reported:** 07/08/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 83Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **PINDOLOL (Other drug)** | | | **Reason:** | |
| | 7.5 | Milligram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **Zolpidem Sandoz (Other drug)** | | | **Reason:** | Specific disorders of sleep |
| | 5.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **ATORVASTATIN (Other drug)** | | | **Reason:** | |
| | 10.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **ISOSORBIDE MONONITRATE (Other drug)** | | | **Reason:** | |
| | 30.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |

## Laboratory Investigations:

## Additional Information:

Medical history - gastroesophageal reflux disease, pernicious anaemia and uriary tract infection. recent history of weight loss 5kg over four months.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 177936 **Seq:** 1
**Reported:** 07/08/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 83Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **RAMIPRIL (Other drug)** | | | **Reason:** | | |
| | 2.5 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 75.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | CONTIN |

### Laboratory Investigations:

### Additional Information:

Medical history - gastroesophageal reflux disease, pernicious anaemia and uriary tract infection. recent history of weight loss 5kg over four months.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 178592 **Seq:** 1
**Reported:** 04/09/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 12/08/2002
**Outcome:** Death, maybe drug

**Gender:** M
**Weight:**
**Age:** 39
**DOB:** 30/08/1962
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cardiac arrest<br>Cardiomyopathy<br>Hypocalcaemia<br>Hypokalaemia<br>Hyponatraemia<br>Neuroleptic malignant syndrome<br>Pyrexia<br>Shock | | | Patient died: 16/8/02. |

### Medicine Details:

**OLANZAPINE (Suspected)** **Reason:**
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

**EPILIM (Suspected)** **Reason:**
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral application 0.0 Oral
**Batch:** **Started:** **Stopped:**

**CLOZARIL (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
**Batch:** **Started:** 16/07/2002 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Calcium | 1.12 - 1.30 MMOL/L | 15/08/2002 | 0.9 | |
| | Creatine [illegible] | 30 - 200 IU/L | 15/08/2002 | 1360 | |
| | Potassium | 3.5 - 5.5 MMOL/L | 15/08/2002 | 2.9 | |
| | Sodium | 135 - 145 MMOL/L | 15/08/2002 | 129 | |

### Additional Information:

Risk factors were: obesity, known aortic valve stenosis. the patient presented to the emergency department, collapsed and could not be resuscitated. the patient died on 16/08/02.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 178660 **Seq:** 1 **Gender:** F
**Reported:** 02/09/2002 **Weight:** 49.00
**Hospitalisation:** **Age:** 79Y
**Onset Date:** 20/08/2002 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Gravitational oedema | | Ankel oedema | Date of recovery 27/08/02. efexor-xr ceased. |

### Medicine Details:

**CARTIA (Other drug)** **Reason:**
Oral application 100.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

**PRAVACHOL (Other drug)** **Reason:**
Oral application 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

**KARVEA (Other drug)** **Reason:** Essential benign hypertension
Oral application 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

**RANI 2 (Other drug)** **Reason:** Other diseases of esophagus
Oral application 300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Suspected drug is cert/rechallenge. had noticed similar reaction when drug was taken previously in 2001.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 178660 **Seq:** 1 **Gender:** F
**Reported:** 02/09/2002 **Weight:** 49.00
**Hospitalisation:** **Age:** 79Y
**Onset Date:** 20/08/2002 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

## Reaction Detail

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 17/07/2002 **Stopped:** 25/08/2002

## Laboratory Investigations:

## Additional Information:

Suspected drug is cert/rechallenge. had noticed similar reaction when drug was taken previously in 2001.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 179121 **Seq:** 1 **Gender:** F
**Reported:** 19/09/2002 **Weight:** 68.00
**Hospitalisation:** **Age:** 36
**Onset Date:** 13/09/2002 **DOB:** 17/02/1966
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Bruxism | | | Required a visit to doctor. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Tablet 75.0 Milligram 1 time Oral

**Batch:** **Started:** 13/09/2002 **Stopped:** 13/09/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 179217 **Seq:** 1 **Gender:** U
**Reported:** 26/09/2002 **Weight:**
**Hospitalisation:** **Age:** 29
**Onset Date:** 28/08/2002 **DOB:** 22/03/1973
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea | | Capsules in faeces. | |
| Drug ineffective | | Recurrance of depression | Patient recovered 16/9/02. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 300.0 Milligram Daily Oral
**Batch:** **Started:** 01/06/2002 **Stopped:** 09/09/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Slow release form of medication not being absorbed.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 179288 **Seq:** 1
**Reported:** 20/09/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 11/05/2002
**Outcome:** Not yet recovered

**Gender:** M
**Weight:**
**Age:** 27
**DOB:** 28/06/1974
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion<br><br><br>Hypertonia<br>Syncope | | | Patient was admitted to hospital. olanzapine treatment was discontinued on 20/6/02, venlafaxine hcl continues. |

### Medicine Details:

**ZYPREXA (Suspected)** **Reason:** Unspecified schizophrenia

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 02/05/2002 **Stopped:** 20/06/2002

**EFEXOR (Suspected)** **Reason:**

Tablet 150.0 Milligram Daily Oral

**Batch:** **Started:** 02/05/2002 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electroencephalog | | | | On 22/6/02 an electroencephalogram performed was abnormal.the record contained epiletiform activity seen on one occasion during the resting record. there were no focal features. a computerised tomography scan performed on 12/5/02 was normal. electroencephalaography/abnormal/22/6/02, computerised axial tomography/cat/ normal 12/5/02. |

### Additional Information:

Medical history included: schizophrenia, no history of seizures. nocturnal bed wetting since age 6 years old. the patient also had no history of electrolyte imbalance, eclampsia, liver failure, renal failure, hypertensive encephalopathy, meningitis, encephalitis/abscess, head trauma, stroke and no history of any anticonvulsant medications. on the 12/6/02 the dose of olanzapine was increased to 30mg/daily.the patients venlafaxine dose had also been increased to 300mg/daily.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 179398 **Seq:** 1 **Gender:** M
**Reported:** 25/09/2002 **Weight:**
**Hospitalisation:** **Age:** 71
**Onset Date:** 10/08/2002 **DOB:** 23/05/1931
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pulmonary oedema<br><br>Tachycardia | | | Efexor ceased, iv lasix, digoxin and carvedilol commenced. patient recovered 12/8/02. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 01/11/2000 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient with limited cardiac reserve. 09/min. with increase to 150mg hr increase to 110+/min. previous mi (1987) decreased cabe (1999) ech 99 lvf, ef <15%. has had 2 previous episodes of pulmonary oedema, ist in 1995 occurred 3 months after commencing venlafaxine on a previous occassion. the dose start date is not necessarily accurate but indicates efexor was started sometime in the month. suspected drug certain rechallenge.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 179546 **Seq:** 1 **Gender:** F
**Reported:** 03/10/2002 **Weight:**
**Hospitalisation:** **Age:** 52Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Visual disturbance | | Visual loss (fluctulatiing ?). | Efexor ceased. |

### Medicine Details:

**KARVEA (Other drug)** **Reason:** Essential benign hypertension
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**PANADEINE (Other drug)** **Reason:** Pain
8.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**TEMAZEPAM (Other drug)** **Reason:** Specific disorders of sleep
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Oral application 37.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 29/07/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 179748 **Seq:** 1 **Gender:** M
**Reported:** 08/10/2002 **Weight:**
**Hospitalisation:** **Age:** 92Y
**Onset Date:** 21/03/2002 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br><br>Inappropriate antidiuretic hormon | | | Was going to start sertraline->chnaged to mirtazapine |

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **AMIODARONE HYDROCHLORIDE (Other drug)** | | | **Reason:** | | |
| Tablet | 100.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **DOCUSATE POTASSIUM (Other drug)** | | | **Reason:** | | |
| Tablet | 2.0 | Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **ISOSORBIDE DINITRATE (Other drug)** | | | **Reason:** | | |
| Tablet | 60.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **OMEPRAZOLE (Other drug)** | | | **Reason:** | | |
| Tablet | 40.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | | | Na=113 |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 179748 **Seq:** 1 **Gender:** M
**Reported:** 08/10/2002 **Weight:**
**Hospitalisation:** **Age:** 92Y
**Onset Date:** 21/03/2002 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **PREDNISONE (Other drug)** | | | **Reason:** | Other puritis conditions | |
| Tablet | 10.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **NICOTINE (Other drug)** | | | **Reason:** | | |
| Tablet | 125.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | 17/03/2002 |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | | |
| Tablet | 75.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 15/03/2002 | | **Stopped:** | 21/03/2002 |

### Laboratory Investigations:

### Additional Information:

## Report Detail

**Case Number:** 179950 **Seq:** 1
**Reported:** 18/10/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 28/09/2002
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 52
**DOB:** 09/02/1950
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion<br>Drug level increased | | | |

## Medicine Details:

**EFEXOR (Interaction)** **Reason:**

0.0

**Batch:** **Started:** **Stopped:**

**CLOZARIL (Interaction)** **Reason:** Unspecified schizophrenia

Tablet 800.0 Milligram Daily Oral

**Batch:** **Started:** 26/08/2002 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 16/12/2002 | Serum drug level | (150-500) | 08/08/2003 | 2300 | |
| 16/12/2002 | Serum drug level | (150-500) | 30/09/2002 | 2310 | |
| 16/12/2002 | Serum drug level | (150-500) | 07/10/2002 | 470 | |
| 16/12/2002 | Serum drug level | | 30/09/2002 | 1300 UG/L | |
| 16/12/2002 | Serum drug level | | 07/10/2002 | 490 UG/L | |

## Additional Information:

Clozaril dossage was decreased to 400mg/day and efexor treatment was ceased.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 179962 **Seq:** 1 **Gender:** F
**Reported:** 18/10/2002 **Weight:** 70.00
**Hospitalisation:** **Age:** 77
**Onset Date:** **DOB:** 29/06/1925
**Outcome:** Recovered 09/10/2002 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Glaucoma | Required Visit to Doctor | | Iridotomies, Pilopt 2%, Predsl |
| Headache | Required Visit to Doctor | | Iridotomies, Pilopt 2%, Predsl |
| Photophobia | Required Visit to Doctor | | Iridotomies, Pilopt 2%, Predsl |
| Vision blurred | Required Visit to Doctor | | Iridotomies, Pilopt 2%, Predsl |

### Medicine Details:

**ALDOMET (Other drug)** **Reason:** Essential benign hypertension
500.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**SERETIDE ACCUHALER NOS (Other drug)** **Reason:** Asthma
4.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:**

**TAMOXIFEN CITRATE (Other drug)** **Reason:** Malignant neoplasm of breast
20.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**ZOCOR (Other drug)** **Reason:** Othr&unspec metabolic diseases
10.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** 03/10/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Blurred vision, headache, photophobia within 24 hrs of taking efexor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 179962 **Seq:** 1 **Gender:** F
**Reported:** 18/10/2002 **Weight:** 70.00
**Hospitalisation:** **Age:** 77
**Onset Date:** **DOB:** 29/06/1925
**Outcome:** Recovered 09/10/2002 **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 01/10/2002 **Stopped:**

### Laboratory Investigations:

### Additional Information:
Blurred vision, headache, photophobia within 24 hrs of taking efexor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 180029 **Seq:** 1
**Reported:** 23/10/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 04/10/2002
**Outcome:** Recovered

**Gender:** F
**Weight:** 45.00
**Age:** 86
**DOB:** 02/04/1916
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorexia<br>Confusional state<br><br><br>Fatigue<br>Hyponatraemia | | | Patient was hospitalised and required a visit to doctor. date of recovery: 17/10/02. ceased efexor |

### Medicine Details:

**CORDARONE X (Other drug)** **Reason:**
200.0 Milligram Daily
**Batch:** **Started:** 04/10/2002 **Stopped:** CONTIN

**LOSEC (Other drug)** **Reason:**
40.0 Milligram Daily
**Batch:** **Started:** 04/10/2002 **Stopped:** CONTIN

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 04/10/2002 **Stopped:** 12/10/2002

**TRAMAL (Suspected)** **Reason:** Pain
Tablet 200.0 Milligram Daily Oral
**Batch:** **Started:** 04/07/2002 **Stopped:** 12/10/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Serum osmolality | | 04/10/2002 | 268 | |
| | Serum osmolality | | 11/10/2002 | 255 | |
| | Sodium | | 04/10/2002 | 15-129 | |
| | Sodium | | 04/10/2002 | 133 | |
| | Sodium | | 11/10/2002 | 15-125 | |
| | Sodium | | 04/10/2002 | 133 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 180029 **Seq:** 1
**Reported:** 23/10/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 04/10/2002
**Outcome:** Recovered

**Gender:** F
**Weight:** 45.00
**Age:** 86
**DOB:** 02/04/1916
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**MAREVAN (Suspected)** **Reason:** Otr&nos disord of heart rhythm

Tablet 1.5 Milligram Daily Oral

**Batch:** **Started:** 28/06/2002 **Stopped:** 04/10/2002

### Laboratory Investigations:

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 180066 **Seq:** 1 **Gender:** F
**Reported:** 25/10/2002 **Weight:**
**Hospitalisation:** **Age:** 72Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Coordination abnormal<br>Dizziness<br>Hypotension | | | Required a visit to doctor. st john's wort ceased. |

## Medicine Details:

**EFEXOR (Interaction)** **Reason:** Essential benign hypertension
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:** CONTIN

**NEULACTIL (Interaction)** **Reason:** Anxiety neurosis
5.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**HYPERICUM-ST JOHN'S WORT (Interaction)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:** 30D

**FOSAMAX (Other drug)** **Reason:** Osteoarthritis
70.0 Milligram Weekly
**Batch:** **Started:** L TERM **Stopped:** CONTIN

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 180066 **Seq:** 1 **Gender:** F
**Reported:** 25/10/2002 **Weight:**
**Hospitalisation:** **Age:** 72Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**KARVEA (Other drug)** **Reason:** Essential benign hypertension
75.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 180117 **Seq:** 1
**Reported:** 28/10/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 28/10/2002
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 64.00
**Age:** 38Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Amnesia<br>Neurosis | | | Patient was hospitalised. |

### Medicine Details:

**TEGRETOL (Other drug)** **Reason:** Other&unspecified epilepsy
Oral application 800.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**EPILIM (Other drug)** **Reason:** Other&unspecified epilepsy
Oral application 1.0 Gram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**LAMICTAL (Other drug)** **Reason:** Other&unspecified epilepsy
Oral application 300.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**RIVOTRIL (Other drug)** **Reason:** Other&unspecified epilepsy
Oral application 1.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Irrational behaviour, abnormal psychiatric state and intermittent memory loss. the date of onset is not necessarily accurate but indicates onset sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 180117 **Seq:** 1
**Reported:** 28/10/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 28/10/2002
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 64.00
**Age:** 38Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Tablet 225.0 Milligram Daily Oral

**Batch:** **Started:** 07/09/2002 **Stopped:**

### Laboratory Investigations:

### Additional Information:

Irrational behaviour, abnormal psychiatric state and intermittent memory loss. the date of onset is not necessarily accurate but indicates onset sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 180120 **Seq:** 1 **Gender:** M
**Reported:** 28/10/2002 **Weight:**
**Hospitalisation:** **Age:** 37
**Onset Date:** 08/09/2002 **DOB:** 25/10/1964
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | Drug overdose | Observation |

## Medicine Details:

**TEMAZEPAM (Other drug)** **Reason:**
Oral application 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**MIRTAZAPINE (Suspected)** **Reason:**
Tablet 15.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
Capsule 300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**OXAZEPAM (Suspected)** **Reason:**
Tablet 120.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

This report is a seq of 180121.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 180185 **Seq:** 1 **Gender:** F
**Reported:** 31/10/2002 **Weight:** 50.00
**Hospitalisation:** **Age:** 15
**Onset Date:** 14/10/2002 **DOB:** 26/11/1986
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia<br>Drug withdrawal syndrome<br>Influenza like illness<br>Nausea<br>Vomiting | | Aching | Required a visit to doctor. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** 26/07/2002 **Stopped:** 13/10/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Moderately severe withdrawal reaction has occurred on 3 occasions with unintentional forgetting of dose of efexor xr. suspected drug certain rechallenge.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 180267 **Seq:** 1
**Reported:** 31/10/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:** 25/10/2002
**Outcome:** Recovered

**Gender:** F
**Weight:** 70.00
**Age:** 35
**DOB:** 05/08/1967
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | | |
| Confusional state | | | |
| Hypertension | | | |
| Mydriasis | | | |
| Pyrexia | | | |
| Serotonin syndrome | | | Patient treated with cyproheptadine. was admitted to hospital. recovered 26/10/02 |
| Tachycardia | | | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Tablet 75.0 Milligram Daily Oral

**Batch:** **Started:** 25/10/2002 **Stopped:** 25/10/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Symptoms persisted >12 hours.

## Report Detail

**Case Number:** 180351 **Seq:** 1
**Reported:** 04/11/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** M
**Weight:** 69.00
**Age:** 63Y
**DOB:**
**Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression<br>Agitation<br><br>Suicide attempt<br>Urinary incontinence | | | Efexor ceased. patient was admitted to hospital. |

## Medicine Details:

**BETALOC (Other drug)** **Reason:** Essential benign hypertension
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

**TRITACE (Other drug)** **Reason:** Essential benign hypertension
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

**CARDIZEM (Other drug)** **Reason:** Essential benign hypertension
0.0
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient took a full foil pack of both the 150mg capsules and the 37.5mg tablets.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 180421 **Seq:** 1 **Gender:** F
**Reported:** 07/11/2002 **Weight:** 65.00
**Hospitalisation:** **Age:** 55
**Onset Date:** 30/10/2002 **DOB:** 25/07/1947
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urticaria | | Severe itching within 12 hours. | |

### Medicine Details:

**EFEXOR-XR (Interaction)** **Reason:**
Capsule 0.0 Oral
**Batch:** **Started:** L TERM **Stopped:**

**TRAMAL (Interaction)** **Reason:**
0.0
**Batch:** **Started:** 04/10/2002 **Stopped:**

**IMOVANE (Other drug)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:**

**PANADEINE FORTE (Other drug)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Seemed to be combination with efexor that caused problem - ie increased itch after taking efexor. no reaction to ther narcotics.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 180421 **Seq:** 1
**Reported:** 07/11/2002
**Hospitalisation:**
**Onset Date:** 30/10/2002
**Outcome:** Recovered

**Gender:** F
**Weight:** 65.00
**Age:** 55
**DOB:** 25/07/1947
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**VALIUM (Other drug)** **Reason:**

0.0

**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

## Additional Information:

Seemed to be combination with efexor that caused problem - ie increased itch after taking efexor. no reaction to ther narcotics.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 180442 **Seq:** 1
**Reported:** 08/11/2002
**Hospitalisation:**
**Onset Date:** 01/06/2001
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 100.00
**Age:** 36
**DOB:** 20/02/1965
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperglycaemia<br>Weight increased | | | Required a visit to doctor. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Unspecified psychosis

Tablet 15.0 Milligram Daily Oral

**Batch:** **Started:** 13/06/2000 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 180467 **Seq:** 1
**Reported:** 11/11/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** M
**Weight:** 80.00
**Age:** 24Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Affect lability | | | |
| Confusional state | | | |
| Dizziness | | | |
| Hallucination | | | |
| Headache | | | |
| Muscle spasms | | | |
| Nausea | | | |
| Nightmare | | | |

## Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:**
Oral application 0.0 Oral
**Batch:** **Started:** **Stopped:**

**TRAMADOL HYDROCHLORIDE (Interaction)** **Reason:**
Oral application 0.0 Oral
**Batch:** **Started:** **Stopped:**

**ZOLOFT (Interaction)** **Reason:**
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**CANNABIS PREPARATION (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

History: illicit drug user, with 3-4 pipes marijuana daily.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 180467 **Seq:** 1
**Reported:** 11/11/2002
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** M
**Weight:** 80.00
**Age:** 24Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Serotonin syndrome<br><br>Thinking abnormal | | | Patient was hospitalised. treated with antipsychotic and was changed rapidly from sertraline back to venlafaxine. |

## Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:**
Oral application 0.0 Oral
**Batch:** **Started:** **Stopped:**

**TRAMADOL HYDROCHLORIDE (Interaction)** **Reason:**
Oral application 0.0 Oral
**Batch:** **Started:** **Stopped:**

**ZOLOFT (Interaction)** **Reason:**
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**CANNABIS PREPARATION (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

History: illicit drug user, with 3-4 pipes marijuana daily.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 180613 **Seq:** 1 **Gender:** M
**Reported:** 13/11/2002 **Weight:** 60.00
**Hospitalisation:** **Age:** 74
**Onset Date:** **DOB:** 27/11/1927
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle twitching | | Twitching hands, face, arms, etc. | Recovered 15/7/02. |

### Medicine Details:

**FOSAMAX (Other drug)** **Reason:** Osteoarthritis
70.0 Milligram Weekly
**Batch:** **Started:** 01/01/2002 **Stopped:** 12/08/2002

**PANADEINE (Other drug)** **Reason:**
0.0 As necessary
**Batch:** **Started:** **Stopped:** 12/08/2002

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 12/07/2002 **Stopped:** 14/07/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 180789 **Seq:** 1
**Reported:** 18/12/2002
**Hospitalisation:**
**Onset Date:** 15/04/2002
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 50Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Osteoarthritis<br><br>Antinuclear antibody positive | | painful, swollen finger joints over last 2/12, blood tests show increased ANA | Patient given brufen. |

### Medicine Details:

**BRUFEN (Other drug)** **Reason:** Other rheumatoid arthritis
1.2 Gram As necessary
**Batch:** **Started:** L TERM **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**BEE POLLEN EXTRACT (Suspected)** **Reason:**
Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient history - Rheumatoid Arthristis.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 180808 **Seq:** 1 **Gender:** F
**Reported:** 18/12/2002 **Weight:** 0.00
**Hospitalisation:** Admitted to hospital **Age:** 85
**Onset Date:** 11/11/2002 **DOB:** 18/06/1917
**Outcome:** Recovered 15/11/2002 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor<br><br>Gait disturbance | | Falls/leading to broken neck of femur, tremor, serotonin syndrome? | Patient hospitalised. |

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **EFEXOR-XR (Interaction)** | | | **Reason:** Pain | | |
| Tablet | 75.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | CONTIN |
| **TRAMAL SR (Interaction)** | | | **Reason:** | | |
| | 400.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **TRAMAL SR (Interaction)** | | | **Reason:** | | |
| Tablet | 400.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** 08/11/2002 | | | **Stopped:** | 12/11/2002 |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient also taking other drugs - Zyprexa, Frusemide, caltrate, Aspirin, Panamax, Vioxx and Prednisolone.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 181020 **Seq:** 1 **Gender:** U
**Reported:** 02/01/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 68
**Onset Date:** **DOB:** 27/06/1934
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Photosensitivity reaction<br>Cutaneous lupus erythematosus | | Photosensitivity and discoid lupus. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 181777 **Seq:** 1 **Gender:** U
**Reported:** 17/01/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 88
**Onset Date:** 03/12/2002 **DOB:** 16/09/1914
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | Hyponatraemia | Efexor stopped |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 29/11/2002 **Stopped:** 03/12/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 17/01/2003 | Sodium | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 181828 **Seq:** 1 **Gender:** F
**Reported:** 20/01/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 19
**Onset Date:** 08/08/2002 **DOB:** 05/04/1983
**Outcome:** Recovered 15/08/2002 **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Visual disturbance<br>Mydriasis | | Pupils dilated to a point where vision was | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Same reaction happened on rechallenge.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 182073 **Seq:** 1 **Gender:** F
**Reported:** 28/01/2003 **Weight:** 45.00
**Hospitalisation:** **Age:** 41
**Onset Date:** 01/12/2002 **DOB:** 22/12/1960
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal discomfort | Required Visit to Doctor | GI Upset, Vaguely Unwell | |
| Malaise | Required Visit to Doctor | | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Oral application 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Dose start and stop date for the drug Venlafaxine - 11/02 to 01/03.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 182119 **Seq:** 1 **Gender:** U
**Reported:** 29/01/2003 **Weight:** 68.00
**Hospitalisation:** **Age:** 95
**Onset Date:** 27/12/2002 **DOB:** 24/07/1907
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Grand mal convulsion | | Seizures requiring ambulance to hospital; Grand Mal. | Efexor ceased. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 20/12/2002 **Stopped:** 27/12/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

No history of epilepsy.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 182120 **Seq:** 1 **Gender:** F
**Reported:** 29/01/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 13
**Onset Date:** 12/03/2002 **DOB:** 07/12/1988
**Outcome:** Recovered 15/03/2002 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Chest discomfort<br><br>Urticaria | | Chest tightness and generalised, fine erythematous urticarial rash. | Antihistamine. and Ventolin. |

### Medicine Details:

**FLUOXETINE HYDROCHLORIDE (Other drug)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 06/03/2002

**OLANZAPINE (Other drug)** **Reason:** Depression
2.5 Milligram Daily
**Batch:** **Started:** 08/03/2002 **Stopped:** 13/03/2002

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
Tablet 18.8 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 182162 **Seq:** 1 **Gender:** M
**Reported:** 30/01/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 37Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Semen abnormal | | Dribbling of semen, after urination and/or defaecation. | Therapy changed to Avanza |

### Medicine Details:

**TRYPTANOL (Other drug)** **Reason:**
Tablet 25.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**XANAX (Other drug)** **Reason:**
2.5 Milligram Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Reaction stopped when therapy was changed to Avanza

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 182212 **Seq:** 1
**Reported:** 31/01/2003
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 65.00
**Age:** 40
**DOB:** 09/01/1963
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br><br>Emotional disorder | | Diminution of physical sensation (touch and temperature - eg. could not feel the cold) and of emotional responses including positive ones eg. to beauty. | Reduction of drug with view to cessation. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule, modified release 150.0 Milligram Reducing Oral

**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 182220 **Seq:** 1
**Reported:** 31/01/2003
**Hospitalisation:**
**Onset Date:** 16/01/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 37
**DOB:** 06/08/1965
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vomiting | Required Visit to Doctor | Vomiting, tingling and hot sensation in upper torso, very weak to point of collapsing | |
| Asthenia | Required Visit to Doctor | | |
| Paraesthesia | Required Visit to Doctor | | |

### Medicine Details:

**CLARATYNE (Other drug)** **Reason:** Hay fever
1.0 Dose Unspecified As necessary
**Batch:** **Started:** **Stopped:**

**NAPROSYN (Other drug)** **Reason:** Pain
1.0 Gram As necessary
**Batch:** **Started:** **Stopped:**

**MICROGYNON (Other drug)** **Reason:** Contraception
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
37.5 Milligram 1 time
**Batch:** **Started:** 16/01/2003 **Stopped:** 16/01/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Similar reaction to zoloft after 3 weeks of treatment.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 182325 **Seq:** 1 **Gender:** U
**Reported:** 04/02/2003 **Weight:** 57.00
**Hospitalisation:** **Age:** 53
**Onset Date:** 10/01/2003 **DOB:** 14/04/1949
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Required Visit to Doctor | hyponatraemia | Ceased Efexor |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** 29/10/2002 **Stopped:** 14/01/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 04/02/2003 | Sodium | | 10/01/2003 | 125 | |
| 04/02/2003 | Sodium | | 10/03/2003 | 138 | |

### Additional Information:

Ceased Efexor 8/02, after 3 years use on 300mg XR daily. Recommenced 29/10/02 75mg daily with normal sodium.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 182339 **Seq:** 1
**Reported:** 04/02/2003
**Hospitalisation:**
**Onset Date:** 13/01/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 18
**DOB:** 28/06/1984
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Epistaxis | Required Visit to Doctor | Epistaxis, drying of lips, headache and | Ceased Exfexor. |
| Dry mouth | Required Visit to Doctor | | |
| Headache | Required Visit to Doctor | | |
| Nausea | Required Visit to Doctor | | |

## Medicine Details:

**ORAL CONTRACEPTIVE NOS (Other drug)** **Reason:**
Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
1 time
**Batch:** **Started:** 13/01/2003 **Stopped:** 15/01/2003

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 182408 **Seq:** 1 **Gender:** M
**Reported:** 05/02/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Penile size reduced | Required Visit to Doctor | Penile size reduced and urinary incontinence | Efexor dose reduced |
| Urinary incontinence | Required Visit to Doctor | | |

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **SOLIAN (Other drug)** | | | **Reason:** | |
| | 800.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **VALIUM (Other drug)** | | | **Reason:** | |
| | 20.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **EFEXOR (Suspected)** | | | **Reason:** | |
| Capsule | 450.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 182561 **Seq:** 1 **Gender:** F
**Reported:** 07/02/2003 **Weight:** 0.00
**Hospitalisation:** Admitted to hospital **Age:** 67
**Onset Date:** 04/10/2002 **DOB:** 20/02/1935
**Outcome:** Unknown 20/10/2002 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delusion | Life | Hyponatraemia and delerium, intentional flopping, tremor. | Efexor ceased. |
| Hyponatraemia | Life | Hyponatraemia and delerium, intentional flopping, tremor. | Efexor ceased. |
| Tremor | Life | Hyponatraemia and delerium, intentional flopping, tremor. | Efexor ceased. |

### Medicine Details:

**OLANZAPINE (Other drug)** **Reason:** Unspecified psychosis
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**STILNOX (Other drug)** **Reason:** Specific disorders of sleep
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 15/11/2002

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 04/10/2002 **Stopped:** 18/10/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 07/02/2003 | Sodium | | | | |

### Additional Information:

Patient was also taking Equisetum.
Used Efexor 300mg for many months without any effects during her previous episode of depression.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 182933 **Seq:** 1 **Gender:** F
**Reported:** 14/02/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 89
**Onset Date:** 14/01/2003 **DOB:** 03/01/1914
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Nausea and vomiting - 3 days drowsy, fall a month previously | |
| Nausea | Caused or prolonged inpatient hospitalisation | Nausea and vomiting - 3 days drowsy, fall a month previously | |
| Somnolence | Caused or prolonged inpatient hospitalisation | Nausea and vomiting - 3 days drowsy, fall a month previously | |

### Medicine Details:

**COVERSYL (Other drug)** **Reason:**
Tablet 4.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**PLAVIX (Other drug)** **Reason:**
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 13/01/2003 **Stopped:** 14/01/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 14/02/2003 | Creatinine | | 14/01/2003 | 0.05 | |
| 14/02/2003 | Sodium | | 14/01/2003 | 125 | |

### Additional Information:

Patient was also taking Fosamax, Normison, melleril.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 182945 **Seq:** 1 **Gender:** F
**Reported:** 17/02/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 72
**Onset Date:** 03/02/2003 **DOB:** 30/08/1930
**Outcome:** Recovered 04/02/2003 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Musculoskeletal stiffness | | Woke up at 10pm, 4 hrs after first dose stiff feeling in whole body | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram 1 time Oral
**Batch:** **Started:** 03/02/2003 **Stopped:** 03/02/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient also taking astrix, moduretic, nexium, vioxx.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 183522 **Seq:** 1
**Reported:** 28/02/2003
**Hospitalisation:**
**Onset Date:** 21/02/2003
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 90.00
**Age:** 34
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor<br><br>Drug ineffective<br>Yawning | | shaking of legs, excessive yawning at the same time and drug ineffective. | |

### Medicine Details:

**METHADONE HYDROCHLORIDE (Interaction)** **Reason:**

Tablet 35.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:** Depression

Oral application 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient compained the the 'rush' he got taking Methadone disappeared after he started Venlafaxine. Other drug - Alcohol.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 183714 **Seq:** 1
**Reported:** 05/03/2003
**Hospitalisation:**
**Onset Date:** 10/02/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 65.00
**Age:** 28
**DOB:** 08/01/1975
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety | Required Specialist Consultation | Anxiety, Nausea, Irritability, Insomnia, Dizziness, Feeling of violence, Heart palpitations, Shaking, "Brain Zaps", Foggy thinking, High blood pressure | Go off drug immediatley |
| Dizziness | Required Specialist Consultation | | |
| Feeling abnormal | Required Specialist Consultation | | |
| Hypertension | Required Specialist Consultation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Oral
**Batch:** **Started:** 03/02/2003 **Stopped:** 27/02/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 183714 **Seq:** 1
**Reported:** 05/03/2003
**Hospitalisation:**
**Onset Date:** 10/02/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 65.00
**Age:** 28
**DOB:** 08/01/1975
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia | Required Specialist Consultation | | |
| Irritability | Required Specialist Consultation | | |
| Nausea | Required Specialist Consultation | | |
| Palpitations | Required Specialist Consultation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Oral
**Batch:** **Started:** 03/02/2003 **Stopped:** 27/02/2003

### Laboratory Investigations:

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 183714 **Seq:** 1
**Reported:** 05/03/2003
**Hospitalisation:**
**Onset Date:** 10/02/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 65.00
**Age:** 28
**DOB:** 08/01/1975
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Thinking abnormal | Required Specialist Consultation | | o off drug immediatley |
| Tremor | Required Specialist Consultation | | |
| Violent ideation | Required Specialist Consultation | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Oral
**Batch:** **Started:** 03/02/2003 **Stopped:** 27/02/2003

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 183832 **Seq:** 1 **Gender:** M
**Reported:** 07/03/2003 **Weight:** 29.00
**Hospitalisation:** Admitted to hospital **Age:** 0
**Onset Date:** 31/12/2002 **DOB:** 31/12/2002
**Outcome:** Recovered 02/01/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tonic convulsion | Caused or prolonged inpatient hospitalisation | Tonic movements within 10 minutes of birth progressing to opistlotonic posturing | |
| Opisthotonus | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** S TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Mother was taking Efexor approx. 3 months before baby was born.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 184013 **Seq:** 1 **Gender:** F
**Reported:** 13/03/2003 **Weight:** 68.00
**Hospitalisation:** **Age:** 60
**Onset Date:** 08/02/2003 **DOB:** 09/02/1942
**Outcome:** Recovered 06/03/2003 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Palpitations | Required Visit to Doctor | Episodes of pulpitations - tachycardia lasting several hours. (2-6 hrs) | |
| Tachycardia | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 04/02/2003 **Stopped:** 04/03/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 184194 **Seq:** 1
**Reported:** 21/03/2003
**Hospitalisation:** Admitted to hospital
**Onset Date:** 12/03/2003
**Outcome:** Recovered

**Gender:** F
**Weight:** 55.00
**Age:** 44
**DOB:** 18/01/1959
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vomiting | Severe | Severe vomiting vertigo and paraesthesia. | Given Maxolon, Stemital and Tropisetron. |
| Paraesthesia | Severe | | |
| Vertigo | Severe | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient did not respond to Maxolon and Stemitil but inproved with Tropisetron. Reaction occurred after the first dose of Efexor XR.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 184208 **Seq:** 1
**Reported:** 20/03/2003
**Hospitalisation:** Admitted to hospital
**Onset Date:** 25/02/2003
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 85
**DOB:** 02/05/1917
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Syncope<br><br><br>Convulsion<br>Dysphasia<br>Movement disorder<br>Orthostatic hypotension | | Syncope, postural hypotension, convulsive episode, expressive dysphasis, chorieform movements. | Given Midazolam and |

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **AVANZA (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 60.0 | Milligram | As necessary | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **SEROQUEL (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 150.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 75.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 184374 **Seq:** 1 **Gender:** F
**Reported:** 25/03/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 42
**Onset Date:** 06/02/2003 **DOB:** 06/04/1960
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatitis | Caused or prolonged inpatient hospitalisation | Hepatitis | Stopped Venlafaxine. |

### Medicine Details:

**NARAMIG (Other drug)** **Reason:**
Tablet 2.5 Milligram As necessary Oral
**Batch:** **Started:** **Stopped:**

**OMEPRAZOLE (Other drug)** **Reason:**
20.0 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 15/01/2002 **Stopped:** 27/02/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

History: Was found to have LFT's increase on a hospital admission for pneumonia, had liver biopsy.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 184513 **Seq:** 1 **Gender:** M
**Reported:** 31/03/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 43
**Onset Date:** 01/12/2002 **DOB:** 18/07/1959
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Affect lability<br>Abnormal dreams<br>Hostility<br>Paranoia | Required Visit to Doctor | Increased emotional lability, bizarre dreams, paranoid ideas and marked hostility. | Cessation of drug. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 11/07/2002 **Stopped:** 30/01/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date of recovery: Feb 03.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 184811 **Seq:** 1 **Gender:** F
**Reported:** 21/03/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 27Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary retention | | The physician also stated the patient was intiated on Effexor (venlafaxine) and two to three days later the patient developed urinary retention. Effexor therapy was ceased. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

**Batch:** **Started:** S TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

A week later the patient was then initiated on Seroquel (quetioapine fumarate)

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 184897 **Seq:** 1 **Gender:** M
**Reported:** 10/04/2003 **Weight:** 48.00
**Hospitalisation:** **Age:** 79
**Onset Date:** 28/02/2003 **DOB:** 28/10/1923
**Outcome:** Recovered 06/03/2003 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ecchymosis | Required Visit to Doctor | Ecchymoses, bruising with minimal trauma. | |

### Medicine Details:

**ATORVASTATIN (Other drug)** **Reason:** Othr&unspec metabolic diseases

Tablet 10.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** Contin

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Oral application 225.0 Milligram Daily Oral

**Batch:** **Started:** 28/01/2003 **Stopped:** 02/04/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Onset 2 weeks after increased dose of Venlafaxine from 150mg daily to 225mg daily. Abated after reduction to 150mg daily.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 184910 **Seq:** 1
**Reported:** 11/04/2003
**Hospitalisation:**
**Onset Date:** 30/09/2002
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 53
**DOB:** 10/03/1949
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug ineffective | | Patient experienced a loss of haematologic and cytogenetic response. | Glivec therapy was interrupted and Efexor was discontinued. |

### Medicine Details:

**EFEXOR (Interaction)** **Reason:** Depression

**Batch:** **Started:** **Stopped:**

**GLIVEC (Interaction)** **Reason:** Chronic myeloid leukemia

600.0 Milligram Daily

**Batch:** **Started:** 01/01/2002 **Stopped:** 01/11/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient experienced a loss of response with Glivec in Sep-Oct 2002. Glivec was resumed at an increased dose with good cytogenetic response (now 5% Ph positive).

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 185225 **Seq:** 1 **Gender:** M
**Reported:** 08/04/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 78Y
**Onset Date:** 05/07/2002 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | Euvolemic hyponatraemia (SIADH). | Venlafaxine ceased and ECT |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 37.5 Milligram Daily Oral
**Batch:** **Started:** 02/07/2002 **Stopped:** 04/07/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 08/04/2003 | Sodium | | 25/06/2002 | 129 | |
| 08/04/2003 | Sodium | | 05/07/2002 | 121 | |

### Additional Information:

Patient also taking Atenolol, Omeprazole, Finasteride, Mirtazapine, Risperidone, Ramipril and Rivastigmine.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 185438 **Seq:** 1
**Reported:** 01/05/2003
**Hospitalisation:** Admitted to hospital
**Onset Date:** 07/04/2003
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 50
**DOB:** 25/06/1952
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Erythema | | Generalised red itchy rash | Given Phenergan 25mg/bd. Luvox 100mg/daily commenced |
| Pruritus | | Generalised red itchy rash | |
| Rash | | Generalised red itchy rash | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** 21/03/2003 **Stopped:** 07/04/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient discharged on 09/04/03. History: Developed a skin rash / palmar erythema coinciding with starting Prothiadin mid March 2003.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 185541 **Seq:** 1 **Gender:** F
**Reported:** 06/05/2003 **Weight:** 67.00
**Hospitalisation:** **Age:** 46
**Onset Date:** 04/03/2003 **DOB:** 03/01/1957
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Required Visit to Doctor | Withdrawal syndrome | |
| Agitation | Required Visit to Doctor | Withdrawal syndrome, severe nightmares, agitation, light headaches and orgasmic sensation constantly. | |
| Headache | Required Visit to Doctor | Withdrawal syndrome, severe nightmares, agitation, light headaches and orgasmic sensation constantly. | |
| Nightmare | Severe | Withdrawal syndrome, severe nightmares, agitation, light headaches and orgasmic sensation constantly. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Oral application 37.5 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 185541 **Seq:** 1 **Gender:** F
**Reported:** 06/05/2003 **Weight:** 67.00
**Hospitalisation:** **Age:** 46
**Onset Date:** 04/03/2003 **DOB:** 03/01/1957
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sensory disturbance | Required Visit to Doctor | Withdrawal syndrome, severe nightmares, agitation, light headaches and orgasmic sensation constantly. | |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Oral application 37.5 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 185637 **Seq:** 1
**Reported:** 08/05/2003
**Hospitalisation:** Admitted to hospital
**Onset Date:** 01/01/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 56.00
**Age:** 49
**DOB:** 30/01/1953
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash papular | | Patient developed papular rash on back, arms and legs especially on buttocks. | Prednisolone, antihistamine |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 15/10/2000 **Stopped:** 31/03/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Reaction onset date: Jan 03.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 185698 **Seq:** 1
**Reported:** 07/05/2003
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 56Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis<br><br>Visual disturbance<br>Weight increased | Required Visit to Doctor | Excessive sweating, body weight increased, vision disturbances. | Changed Effexor XR |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 186015 **Seq:** 1 **Gender:** F
**Reported:** 07/05/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 56Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nightmare<br>Drug withdrawal syndrome<br>Coordination abnormal<br>Dizziness<br>Dysphoria<br>Insomnia<br>Irritability | | Nightmares, irritability, dysphoria, ataxia.<br>Withdrawal symptons, Dizziness, | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 186050 **Seq:** 1 **Gender:** M
**Reported:** 19/05/2003 **Weight:** 0.00
**Hospitalisation:** Admitted to hospital **Age:** 56Y
**Onset Date:** 13/03/2003 **DOB:**
**Outcome:** Recovered 20/03/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Life | Severe hyponatremia and hypokalemia | Ceased Efexor XR |
| Hypokalaemia | Life | | |

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **EFEXOR-XR (Interaction)** | | **Reason:** | Anxiety neurosis | |
| Capsule | 75.0 Milligram | Daily | Oral | |
| **Batch:** | **Started:** 11/03/2003 | | **Stopped:** 18/03/2003 | |
| **INDAPAMIDE HEMIHYDRATE (Interaction)** | | **Reason:** | Essential benign hypertension | |
| Tablet | 2.5 Milligram | Daily | Oral | |
| **Batch:** | **Started:** 17/05/1996 | | **Stopped:** | contin |
| **ATENOLOL (Interaction)** | | **Reason:** | Essential benign hypertension | |
| Oral application | 50.0 Milligram | Daily | | |
| **Batch:** | **Started:** 21/05/1999 | | **Stopped:** | contin |
| **LISINOPRIL (Interaction)** | | **Reason:** | Essential benign hypertension | |
| Oral application | 20.0 Milligram | Daily | | |
| **Batch:** | **Started:** 10/04/1995 | | **Stopped:** | contin |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 19/05/2003 | Potassium | | | | |
| 19/05/2003 | Sodium | | | | |

### Additional Information:

Patient was also taking Atenolol, Lisinopril
Recovery:within 3-5 days of stopping Efexor XR 75mg. Report no: 184376 is a duplicate of this report.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 186408 **Seq:** 1
**Reported:** 30/05/2003
**Hospitalisation:** Admitted to hospital
**Onset Date:** 11/05/2003
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 50
**DOB:** 25/09/1952
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash pustular | | Acute generalised exanthematous | Emollients, Prednisolone, Panadeine Forte, Phenergan, Tridione, Ibuprofen and Colchicine. |

### Medicine Details:

**ZYLOPRIM (Other drug)** **Reason:** Gout
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**NATURE'S OWN MULTI VITAMIN & MINERAL (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

**INDOCID (Suspected)** **Reason:** Gout
Dose Unspecified As necessary
**Batch:** **Started:** **Stopped:** 11/05/2003

**RULIDE (Suspected)** **Reason:** Ac upr resp inf,mult,unsp stes
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 01/05/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Complicated by folliculitis. Gout difficult to manage - Colchicine and Ibuprofen.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 186408 **Seq:** 1
**Reported:** 30/05/2003
**Hospitalisation:** Admitted to hospital
**Onset Date:** 11/05/2003
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 50
**DOB:** 25/09/1952
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression | |
| Capsule | 75.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | 19/05/2003 |

### Laboratory Investigations:

### Additional Information:

Complicated by folliculitis. Gout difficult to manage - Colchicine and Ibuprofen.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 186425 **Seq:** 1 **Gender:** M
**Reported:** 30/05/2003 **Weight:** 65.00
**Hospitalisation:** **Age:** 15
**Onset Date:** 28/02/2002 **DOB:** 03/06/1986
**Outcome:** Recovered 28/04/2002 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary retention | | Urinary retention | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Oral application 75.0 Milligram Daily Oral
**Batch:** **Started:** 27/02/2002 **Stopped:** 26/04/2002

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 186451 **Seq:** 1 **Gender:** F
**Reported:** 02/06/2003 **Weight:** 60.00
**Hospitalisation:** **Age:** 33
**Onset Date:** 07/05/2003 **DOB:** 23/06/1969
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness | Required Visit to Doctor | Withdrawal symptoms - nausea, vomiting, dizziness, shaking, feeling hot and cold. | |
| Drug withdrawal syndrome | Required Visit to Doctor | Withdrawal symptoms - nausea, vomiting, dizziness, shaking, feeling hot and cold. | Symptomatic |
| Feeling hot and cold | Required Visit to Doctor | Withdrawal symptoms - nausea, vomiting, dizziness, shaking, feeling hot and cold. | |
| Nausea | Required Visit to Doctor | Withdrawal symptoms - nausea, vomiting, dizziness, shaking, feeling hot and cold. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 01/04/2003 **Stopped:** 07/05/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 186451 **Seq:** 1
**Reported:** 02/06/2003
**Hospitalisation:**
**Onset Date:** 07/05/2003
**Outcome:** Recovered

**Gender:** F
**Weight:** 60.00
**Age:** 33
**DOB:** 23/06/1969
**Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | Required Visit to Doctor | Withdrawal symptoms - nausea, vomiting, dizziness, shaking, feeling hot and cold. | |
| Vomiting | Required Visit to Doctor | Withdrawal symptoms - nausea, vomiting, dizziness, shaking, feeling hot and cold. | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** 01/04/2003 **Stopped:** 07/05/2003

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 186583 **Seq:** 1 **Gender:** M
**Reported:** 04/06/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 82Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor<br>Fall<br>Muscle rigidity | | Unilateral tremors of hand, rigidity, frequent | Stopped Efexor XR |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 21/11/2002 **Stopped:** 19/12/2002

**OLANZAPINE (Suspected)** **Reason:**
Tablet 2.5 Milligram Daily Oral
**Batch:** **Started:** 21/11/2002 **Stopped:** 16/01/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was also taking Renitec, Zyloprim, Aspirin.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 186614 **Seq:** 1 **Gender:** F
**Reported:** 05/06/2003 **Weight:** 57.00
**Hospitalisation:** **Age:** 57
**Onset Date:** 20/02/2003 **DOB:** 06/04/1945
**Outcome:** Recovered 14/03/2003 **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| International normalised ratio dec | Required Visit to Doctor | Difficulties with anticoagulation with Warfarin. INR continued to be subtheraputic once Venlafaxine commenced on 19/02/03 despite increasing Warfarin dose. | |

## Medicine Details:

**WARFARIN SODIUM (Interaction)** **Reason:** Otr&nos disord of heart rhythm
Tablet Dose Unspecified As necessary Oral
**Batch:** **Started:** **Stopped:** Contin

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 19/02/2003 **Stopped:** 28/02/2003

**MIRTAZAPINE (Other drug)** **Reason:** Depression
Tablet 45.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** Contin

**DILTIAZEM HYDROCHLORIDE (Other drug)** **Reason:** Otr&nos disord of heart rhythm
Capsule 180.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** Contin

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 186614 **Seq:** 1 **Gender:** F
**Reported:** 05/06/2003 **Weight:** 57.00
**Hospitalisation:** **Age:** 57
**Onset Date:** 20/02/2003 **DOB:** 06/04/1945
**Outcome:** Recovered 14/03/2003 **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**OLANZAPINE (Other drug)** **Reason:** Depression

Tablet 2.5 Milligram Daily Oral

**Batch:** **Started:** 13/02/2003 **Stopped:** Contin

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 186692 **Seq:** 1 **Gender:** M
**Reported:** 06/06/2003 **Weight:** 67.50
**Hospitalisation:** **Age:** 48
**Onset Date:** 29/05/2003 **DOB:** 12/02/1955
**Outcome:** Recovered 02/06/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension | Required Visit to Doctor | Hypertension BP up 170/100, BP pre treatment 140/80 resolved on discontinuation to 130/90. No hypertension, history of excess Alcohol intake | Zoloft discontinued |

### Medicine Details:

**ZOLOFT (Suspected)** **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** 17/01/2003 **Stopped:** 14/02/2003

**VALIUM (Suspected)** **Reason:** Depression
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** 14/02/2003 **Stopped:** 26/02/2003

**EFEXOR (Suspected)** **Reason:**
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 187511 **Seq:** 1 **Gender:** M
**Reported:** 20/06/2003 **Weight:** 67.50
**Hospitalisation:** **Age:** 48
**Onset Date:** 29/05/2003 **DOB:** 12/02/1955
**Outcome:** Recovered 02/06/2003 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension | | Hypertension. | |

### Medicine Details:

**ZOLOFT (Other drug)** **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** 17/01/2003 **Stopped:** 14/02/2003

**VALIUM (Other drug)** **Reason:** Depression
Oral application 5.0 Milligram Daily Oral
**Batch:** **Started:** 14/02/2003 **Stopped:** 26/02/2003

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 14/05/2003 **Stopped:** 01/06/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 20/06/2003 | Other data | | | | |

### Additional Information:

BP rose to 170/00 from 140/80 on discontinuation of Efexor BP was reduced back to 30/90.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 187521 **Seq:** 1 **Gender:** F
**Reported:** 20/06/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 19
**Onset Date:** **DOB:** 09/04/1984
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Bleeding time prolonged | | Bleeding time prolonged - prolonged bleeding post ear piercing. | |

### Medicine Details:

**ASPIRIN (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EPILIM (Suspected)** **Reason:**
Tablet 1.2 Gram Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
225.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 187751 **Seq:** 1 **Gender:** F
**Reported:** 24/06/2003 **Weight:** 48.00
**Hospitalisation:** **Age:** 49
**Onset Date:** 16/06/2003 **DOB:** 18/10/1953
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | Required Visit to Doctor | Agitation, insomnia, nightmares, aggression, withdrawal syndrome on abrupt withdrawal of efexor | Therapy changed to other SSR |
| Aggression | | Agitation, insomnia, nightmares, aggression, withdrawal syndrome. | |
| Drug withdrawal syndrome | | Agitation, insomnia, nightmares, aggression, withdrawal syndrome. | |
| Insomnia | | Agitation, insomnia, nightmares, aggression, withdrawal syndrome. | |
| Nightmare | | Agitation, insomnia, nightmares, aggression, withdrawal syndrome. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

Tablet 150.0 Milligram Daily Oral

**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 188072 **Seq:** 1 **Gender:** F
**Reported:** 02/07/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | Agitation, anxiety, dry mouth, nausea, vomiting, dizziness, headache, sweating, | |
| Headache | | Chronic headache | |
| Diarrhoea | | Diarrhoea for 3 months. | |
| Drug ineffective | | Feels the Efexor may not be working. | |
| Decreased appetite | | Loss of appetite | |
| Insomnia | | Problems sleeping | |
| Suicidal ideation | | Sometimes feels suicidal | |
| Depression | | | |
| Dizziness | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was also taking Losec, Valium, paracetamol, Multivitamins.
Patient was initally on 375mg dose then 225mg, then took 150mg then 75mg for a few weeks and has now been on 150mg dose for last 6 months.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 188072 **Seq:** 1 **Gender:** F
**Reported:** 02/07/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dry mouth<br>Hyperhidrosis<br>Nausea<br>Vomiting | | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

## Additional Information:

Patient was also taking Losec, Valium, paracetamol, Multivitamins.
Patient was initally on 375mg dose then 225mg, then took 150mg then 75mg for a few weeks and has now been on 150mg dose for last 6 months.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 188195 **Seq:** 1 **Gender:** F
**Reported:** 28/04/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 31
**Onset Date:** 16/01/2003 **DOB:** 18/08/1971
**Outcome:** Recovered 25/01/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary retention | Caused or prolonged inpatient hospitalisation | Urinary retention | Ceased Efexor and a week later patient was initiated on Seroquel |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 188220 **Seq:** 1 **Gender:** M
**Reported:** 07/07/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 63
**Onset Date:** 10/06/2003 **DOB:** 13/09/1939
**Outcome:** Recovered 13/06/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination | Life | Hallucinations and delerium, became agitated and aggressive. | Required sedation. |
| Aggression | Life | | |
| Agitation | Life | | |
| Delirium | Life | | |

### Medicine Details:

**SODIUM NITROPRUSSIDE (Suspected)** **Reason:** Essential benign hypertension
Injection 1.0 Dose Unspecified Daily
**Batch:** **Started:** 09/06/2003 **Stopped:** 16/06/2003

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 08/06/2003

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
37.5 Milligram Daily
**Batch:** **Started:** 09/06/2003 **Stopped:** 13/06/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 07/07/2003 | Pharmacokinetics | | | | |

### Additional Information:

Patient was also taking Pantiprazole, Amlodipine, Atenolol,Glyceryl trinitrate, Frusemide, Morphine, metoclopramide, Ondansetron, paracetamol, Heparin.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 188264 **Seq:** 1 **Gender:** F
**Reported:** 09/07/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 29
**Onset Date:** 13/02/2003 **DOB:** 04/02/1974
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rhabdomyolysis | | Admitted with rhabdomyolysis secondary to seizures. | |
| Pyrexia | | Elevated temp (to 39 degress celsius). | |
| Neuroleptic malignant syndrome | | Neuroleptic malignant syndrome. | Ceased Valproate, Venlafaxine and Quetiepine 13/02/03. Pt rescusitated, intubated and ventilated and required inotropes. |
| Somnolence | | Spent most of the day sleeping and was difficult to rouse. | |
| Acidosis | | | |
| Blood creatine phosphokinase in | | | |

## Medicine Details:

**STILNOX (Interaction)** **Reason:**
**Batch:** **Started:** **Stopped:**

**QUETIAPINE (Interaction)** **Reason:** Convulsions
150.0 Milligram Daily
**Batch:** **Started:** S TERM **Stopped:**

**SODIUM VALPROATE (Interaction)** **Reason:** Convulsions
1.0 Gram Daily
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 09/07/2003 | Creatine | | | | |

## Additional Information:

Patient also taking Valproate, Venlafaxine, Panadol, Stilnox, Sandomigran, Mersyndol, Diazepam, Phenergan and Ventolin. Valproate and Venlafaxine were both restarted without adverse effect.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 188264 **Seq:** 1 **Gender:** F
**Reported:** 09/07/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 29
**Onset Date:** 13/02/2003 **DOB:** 04/02/1974
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion<br>Depressed level of consciousnes<br>Hyperkalaemia | | | |

### Medicine Details:

**STILNOX (Interaction)** **Reason:**
**Batch:** **Started:** **Stopped:**

**QUETIAPINE (Interaction)** **Reason:** Convulsions
150.0 Milligram Daily
**Batch:** **Started:** S TERM **Stopped:**

**SODIUM VALPROATE (Interaction)** **Reason:** Convulsions
1.0 Gram Daily
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

Patient also taking Valproate, Venlafaxine, Panadol, Stilnox, Sandomigran, Mersyndol, Diazepam, Phenergan and Ventolin. Valproate and Venlafaxine were both restarted without adverse effect.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 188392 **Seq:** 1
**Reported:** 10/07/2003
**Hospitalisation:**
**Onset Date:** 15/06/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 55.00
**Age:** 35
**DOB:** 20/08/1967
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Galactorrhoea | Required Visit to Doctor | Galactorrhoea | Gradual reduction |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 03/06/2003 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 10/07/2003 | Prolactin | | | | |

### Additional Information:

Used phytoestrolins 6 months prior with simialr reaction.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 188450 **Seq:** 1 **Gender:** F
**Reported:** 14/07/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** 07/07/2003 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Contusion | Required Visit to Doctor | Bruising, breakthrough bleeding. | Ceased Efexor. |
| Metrorrhagia | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient Vitamin B, Vitamin C, Panadol, Aspirin.
Efexor was started sometime in Dec 02 and stopped sometime in Feb 03.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 188547 **Seq:** 1 **Gender:** F
**Reported:** 17/07/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 71
**Onset Date:** 30/06/2003 **DOB:** 30/09/1931
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cough | Caused or prolonged inpatient hospitalisation | Coughing, fever, sweats. | |
| Hyperhidrosis | Caused or prolonged inpatient hospitalisation | | |
| Pyrexia | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**TRYPTANOL (Interaction)** **Reason:**
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Interaction)** **Reason:**
Tablet 37.5 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 17/07/2003 | Chest X-ray | | | | |

## Additional Information:

Tryptenol was started sometime in jan 2003 and stopped sometime in July 2003.
Efexor was started sometime in 2000.
Serotonin syndrome.
Patient was also taking Serepax and Lipitor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 188695 **Seq:** 1
**Reported:** 22/07/2003
**Hospitalisation:**
**Onset Date:** 15/03/2002
**Outcome:** Not yet recovered

**Gender:** U
**Weight:** 60.00
**Age:** 43
**DOB:** 15/04/1958
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Required Visit to Doctor | Shocks in brain when drowsy or tired, sometimes triggered by noise | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/12/2001 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was also taking bricanyl, Ibilex, Rhinocort, Kenocomb.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 188862 **Seq:** 1 **Gender:** M
**Reported:** 29/07/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 40
**Onset Date:** 05/06/2003 **DOB:** 17/09/1962
**Outcome:** Recovered 06/06/2003 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Angioedema | | Felt unwell, lips swelled, red rash and itch around mouth. | |
| Pruritus | | Felt unwell, lips swelled, red rash and itch around mouth. | |
| Rash | | Felt unwell, lips swelled, red rash and itch around mouth. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Total Oral
**Batch:** **Started:** 05/06/2003 **Stopped:** 05/06/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 188902 **Seq:** 1 **Gender:** M
**Reported:** 28/07/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 48
**Onset Date:** 01/07/2003 **DOB:** 18/08/1954
**Outcome:** Recovered 22/07/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatitis | | Hepatitis moderate. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
225.0 Milligram Daily
**Batch:** **Started:** 23/05/2003 **Stopped:** 22/07/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 189050 **Seq:** 1 **Gender:** F
**Reported:** 01/08/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 23
**Onset Date:** 23/04/2003 **DOB:** 26/06/1979
**Outcome:** Unknown 30/07/2003 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Alopecia | | Significant hair loss when Efexor dose was increased from 75mg to 150mg, stopped when drug was ceased.. | Ceased Efexor XR. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 23/04/2003 **Stopped:** 04/06/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 189157 **Seq:** 1 **Gender:** M
**Reported:** 04/08/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 54
**Onset Date:** **DOB:** 15/04/1949
**Outcome:** Recovered 20/07/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Constipation | | Severe constipation | Ceased Venlefaxine. Used |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was also taking Astrix, Avandia, Avanza, Cardizem, Diaformin, Diamicron, Imdur, Mersyndol, Monopril, Somac, Xanax, Zocor, Zyloprim.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 189192 **Seq:** 1 **Gender:** M
**Reported:** 06/08/2003 **Weight:** 70.00
**Hospitalisation:** **Age:** 27
**Onset Date:** 20/07/2003 **DOB:** 20/03/1976
**Outcome:** Recovered 24/07/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mydriasis | Required Visit to Doctor | Mydriasis | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Phobic neurosis
75.0 Milligram Daily
**Batch:** **Started:** 15/07/2003 **Stopped:** 21/07/2003

**AVANZA (Suspected)** **Reason:** Anxiety neurosis
30.0 Milligram Daily
**Batch:** **Started:** 10/07/2003 **Stopped:** 21/07/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Prior therapy with efexor year ago "felt strange" and discontinued.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 189304 **Seq:** 1 **Gender:** F
**Reported:** 08/08/2003 **Weight:** 55.00
**Hospitalisation:** **Age:** 54
**Onset Date:** 21/06/2003 **DOB:** 05/07/1948
**Outcome:** Recovered 21/06/2003 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vomiting | Required Visit to Doctor | Creepy Crawy feeling over whole body and saw yellow-red lights , vomited up the tablet within an hour. | |
| Hallucinations, mixed | Required Visit to Doctor | Creepy Crawy feeling over whole body and saw yellow-red lights , vomited up the tablet within an hour. | |

### Medicine Details:

**LOSEC (Other drug)** **Reason:** Other diseases of esophagus
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 12/03/2002 **Stopped:**

**DIAZEPAM (Other drug)** **Reason:** Abnormal involuntary movement
Tablet 6.0 Milligram Daily Oral
**Batch:** **Started:** 15/02/2002 **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Allergies: Rulide - rash.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 189305 **Seq:** 1 **Gender:** F
**Reported:** 08/08/2003 **Weight:** 68.00
**Hospitalisation:** **Age:** 34
**Onset Date:** 23/07/2003 **DOB:** 14/12/1968
**Outcome:** Recovered 30/07/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | Severe | Agitation. | Required a visit to doctor. |
| Anxiety | Severe | Anxiety. | |
| Dry mouth | Severe | Dry mouth. | |
| Hot flush | Severe | Hot flushes. | |
| Palpitations | Severe | Palpitations | |
| Tremor | Severe | Tremor. | |
| Vomiting | Severe | Vomiting. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 23/07/2003 **Stopped:** 23/07/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

History: Patient has had previous problems with other SSRI's.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 189380 **Seq:** 1
**Reported:** 12/08/2003
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 43
**DOB:** 31/12/1959
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vomiting | Required Visit to Doctor | Vomiting and nausea in weaning phase. From Efexor XR 300 mg over 3 weeks to 75 mg, but onset of vomiting and nausea when decreased to 37 mg after 2/7 on 75 mg | |
| Drug withdrawal syndrome | Required Visit to Doctor | | |
| Nausea | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 300.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient also taking Lamictal, Lithucarb, Aeimax, Vibratabs.
Dose of Efexor re-increased to 75 mg with plan to wean more slowly with resolution of symptoms.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 189416 **Seq:** 1 **Gender:** F
**Reported:** 11/08/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 35
**Onset Date:** 02/08/2003 **DOB:** 30/12/1967
**Outcome:** Recovered 02/08/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Grand mal convulsion | Life | Grand mal seizure, lasted 2-3 minutes. | |

### Medicine Details:

**TRAMADOL HYDROCHLORIDE (Interaction)** **Reason:** Pain
Injection 100.0 Milligram 1 time Intravenous
**Batch:** **Started:** 02/08/2003 **Stopped:** 02/08/2003

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 05/08/2003

**PETHIDINE HYDROCHLORIDE (Interaction)** **Reason:** Pain
Injection 1000.0 Milligram Daily Intravenous
**Batch:** **Started:** 01/08/2003 **Stopped:** 02/08/2003

**INDOCID (Interaction)** **Reason:** Pain
Suppositories and pessaries 200.0 Milligram Daily Rectal
**Batch:** **Started:** 01/08/2003 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Likely to be a combination drug reaction, with all meds reducing seizure threshold.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 189565 **Seq:** 1 **Gender:** F
**Reported:** 15/08/2003 **Weight:** 0.00
**Hospitalisation:** Admitted to hospital **Age:** 99U
**Onset Date:** 31/07/2003 **DOB:**
**Outcome:** Recovered 12/08/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome neona | Caused or prolonged inpatient hospitalisation | DoB: 03/07/2003 | |
| Restlessness<br>Agitation | Caused or prolonged inpatient hospitalisation | Extreme restlessness, agitations, withdrawal syndrome. | Phenobarditone: Morphine |

### Medicine Details:

**ENDONE (Other drug)** **Reason:** Otr&unsp vertebrogen pain synd
Tablet 50.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 189675 **Seq:** 1 **Gender:** M
**Reported:** 10/06/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 37
**Onset Date:** 10/04/2003 **DOB:** 08/10/1965
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | | Diaphoresis | |
| Gait disturbance | | Difficult walking | |
| Somnolence | | Drowsiness | Ceased Efexor and |
| Hypoaesthesia | | Numb hands and feet | |
| Tremor | | Some shakes. | |
| Drug withdrawal syndrome | | | |

### Medicine Details:

**TEMAZEPAM (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:** 07/04/2003

**EFEXOR (Suspected)** **Reason:**

Tablet 150.0 Milligram Daily Oral

**Batch:** **Started:** 01/04/2003 **Stopped:** 08/04/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 189858 **Seq:** 1 **Gender:** F
**Reported:** 26/08/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 23
**Onset Date:** 12/08/2003 **DOB:** 09/03/1980
**Outcome:** Recovered 15/08/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Leukopenia | Caused or prolonged inpatient hospitalisation | Low WBC | |

### Medicine Details:

**SPIRONOLACTONE (Suspected)** **Reason:** Diseases of hair&hair follicle
Tablet 100.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 12/08/2003

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** 07/05/2003 **Stopped:** 12/08/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Efexor XR was started at 75mg then increased to 225mg.
Multiple infected sites eg: paper cuts, cat scratch.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 189980 **Seq:** 1
**Reported:** 29/08/2003
**Hospitalisation:** Admitted to hospital
**Onset Date:** 08/08/2003
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 62
**DOB:** 09/11/1940
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delusion | Caused or prolonged inpatient hospitalisation | Paranoid delusions | Zyprexa |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** 22/07/2003 **Stopped:** 11/08/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 190053 **Seq:** 1 **Gender:** F
**Reported:** 01/09/2003 **Weight:** 57.00
**Hospitalisation:** **Age:** 30Y
**Onset Date:** 15/10/2002 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | Required Visit to Doctor | Severe headache with vomiting and photophobia hours after dose. Severe hypotension 80/- with unrecordable postural drop lasting 2/52. | |
| Hypotension | Required Visit to Doctor | | |
| Orthostatic hypotension | Required Visit to Doctor | | |
| Photophobia | Required Visit to Doctor | | |
| Vomiting | Required Visit to Doctor | | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Tablet 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Occurred after 2/52 washout from Citalapram then 1/52 at 37.5mg/daily Venlafaxine.
Patient history of undiagnosed pernicious anaemia at the time.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 190277 **Seq:** 1 **Gender:** F
**Reported:** 08/09/2003 **Weight:** 74.00
**Hospitalisation:** Admitted to hospital **Age:** 54
**Onset Date:** 16/04/2003 **DOB:** 07/12/1948
**Outcome:** Recovered 24/04/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ocular hyperaemia | Caused or prolonged inpatient hospitalisation | Left eye pain, redness and headache (put down to migraine), visual disturbance and headache. | Admitted, treatment for acute glaucoma. |
| Eye pain | Caused or prolonged inpatient hospitalisation | | |
| Glaucoma | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** 16/04/2003 **Stopped:** 16/04/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 08/09/2003 | Other data | | | | |

### Additional Information:

Sulpha drug allergies -urticaria

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 190277 **Seq:** 1 **Gender:** F
**Reported:** 08/09/2003 **Weight:** 74.00
**Hospitalisation:** Admitted to hospital **Age:** 54
**Onset Date:** 16/04/2003 **DOB:** 07/12/1948
**Outcome:** Recovered 24/04/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | Caused or prolonged inpatient hospitalisation | | |
| Visual disturbance | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** 16/04/2003 **Stopped:** 16/04/2003

### Laboratory Investigations:

### Additional Information:
Sulpha drug allergies -urticaria

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 190284 **Seq:** 1
**Reported:** 08/09/2003
**Hospitalisation:** Admitted to hospital
**Onset Date:** 20/05/2003
**Outcome:** Unknown

**Gender:** M
**Weight:** 90.00
**Age:** 26
**DOB:** 13/02/1977
**Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delusion | Caused or prolonged inpatient hospitalisation | Paranoid delusions | Zyprexa |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** 13/05/2003 **Stopped:** 27/05/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Probable similar reaction when GP Rx Efexor-XR 15mg on 20/06/00 - admitted to Psych 11/08/00 - paranoid psychosis.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 190298 **Seq:** 1 **Gender:** M
**Reported:** 08/09/2003 **Weight:** 80.00
**Hospitalisation:** **Age:** 19
**Onset Date:** 05/06/2003 **DOB:** 24/09/1983
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Alopecia | Required Visit to Doctor | Rapid hair loss | Epilim stopped. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 04/06/2003 **Stopped:** 06/06/2003

**EPILIM (Suspected)** **Reason:** Epilepsy
Tablet 1.0 Gram Daily Oral
**Batch:** **Started:** 30/05/2003 **Stopped:** 06/06/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Report 190320 is Seq 2

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 190330 **Seq:** 1 **Gender:** F
**Reported:** 09/09/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Facial palsy | | Paralysis on left side of face started in the last 3 days. | |
| Head discomfort | | Heaviness of head started a couple of weeks after starting Efexor XR. Eyelid flutter started in the last 4 weeks. | |
| Visual disturbance | | | |

### Medicine Details:

**LIPITOR (Other drug)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:** contin

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 190387 **Seq:** 1 **Gender:** M
**Reported:** 10/09/2003 **Weight:** 75.00
**Hospitalisation:** **Age:** 64
**Onset Date:** 08/01/2003 **DOB:** 26/07/1938
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delusion | Required Visit to Doctor | Paranoid delusions | Zyprexa |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 06/01/2003 **Stopped:** 09/01/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 190449 **Seq:** 1 **Gender:** F
**Reported:** 12/09/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 42
**Onset Date:** 01/01/2003 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence<br>Apathy<br>Blood pressure increased<br>Libido decreased<br>Thinking abnormal<br>Tongue disorder | | Apathetic, somnolence, argumentative, decreased libido, blood pressure increased, thick white tongue, slowed mentation | Ceased Efexor |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Tablet 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Other drugs used:Dexamphetamine

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 190450 **Seq:** 1
**Reported:** 12/09/2003
**Hospitalisation:**
**Onset Date:** 04/09/2003
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 110.00
**Age:** 30
**DOB:** 13/03/1973
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Schizophrenia | Required Visit to Doctor | Exacerbation of schizophrenic condition with derealisation, depersonalization, depression, anxiety and hallucinations. | Tetracycline and Quetiapine 100mg/daily. |
| Anxiety | Required Visit to Doctor | | |
| Depersonalisation | Required Visit to Doctor | | |
| Depression | Required Visit to Doctor | | |
| Derealisation | Required Visit to Doctor | | |

### Medicine Details:

**DOXYCYCLINE HYDROCHLORIDE (Suspected)** **Reason:** Chronic sinusitis
Tablet 100.0 Milligram Daily Oral
**Batch:** **Started:** 21/08/2003 **Stopped:** 09/09/2003

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 450.0 Milligram Daily Oral
**Batch:** **Started:** 12/08/2003 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Other medication taken: Olanzapine, Risperidone.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 190450 **Seq:** 1
**Reported:** 12/09/2003
**Hospitalisation:**
**Onset Date:** 04/09/2003
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 110.00
**Age:** 30
**DOB:** 13/03/1973
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination | Required Visit to Doctor | | |

### Medicine Details:

**DOXYCYCLINE HYDROCHLORIDE (Suspected)** **Reason:** Chronic sinusitis

Tablet 100.0 Milligram Daily Oral

**Batch:** **Started:** 21/08/2003 **Stopped:** 09/09/2003

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 450.0 Milligram Daily Oral

**Batch:** **Started:** 12/08/2003 **Stopped:**

### Laboratory Investigations:

### Additional Information:

Other medication taken: Olanzapine, Risperidone.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 190466 **Seq:** 1
**Reported:** 15/09/2003
**Hospitalisation:**
**Onset Date:** 05/09/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 31
**DOB:** 21/06/1972
**Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Haemorrhage | Required Visit to Doctor | PV bleeding, thick brown lumps. | |

### Medicine Details:

**IMPLANON IMPLANT (Other drug)** **Reason:**
Injection 1.0 Dose Unspecified Daily Subcutaneous
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 21/07/2003 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Has Implanon since April 2002. Also an earlier episode the same when Venlafaxine dose had just been increased from 150 to 225mg.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 190947 **Seq:** 1 **Gender:** F
**Reported:** 29/09/2003 **Weight:** 42.00
**Hospitalisation:** **Age:** 87
**Onset Date:** 14/09/2003 **DOB:** 02/07/1916
**Outcome:** Recovered 24/09/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Inappropriate antidiuretic hormon | Caused or prolonged inpatient hospitalisation | SIADH - no lab data, hyponatraemia | Fluid restriction and cessation of Efexor. |
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 08/09/2003 **Stopped:** 17/09/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was also taking Aspirin, Clopidogrel, calsup, Atrovent, Somac.

## Report Detail

**Case Number:** 191284 **Seq:** 1 **Gender:** M
**Reported:** 14/10/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 35
**Onset Date:** 01/10/2003 **DOB:** 10/06/1968
**Outcome:** Recovered 01/10/2003 **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Grand mal convulsion | Caused or prolonged inpatient hospitalisation | grand mal seizure, hypertension aggravated, sweating . | |
| Flushing | Caused or prolonged inpatient hospitalisation | Red faced | |
| Hyperhidrosis | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**TRAMADOL HYDROCHLORIDE (Interaction)** **Reason:** Headache
Tablet 1.0 Gram 1 time Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Interaction)** **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient History: alcoholism.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 191284 **Seq:** 1 **Gender:** M
**Reported:** 14/10/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 35
**Onset Date:** 01/10/2003 **DOB:** 10/06/1968
**Outcome:** Recovered 01/10/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypotension | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**TRAMADOL HYDROCHLORIDE (Interaction)** **Reason:** Headache
Tablet 1.0 Gram 1 time Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Interaction)** **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:
Patient History: alcoholism.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 191350 **Seq:** 1 **Gender:** F
**Reported:** 16/10/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 49
**Onset Date:** **DOB:** 31/05/1954
**Outcome:** Recovered 01/09/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypomania | Required Visit to Doctor | Addition of Olanzepine to Efexor XR and Lithium in a patient in a depressed phase of bipolar disorder (depression present for some years) led to immediate cycling to hypomania. Increase of the Olanzepine worsened her condition. | Changed drug to Thioridazine, increased Lithium, stopped Efexor |

### Medicine Details:

**OLANZAPINE (Suspected)** **Reason:** Depression
5.0 Milligram Daily
**Batch:** **Started:** 20/05/2003 **Stopped:** 04/07/2003

**LITHIUM CARBONATE (Suspected)** **Reason:** Depression
Tablet 900.0 Milligram Daily Oral
**Batch:** **Started:** 21/01/2003 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Tablet 450.0 Milligram Daily Oral
**Batch:** **Started:** 15/06/2002 **Stopped:** 28/08/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Last hypomanic during 1996. Since then depressed. Long past history of anorexia nervosa, normal weight since 1996.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 191478 **Seq:** 1 **Gender:** F
**Reported:** 21/10/2003 **Weight:** 58.00
**Hospitalisation:** **Age:** 34
**Onset Date:** **DOB:** 08/08/1969
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Liver function test abnormal | | Raised LFT | |

### Medicine Details:

**THIAMINE (Other drug)** **Reason:**
Tablet 100.0 Gram Daily Oral
**Batch:** **Started:** 28/06/2003 **Stopped:** 10/09/2003

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 02/09/2003 **Stopped:** 18/09/2003

**CLONAZEPAM (Suspected)** **Reason:** Specific disorders of sleep
1.5 Gram Daily
**Batch:** **Started:** 29/08/2003 **Stopped:** 10/09/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 21/10/2003 | Albumin | | | | |
| 21/10/2003 | GGT = SGGT = | | 03/10/2003 | 164 | |
| 21/10/2003 | Other data | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 191531 **Seq:** 1 **Gender:** M
**Reported:** 23/10/2003 **Weight:** 100.00
**Hospitalisation:** **Age:** 46
**Onset Date:** **DOB:** 12/11/1956
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Liver function test abnormal | Required Visit to Doctor | Grossly abnormal LFT's reverted to normal when Efexor was ceased. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 16/09/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 23/10/2003 | ALT = SGPT | 0 - 40 U/L | 16/09/2003 | 1101 | |
| 23/10/2003 | ALT = SGPT | 0 - 40 U/L | 22/09/2003 | 421 | |
| 23/10/2003 | AST = SGOT | 0 - 40 U/L | 16/09/2003 | 404 | |
| 23/10/2003 | AST = SGOT | 0 - 40 U/L | 22/09/2003 | 67 | |
| 23/10/2003 | GGT = SGGT = | 0 - 45 U/L | 16/09/2003 | 467 | |
| 23/10/2003 | GGT = SGGT = | 0 - 45 U/L | 22/09/2003 | 658 | |
| 23/10/2003 | LDH | 100 - 225 U/L | 16/09/2003 | 428 | |

### Additional Information:

Efexor started in Nov 2002. Recovered in October 2003. Other causes of hepatitis excluded.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 191531 **Seq:** 1
**Reported:** 23/10/2003
**Hospitalisation:**
**Onset Date:**
**Outcome:** Recovered

**Gender:** M
**Weight:** 100.00
**Age:** 46
**DOB:** 12/11/1956
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 300.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 16/09/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 23/10/2003 | LDH | 100 - 225 U/L | 22/09/2003 | 189 | |
| 23/10/2003 | Other data | | | | |
| 23/10/2003 | SAP = ALP | 30 - 115 U/L | 16/09/2003 | 132 | |
| 23/10/2003 | SAP = ALP | 30 - 115 U/L | 22/09/2003 | 123 | |

### Additional Information:

Efexor started in Nov 2002. Recovered in October 2003. Other causes of hepatitis excluded.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 191534 **Seq:** 1 **Gender:** F
**Reported:** 23/10/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anger | Caused or prolonged inpatient hospitalisation | excessive rage | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 02/10/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 191543 **Seq:** 1
**Reported:** 23/10/2003
**Hospitalisation:**
**Onset Date:** 15/12/2000
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 50.00
**Age:** 99U
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | Seizures 2 to 3 months after Efexor | Epilim and Tegretol |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

150.0 Milligram Daily Oral

**Batch:** **Started:** 01/10/2000 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient has early onset dementia.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 191576 **Seq:** 1
**Reported:** 23/10/2003
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 99U
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Caused or prolonged inpatient hospitalisation | Nausea, disorientation, dizziness and physical exhaustion. | |
| Disorientation | Caused or prolonged inpatient hospitalisation | | |
| Dizziness | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 02/10/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Efexor-XR 150mg initially , then alternating between 150mg and 75 mg, then 75mg for one week, then 75mg on alternate days for one week.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 191576 **Seq:** 1
**Reported:** 23/10/2003
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 99U
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fatigue | Caused or prolonged inpatient hospitalisation | | |
| Nausea | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 02/10/2003

## Laboratory Investigations:

## Additional Information:

Efexor-XR 150mg initially , then alternating between 150mg and 75 mg, then 75mg for one week, then 75mg on alternate days for one week.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 191582 **Seq:** 1 **Gender:** F
**Reported:** 24/10/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** 01/10/2003 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urticaria | Required Visit to Doctor | Severe urticaria with angioedema of the | Given oral Prednisone |
| Angioedema | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 9.0 Milligram Daily Oral
**Batch:** **Started:** 15/05/2003 **Stopped:** Contin

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Follow-up information: The urticaria that the patient experienced previously was found be of a genetic origin and was unrelated to Efeor-XR use. Efexor-XR dose was tapered without medical advice. Treatment at this dose is currently ongoing.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 192000 **Seq:** 1 **Gender:** F
**Reported:** 10/11/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 82Y
**Onset Date:** 17/09/2003 **DOB:**
**Outcome:** Unknown **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Blood pressure decreased | | Lowering of blood pressure - dose related (approx) (as Venlafaxine XR decreased. BP lowered). Dose of Venlafaxine XR then divided. Now 150 mg XR morning 75mg XR evening | BP continuing to be monitored. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** 17/09/2003 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Other drugs taken: Quetiapine, Sodium Valproate, Temazepam, Lorazepam.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 192088 **Seq:** 1
**Reported:** 11/11/2003
**Hospitalisation:**
**Onset Date:** 30/09/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 24
**DOB:** 11/01/1979
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor<br>Headache<br>Hyperreflexia<br>Muscle spasms<br>Nausea<br>Trismus<br>Vision blurred | | Patient developed nausea, spasm in leg, headache, also tremor in right leg/ frontal headache/ right eye blur vision/ clenchy jaw | |

### Medicine Details:

**MOCLOBEMIDE (Interaction)** **Reason:** Depression
1.2 Gram Daily
**Batch:** **Started:** 30/05/2003 **Stopped:** 30/09/2003

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:** Depression
37.5 Milligram Daily
**Batch:** **Started:** 30/09/2003 **Stopped:**

**DIAZEPAM (Other drug)** **Reason:**
1.0 Dose Unspecified As necessary
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 192095 **Seq:** 1 **Gender:** U
**Reported:** 11/11/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** 20/06/2003 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic failure<br>Coagulopathy | | Hepatic failure with coagulopathy. | IV Acetylcysteine |

### Medicine Details:

**PARACETAMOL (Suspected)** **Reason:** Pain
4.0 Gram Daily
**Batch:** **Started:** 03/06/2003 **Stopped:** 20/06/2003

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 23/06/2003

**TEGRETOL (Suspected)** **Reason:**
Tablet 200.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 20/06/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 192104 **Seq:** 1
**Reported:** 11/11/2003
**Hospitalisation:**
**Onset Date:** 08/11/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 38
**DOB:** 24/01/1965
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | Caused or prolonged inpatient hospitalisation | Elation, excitement, euphoria, irritability, restlessness and racing thoughts. | Cessation of Efexor; diazepam and/or chlorpromazine for symptoms of anxiety and restlessness. |
| Euphoric mood | Caused or prolonged inpatient hospitalisation | Elation, excitement, euphoria, irritability, restlessness and racing thoughts. | Cessation of Efexor; diazepam and/or chlorpromazine for symptoms of anxiety and restlessness. |
| Inappropriate affect | Caused or prolonged inpatient hospitalisation | Elation, excitement, euphoria, irritability, restlessness and racing thoughts. | Cessation of Efexor; diazepam and/or chlorpromazine for symptoms of anxiety and restlessness. |

## Medicine Details:

**EFEXOR (Interaction)** **Reason:**
Tablet 37.5 Milligram 1 time Oral
**Batch:** **Started:** 07/11/2003 **Stopped:** 09/11/2003

**Mirtazon (Interaction)** **Reason:**
Tablet 60.0 Milligram 1 time Oral
**Batch:** **Started:** **Stopped:**

**ZYPREXA (Other drug)** **Reason:**
Tablet 5.0 Milligram 2 times Oral
**Batch:** **Started:** **Stopped:**

**ANTENEX (Other drug)** **Reason:**
Tablet 5.0 Milligram As necessary Oral
**Batch:** **Started:** 02/11/2003 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 192104 **Seq:** 1
**Reported:** 11/11/2003
**Hospitalisation:**
**Onset Date:** 08/11/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 38
**DOB:** 24/01/1965
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Irritability | Caused or prolonged inpatient hospitalisation | Elation, excitement, euphoria, irritability, restlessness and racing thoughts. | Cessation of Efexor; diazepam and/or chlorpromazine for symptoms of anxiety and restlessness. |
| Restlessness | Caused or prolonged inpatient hospitalisation | Elation, excitement, euphoria, irritability, restlessness and racing thoughts. | Cessation of Efexor; diazepam and/or chlorpromazine for symptoms of anxiety and restlessness. |
| Thinking abnormal | Caused or prolonged inpatient hospitalisation | Elation, excitement, euphoria, irritability, restlessness and racing thoughts. | Cessation of Efexor; diazepam and/or chlorpromazine for symptoms of anxiety and restlessness. |

### Medicine Details:

**PANADOL (Other drug)** **Reason:**
Tablet 500.0 Milligram As necessary Oral
**Batch:** **Started:** 02/11/2003 **Stopped:** 08/11/2003

**LARGACTIL (Other drug)** **Reason:**
Tablet 50.0 Milligram As necessary Oral
**Batch:** **Started:** 02/11/2003 **Stopped:**

**ZYPREXA (Other drug)** **Reason:**
Tablet 50.0 Milligram As necessary Oral
**Batch:** **Started:** 02/11/2003 **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 192311 **Seq:** 1 **Gender:** F
**Reported:** 18/11/2003 **Weight:** 76.00
**Hospitalisation:** **Age:** 69Y
**Onset Date:** 15/09/2003 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence | | Patient has had severe drowsiness occurring especially about 2-3 hours after taking both in morning. | |

### Medicine Details:

**NEXIUM (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Other drugs taken: Carbaser, Celebrex, Fluvax, Lipex, PolyTears, Prinivil, Voltaren Emulgel.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 192317 **Seq:** 1 **Gender:** F
**Reported:** 19/11/2003 **Weight:** 76.00
**Hospitalisation:** **Age:** 83
**Onset Date:** 29/10/2003 **DOB:** 17/04/1920
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatitis | | Acute hepatitis secondary to venlefaxine. | Folate, panadol, movical. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 23/10/2003 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 19/11/2003 | Other data | | | | |

### Additional Information:

Known haemochromatosis C282Y hamozygote.
Other drugs taken: Coversyl, Vitamin D, Tegretol, Hexamine.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 192446 **Seq:** 1 **Gender:** F
**Reported:** 24/11/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Blood pressure increased | Caused or prolonged inpatient hospitalisation | High blood pressure, racing heart, giddiness, electric impulses, aches and pains. | |
| Dizziness | | | |
| Feeling abnormal | | | |
| Heart rate increased | | | |
| Pain | | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Efexor XR 150mg for 3 years reduced to 75mg for 3 weeks before stopping.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 192457 **Seq:** 1 **Gender:** M
**Reported:** 24/11/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pain | Caused or prolonged inpatient hospitalisation | Unknown if joint pain or muscular pain- | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 450.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 24/11/2003 | Other data | | | | |

### Additional Information:

Very severe pain, patient unable to walk or dress himself.
Other drugs used: Lithicarb, Quilonum and Lipitor which has been stopped.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 192586 **Seq:** 1 **Gender:** F
**Reported:** 28/11/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** 03/10/2003 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vomiting<br>Diarrhoea<br>Dizziness<br>Headache<br>Vision blurred | Required Visit to Doctor | Vomiting, diarrhoea, dizziness, headache and blurred vision. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 1.0 Dose Unspecified 1 time Oral
**Batch:** **Started:** 03/10/2003 **Stopped:** 03/10/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Symptoms within half hour of taking first dose of Efexor. Patient also taking Multivitamin, Valium.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 192601 **Seq:** 1 **Gender:** F
**Reported:** 28/11/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 40
**Onset Date:** 26/11/2003 **DOB:** 22/11/1963
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia | Required Visit to Doctor | dystonic reaction jaw and neck within 1/2 hour of taking the first dose of Efexor XR 75mg. Not on any phenothiazines | dystonia |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 26/11/2003 **Stopped:** 27/11/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 192787 **Seq:** 1 **Gender:** M
**Reported:** 02/12/2003 **Weight:** 115.00
**Hospitalisation:** **Age:** 56
**Onset Date:** 15/10/2003 **DOB:** 01/10/1947
**Outcome:** Recovered 30/10/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sleep apnoea syndrome | Severe | I was stopping breathoing for periods of time during the night. Prior to this I had been diagnosed with mild sleep aponea (6 years prior)- the higher dose of EFFEXOR-XR increased it tremendously although there was no listing of a warning to this effect (even though sleep aponea can well be a cause of depression). | |
| Tremor | Severe | This I did only to find that my wife suddenly started waking me up saying my legs were [illegible] | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 192787 **Seq:** 1 **Gender:** M
**Reported:** 02/12/2003 **Weight:** 115.00
**Hospitalisation:** **Age:** 56
**Onset Date:** 15/10/2003 **DOB:** 01/10/1947
**Outcome:** Recovered 30/10/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Condition aggravated | Severe | while being treated for mild depression with effexor-xr, my depression suddenly increased, my doctor suggested that I increase my medication from one tablet per day to two during peaks in depression. | ceased treatment totally |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 192870 **Seq:** 1 **Gender:** F
**Reported:** 05/12/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** 15/09/2003 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness | | A number of other symptoms reported | |
| Coordination abnormal | Caused or prolonged inpatient hospitalisation | Loss of balance, shunting in head and | |
| Glossitis | | Swollen, sore and tender tongue | |
| Fatigue | | Tiredness | |
| Anorexia | | | |
| Dry mouth | | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/2003 S TERM **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

The start date for Efexor is not necessarily accirate but indicates that the drug was started sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 192870 **Seq:** 1 **Gender:** F
**Reported:** 05/12/2003 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** 15/09/2003 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Feeling abnormal | Caused or prolonged inpatient hospitalisation | | |
| Headache | Caused or prolonged inpatient hospitalisation | | |
| Photophobia | | | |
| Pruritus | | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/2003 S TERM **Stopped:**

## Laboratory Investigations:

## Additional Information:

The start date for Efexor is not necessarily accirate but indicates that the drug was started sometime in the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 192958 **Seq:** 1 **Gender:** F
**Reported:** 08/12/2003 **Weight:** 60.00
**Hospitalisation:** **Age:** 45
**Onset Date:** **DOB:** 23/12/1957
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diabetes mellitus | Required Visit to Doctor | Patient is an insulin dependant diabetic. After several years of good, control with insulin, morning blood sugar levels became extremely high (15-20). this correlated with taking Efexor. | Weaned off efexor |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 08/12/2003 | Other data | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 193240 **Seq:** 1
**Reported:** 17/12/2003
**Hospitalisation:**
**Onset Date:** 10/12/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 53
**DOB:** 29/04/1950
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Disorientation<br>Chills<br>Diarrhoea<br>Headache<br>Hyperhidrosis<br>Mental status changes<br>Nausea<br>Tearfulness | | Disorientation, nausea, diarrhoea, headache, tearful, sweating, shivering and altered mental state. | |

### Medicine Details:

**TRAMADOL HYDROCHLORIDE (Interaction)** **Reason:** Other disturbance of sensation
Tablet 100.0 Milligram As necessary Oral
**Batch:** **Started:** 03/12/2003 **Stopped:** 10/12/2003

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 09/12/2003 **Stopped:** 10/12/2003

**PAROXETINE HYDROCHLORIDE (Interaction)** **Reason:** Depression
50.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** 09/12/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was also taking Cephalexin, prednisolone, Seretide, Salbutamol.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 193280 **Seq:** 1 **Gender:** F
**Reported:** 18/12/2003 **Weight:** 57.00
**Hospitalisation:** **Age:** 54
**Onset Date:** 08/12/2003 **DOB:** 01/05/1949
**Outcome:** Recovered 15/12/2003 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea<br>Insomnia<br>Mydriasis | | Severe nausea, dilated pupils and unable | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Tablet 37.5 Milligram Daily Oral

**Batch:** **Started:** 08/12/2003 **Stopped:** 08/12/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 193499 **Seq:** 1 **Gender:** F
**Reported:** 18/12/2003 **Weight:** 94.00
**Hospitalisation:** **Age:** 36
**Onset Date:** 20/11/2003 **DOB:** 06/10/1967
**Outcome:** Recovered 21/11/2003 **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea<br><br><br><br>Chills<br>Feeling hot and cold<br>Vomiting | | 1.5 hours after taking first dose: onset of nausea, feeling hot & cold<br>,<br>shivers, vomiting<br>. | Cessation of drug. |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Tablet 37.5 Milligram 2 times Oral

**Batch:** **Started:** 20/11/2003 **Stopped:** 21/11/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Lasted one hour and recovered fully. Rechallenged next night, same dose, same effects. No further doses given. Symptoms suggestive of serotonin syndrome but atypical because occurred after first dose, low dose, and only other medication is high dose interferon. Suspected Drug Positive Rechallenge.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 193863 **Seq:** 1 **Gender:** M
**Reported:** 12/01/2004 **Weight:** 79.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination, auditory | Required Visit to Doctor | Auditory hallucinations - hearing voices | |
| Psychotic disorder | Required Visit to Doctor | Psychotic reaction - aggressive, violent mood swings, auditory hallucinations, visual hallucinations. | |
| Mood swings | | Violent mood swings | |
| Hallucination, visual | Required Visit to Doctor | Visual hallucinations - moving images, | |

### Medicine Details:

**LITHIUM CARBONATE (Other drug)** **Reason:**
Tablet 500.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** Contin

**EFEXOR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 17/11/2003 **Stopped:** Contin

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient's wife rang the AME line. Their psychiatrist's advice was to persevere with the Efexor and the psychotic reaction would subside. Last I heard the patient was seeking a new psychiatrist. Mood swings continued but medicines were unchanged. Ceased Avanza changed to Efexor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 193880 **Seq:** 1 **Gender:** F
**Reported:** 14/01/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Paraesthesia | | Tingling and electric shocks. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Dose Unspecified Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Hasn't been able to work for weeks.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 193959 **Seq:** 1
**Reported:** 19/01/2004
**Hospitalisation:**
**Onset Date:** 08/07/2003
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 78.00
**Age:** 48
**DOB:** 13/03/1955
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Blood cholesterol increased | Required Visit to Doctor | Cholesterol total increased, HDL/cholesterol increased, Triglycerides increased. | |
| Blood triglycerides increased | Required Visit to Doctor | | |
| Total cholesterol/HDL ratio decre | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

**AVANZA (Suspected)** **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 19/01/2004 | Cholesterol | | | | |
| 19/01/2004 | High density | | | | |
| 19/01/2004 | Triglyceride | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194032 **Seq:** 1 **Gender:** M
**Reported:** 22/01/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anger<br>Elevated mood | | Difficult to control temper and outburst of<br>Mood has "escalated", | Change in medications from Risperdal 1.5mg/nocte, Zoloft 100mg/mane and Zoloft 50mg/mid-day. Prescribed with 5mg Diazepam tablets since the adverse event. |
| Violent ideation<br>Aggression | | Violent thoughts of "wanted to kill my<br>Which lead to being placed under arrest by | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**RISPERDAL (Suspected)** **Reason:**
3.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Seeing a psychiatrist for 5 years. Diagnosed with schizophrenia. Advised that he did not have a history of violence.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 194059 **Seq:** 1
**Reported:** 23/01/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 51
**DOB:** 17/07/1952
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hemihypertrophy | Required Visit to Doctor | Hemihypertrophy right leg. | Ceased Venlafaxine. |

## Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Hemihypertrophy ceased worsening after Venalafaxine ceased.
Reaction occurred sometime in June 03.
Venlafaxine was started sometime in Jan 03.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194096 **Seq:** 1 **Gender:** M
**Reported:** 27/01/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 58Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fatigue | Caused or prolonged inpatient hospitalisation | Fatigue "burn out" | Coversyl together with an unspecified beta-blocker for the hypertension |
| Pollakiuria | Caused or prolonged inpatient hospitalisation | Frequent urinating. | |
| Agitation | Caused or prolonged inpatient hospitalisation | Mild agitation in the mornings. | |

### Medicine Details:

**ATACAND (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 300.0 Milligram Daily Oral
**Batch:** **Started:** 15/07/2003 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Other drugs: Valium, Atacand, Mogadon and Naprosyn. Efexor-XR initiated at 300mg, reduced to 225mg then 150mg and currently on 75mg. Dose start date: 06/03

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 194096 **Seq:** 1
**Reported:** 27/01/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 58Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety | Caused or prolonged inpatient hospitalisation | | |
| Condition aggravated | Caused or prolonged inpatient hospitalisation | | |
| Cough | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**ATACAND (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 300.0 Milligram Daily Oral
**Batch:** **Started:** 15/07/2003 **Stopped:**

## Laboratory Investigations:

## Additional Information:

Other drugs: Valium, Atacand, Mogadon and Naprosyn. Efexor-XR initiated at 300mg, reduced to 225mg then 150mg and currently on 75mg. Dose start date: 06/03

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 194096 **Seq:** 1
**Reported:** 27/01/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 58Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea | Caused or prolonged inpatient hospitalisation | | |
| Drug ineffective | Caused or prolonged inpatient hospitalisation | | |
| Drug withdrawal syndrome | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**ATACAND (Other drug)** **Reason:**

**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis

Capsule 300.0 Milligram Daily Oral

**Batch:** **Started:** 15/07/2003 **Stopped:**

## Laboratory Investigations:

## Additional Information:

Other drugs: Valium, Atacand, Mogadon and Naprosyn. Efexor-XR initiated at 300mg, reduced to 225mg then 150mg and currently on 75mg. Dose start date: 06/03

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 194096 **Seq:** 1
**Reported:** 27/01/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 58Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Frequent bowel movements | Caused or prolonged inpatient hospitalisation | | |
| Hyperhidrosis | Caused or prolonged inpatient hospitalisation | | |
| Hypertension | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**ATACAND (Other drug)** **Reason:**

**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis

Capsule 300.0 Milligram Daily Oral

**Batch:** **Started:** 15/07/2003 **Stopped:**

## Laboratory Investigations:

## Additional Information:

Other drugs: Valium, Atacand, Mogadon and Naprosyn. Efexor-XR initiated at 300mg, reduced to 225mg then 150mg and currently on 75mg. Dose start date: 06/03

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 194096 **Seq:** 1
**Reported:** 27/01/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 58Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Influenza like illness | Caused or prolonged inpatient hospitalisation | | |
| Insomnia | Caused or prolonged inpatient hospitalisation | | |
| Weight decreased | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**ATACAND (Other drug)** **Reason:**

**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis

Capsule 300.0 Milligram Daily Oral

**Batch:** **Started:** 15/07/2003 **Stopped:**

## Laboratory Investigations:

## Additional Information:

Other drugs: Valium, Atacand, Mogadon and Naprosyn. Efexor-XR initiated at 300mg, reduced to 225mg then 150mg and currently on 75mg. Dose start date: 06/03

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194178 **Seq:** 1 **Gender:** M
**Reported:** 30/01/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 83Y
**Onset Date:** 29/01/2003 **DOB:**
**Outcome:** Unrelated death **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperventilation | Caused or prolonged inpatient hospitalisation | Hyperventilation, respiratory alkalosis. | Withheld all meds except Warfarin. Rebreath into Hudson mask |
| Respiratory alkalosis | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 21/01/2003 **Stopped:** 29/01/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was also taking Fludrocortisone, pantoprazole, Warfarin, Oxazepam, Sotalol, Trimethoprim, Metoclopramide.
Hyperventilation/resp.alkalosis traced back to 99.
Patient died 12/03/03.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194479 **Seq:** 1
**Reported:** 10/02/2004
**Hospitalisation:**
**Onset Date:** 06/11/2003
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 83
**DOB:** 17/09/1920
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Parkinsonism<br>Agitation<br>Confusional state<br>Dysphagia<br>Hallucination<br>Mobility decreased<br>Muscle twitching<br>Speech disorder | | Acute parkinsonism, speech disorder (decreased), swallowing disorder (unable), agitation - increased, hallucinations, confusion - increased, twitching - increased, mobility decreased. | |

### Medicine Details:

**DONEPEZIL HYDROCHLORIDE (Suspected)** **Reason:** Unspecified psychosis
Tablet 5.0 Milligram Daily
**Batch:** **Started:** 28/10/2003 **Stopped:** 06/11/2003

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
37.5 Milligram Daily
**Batch:** **Started:** 05/09/2003 **Stopped:** 06/11/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194510 **Seq:** 1 **Gender:** M
**Reported:** 11/02/2004 **Weight:** 80.00
**Hospitalisation:** **Age:** 39
**Onset Date:** **DOB:** 10/08/1964
**Outcome:** Recovered 03/02/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Restlessness | Caused or prolonged inpatient hospitalisation | Restlessness, agitated, anxious, pallor, hyperventilation, shaking (limbs and trunk). | |
| Agitation | Caused or prolonged inpatient hospitalisation | | |
| Anxiety | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**OLANZAPINE (Suspected)** **Reason:** Schizophrenia
10.0 Milligram Daily
**Batch:** **Started:** 22/10/2002 **Stopped:** 25/11/2003

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily
**Batch:** **Started:** 07/10/2003 **Stopped:** 25/11/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient also administered: Lovan tabs, Alprazolam, Valium.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194510 **Seq:** 1 **Gender:** M
**Reported:** 11/02/2004 **Weight:** 80.00
**Hospitalisation:** **Age:** 39
**Onset Date:** **DOB:** 10/08/1964
**Outcome:** Recovered 03/02/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperventilation | Caused or prolonged inpatient hospitalisation | | |
| Pallor | Caused or prolonged inpatient hospitalisation | | |
| Tremor | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**OLANZAPINE (Suspected)** **Reason:** Schizophrenia
10.0 Milligram Daily
**Batch:** **Started:** 22/10/2002 **Stopped:** 25/11/2003

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily
**Batch:** **Started:** 07/10/2003 **Stopped:** 25/11/2003

### Laboratory Investigations:

### Additional Information:
Patient also administered: Lovan tabs, Alprazolam, Valium.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194538 **Seq:** 1 **Gender:** M
**Reported:** 11/02/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Angioedema<br>Rash<br>Urticaria | | Angioedema, rash, urticaria. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 300.0 Milligram Daily Oral
**Batch:** **Started:** S TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194553 **Seq:** 1 **Gender:** F
**Reported:** 12/02/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 51
**Onset Date:** 20/01/2004 **DOB:** 09/08/1952
**Outcome:** Recovered 03/02/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pneumonitis | Caused or prolonged inpatient hospitalisation | Pneumonitis (drug induced?) | Ceftriaxone IV 1g daily and erythromycin IV 600mg qid and clexane 40mg daily. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Tablet 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 21/01/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Other drug therapy kapanol, voltaren, gemfibrozil, zyprexa, epilim, premarin, solian, valium.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194710 **Seq:** 1 **Gender:** F
**Reported:** 18/02/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Metrorrhagia | | breakthrough bleeding. | |

### Medicine Details:

**EFEXOR-XR (Interaction)** **Reason:** Depression
**Batch:** **Started:** **Stopped:**

**DIANE-35 ED (Interaction)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Efexor-XR has now been resarted due to hospitalisation.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194712 **Seq:** 1 **Gender:** F
**Reported:** 18/02/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Insomnia<br>Suicidal ideation | | Suicidal ideation, can't sleep, withdrawal | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194714 **Seq:** 1 **Gender:** M
**Reported:** 18/02/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 48
**Onset Date:** 23/01/2004 **DOB:** 15/12/1955
**Outcome:** Recovered 29/01/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delirium | Caused or prolonged inpatient hospitalisation | Acute delirium | |

### Medicine Details:

**COVERSYL PLUS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:** Contin

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 11/01/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194765 **Seq:** 1 **Gender:** F
**Reported:** 19/02/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 65Y
**Onset Date:** 28/05/2003 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension | Required Visit to Doctor | Hypertension, impaired renal function. | Ceased Efexor. |
| Renal impairment | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Essential benign hypertension
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 24/07/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was also taking Atenolol, Fosinopril sodium, Simvastatin, Tibolone.
Micro-haematuria attributed to 'benign' glomerulonephritis (IgA nephropathy or thin membrane disease).

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194855 **Seq:** 1 **Gender:** F
**Reported:** 24/02/2004 **Weight:** 47.00
**Hospitalisation:** **Age:** 85
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | Life | Seizures - recurrent (petit mal and grand | Tegretol (carbamazepine) 200mg at night, increased to |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** Contin

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient also administered: Iscover, Somac, Asthma inhalers.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 194880 **Seq:** 1
**Reported:** 25/02/2004
**Hospitalisation:**
**Onset Date:** 27/01/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 70.00
**Age:** 20
**DOB:** 08/06/1983
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Choreoathetosis | Caused or prolonged inpatient hospitalisation | Choreoathetoid movements, dysarthia, | |
| Dysarthria | Caused or prolonged inpatient hospitalisation | | |
| Trismus | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**ZOLOFT (Other drug)** **Reason:** Depression
50.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** 19/01/2004

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 20/01/2004 **Stopped:** 01/02/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 195005 **Seq:** 1 **Gender:** F
**Reported:** 01/03/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br>Insomnia | | Suicidal thoughts, Can not sleep. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** S TERM **Stopped:** Contin

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 195027 **Seq:** 1
**Reported:** 01/03/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 60.00
**Age:** 19
**DOB:** 05/05/1984
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mydriasis | Required Visit to Doctor | Mydriasis (right sided), impaired coordination, movement disorder (less control of eyebrow movements), sweating decreased, numbness, pain | |
| Anhidrosis | Required Visit to Doctor | | |
| Coordination abnormal | Required Visit to Doctor | | |
| Hypoaesthesia | Required Visit to Doctor | | |
| Movement disorder | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily
**Batch:** **Started:** S TERM **Stopped:** 15/10/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 195027 **Seq:** 1
**Reported:** 01/03/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 60.00
**Age:** 19
**DOB:** 05/05/1984
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pain | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily

**Batch:** **Started:** S TERM **Stopped:** 15/10/2003

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 195071 **Seq:** 1 **Gender:** F
**Reported:** 03/03/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 40
**Onset Date:** 17/02/2004 **DOB:** 27/07/1963
**Outcome:** Recovered 19/02/2004 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abnormal dreams<br><br>Suicidal ideation<br>Thinking abnormal | | Abnormal dreams, suicidal ideation, thinking abnormal. | Ceased Efexor-XR |

### Medicine Details:

**LOETTE (Other drug)** **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 01/06/2003 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 17/02/2004 **Stopped:** 18/02/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 195157 **Seq:** 1 **Gender:** F
**Reported:** 05/03/2004 **Weight:** 51.00
**Hospitalisation:** **Age:** 77
**Onset Date:** 16/02/2004 **DOB:** 13/03/1926
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Severe | Exacerbation of chronic hyponatraemia with administration of venlafaxine | withdrawal of drug, fluid |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 37.0 Milligram Daily Oral
**Batch:** **Started:** 06/02/2004 **Stopped:** 23/02/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 05/03/2004 | Sodium | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 195217 **Seq:** 1
**Reported:** 09/03/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 54
**DOB:** 20/05/1949
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fluid retention | | Fluid retention, tiredness | Ceased Efexor |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Tablet 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was also taking Dexamphetamine sulfate, Losec, Lasix, Aldactone, Lipitor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 195259 **Seq:** 1 **Gender:** F
**Reported:** 11/03/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 40
**Onset Date:** **DOB:** 21/12/1963
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Loss of consciousness | | Blackout | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 29/01/2004 **Stopped:** 10/02/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 195462 **Seq:** 1 **Gender:** M
**Reported:** 12/03/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 40
**Onset Date:** 25/12/2003 **DOB:** 16/08/1963
**Outcome:** Recovered with sequelae 25/12/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Grand mal convulsion | Caused or prolonged inpatient hospitalisation | 4 grand mal seizures. | I/P Phenytoin |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 29/11/2003 **Stopped:**

**MIRTAZAPINE (Interaction)** **Reason:** Depression
Tablet 15.0 Milligram Daily Oral
**Batch:** **Started:** 18/12/2003 **Stopped:** 25/12/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient also taking Zithromax and Clonazepam. No previous history.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 195490 **Seq:** 1 **Gender:** M
**Reported:** 16/03/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 44
**Onset Date:** 27/02/2004 **DOB:** 16/06/1959
**Outcome:** Recovered 03/03/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mydriasis<br>Bruxism<br>Tremor | | Pupillary dilatation, tremoring jaws, | Spontaneous resolution. |

### Medicine Details:

**ZOCOR (Other drug)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 25/02/2004 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 195697 **Seq:** 1
**Reported:** 09/03/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 54
**DOB:** 20/05/1949
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Thrombosis | Caused or prolonged inpatient hospitalisation | Thrombosis (both legs), fluid retention, slurred speech, sore feet, swelling legs, difficulty standing, dry mouth, confusion, breasts swollen, breathlessness, sleep apnoea, "revolting taste" in her mouth, clots in her legs. | Warfarin for clots in legs to be taken for 9 months. |
| Breast swelling | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** S TERM **Stopped:** Contin

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was also taking Dexamphetamine sulfate, Losec, Lasix, Aldactone, Lipitor.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 195697 **Seq:** 1
**Reported:** 09/03/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 54
**DOB:** 20/05/1949
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state | Caused or prolonged inpatient hospitalisation | | |
| Dry mouth | Caused or prolonged inpatient hospitalisation | | |
| Dysarthria | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** S TERM **Stopped:** Contin

## Laboratory Investigations:

## Additional Information:

Patient was also taking Dexamphetamine sulfate, Losec, Lasix, Aldactone, Lipitor.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 195697 **Seq:** 1
**Reported:** 09/03/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 54
**DOB:** 20/05/1949
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysgeusia | Caused or prolonged inpatient hospitalisation | | |
| Dyspnoea | Caused or prolonged inpatient hospitalisation | | |
| Dysstasia | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** S TERM **Stopped:** Contin

## Laboratory Investigations:

## Additional Information:

Patient was also taking Dexamphetamine sulfate, Losec, Lasix, Aldactone, Lipitor.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 195697 **Seq:** 1
**Reported:** 09/03/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 54
**DOB:** 20/05/1949
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fluid retention | Caused or prolonged inpatient hospitalisation | | |
| Oedema peripheral | Caused or prolonged inpatient hospitalisation | | |
| Pain in extremity | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** S TERM **Stopped:** Contin

## Laboratory Investigations:

## Additional Information:

Patient was also taking Dexamphetamine sulfate, Losec, Lasix, Aldactone, Lipitor.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 195697 **Seq:** 1
**Reported:** 09/03/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 54
**DOB:** 20/05/1949
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pulmonary embolism | Caused or prolonged inpatient hospitalisation | | |
| Sleep apnoea syndrome | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** S TERM **Stopped:** Contin

## Laboratory Investigations:

## Additional Information:

Patient was also taking Dexamphetamine sulfate, Losec, Lasix, Aldactone, Lipitor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 195884 **Seq:** 1 **Gender:** M
**Reported:** 24/03/2004 **Weight:** 95.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** 15/02/2004 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis<br>Headache<br>Muscle spasms | | Sweating, muscle spasms, headaches. | Cessation of drug. |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Tablet 150.0 Milligram Daily Oral

**Batch:** **Started:** 03/02/2004 **Stopped:** 15/02/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 196124 **Seq:** 1
**Reported:** 31/03/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 48
**DOB:** 08/09/1955
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myasthenia gravis | Required Visit to Doctor | Myasthenia Gravis. | Patient given 60mg Mestinon. Efexor-XR dose reduced to 375mg daily. However, reaction did not abate after dose reduction. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 450.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/2003 L TERM **Stopped:**

**BUSPAR (Suspected)** **Reason:**
Tablet 15.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**SOLIAN (Suspected)** **Reason:** Depression
200.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient has emphysema secondary to chronic chest infection from childhood.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 196148 **Seq:** 1
**Reported:** 01/04/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 85.00
**Age:** 45
**DOB:** 21/02/1959
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Gynaecomastia | | Bilateral gynaecomastia. | No treatment given. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Tablet 300.0 Milligram Daily Oral

**Batch:** **Started:** 19/05/2003 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 196150 **Seq:** 1 **Gender:** F
**Reported:** 01/04/2004 **Weight:** 60.00
**Hospitalisation:** **Age:** 66
**Onset Date:** 16/03/2004 **DOB:** 10/05/1937
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Loss of consciousness | Caused or prolonged inpatient hospitalisation | 4 episodes of loss of consciousness in 12 hours, nausea and vomiting following each episode lasting about 5 minutes. | Observation required. |
| Nausea | Caused or prolonged inpatient hospitalisation | | |
| Vomiting | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Total Oral
**Batch:** **Started:** 15/03/2004 **Stopped:** 16/03/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Onset of hypertension over the past 12 months. Other drugs: Caltrate and Xalatan Eye Drop.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 196353 **Seq:** 1 **Gender:** U
**Reported:** 08/04/2004 **Weight:** 38.00
**Hospitalisation:** **Age:** 75
**Onset Date:** **DOB:** 14/04/1928
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | Caused or prolonged inpatient hospitalisation | Patient experienced progression in tremor, bradykinesia, stiffness. | |
| Bradykinesia | Caused or prolonged inpatient hospitalisation | | |
| Musculoskeletal stiffness | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Onset date: 03/2004. Progression when dose increased to 150mg and lessened when dose reduced back to 75mg. Other drugs: Madopar and Comtan.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 196516 **Seq:** 1
**Reported:** 16/04/2004
**Hospitalisation:**
**Onset Date:** 23/03/2004
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 47
**DOB:** 18/10/1956
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | Required Visit to Doctor | Patient experienced tremor, hypertension (180/120) and fatigue. | Karvea 300mg/daily given. |
| Fatigue | Required Visit to Doctor | | |
| Hypertension | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** 01/03/2004 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Other drugs: Lithium, Cipramil, Pariet and Normal Immunoglobulin. Allergies: Avelox - rash, unwell, swollen face in 2002.

## Report Detail

**Case Number:** 196696 **Seq:** 1 **Gender:** M
**Reported:** 22/04/2004 **Weight:** 90.00
**Hospitalisation:** **Age:** 47Y
**Onset Date:** 23/03/2004 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension | Required Visit to Doctor | Hypertension. | Efexor-XR "on reduction, dose regimen to cease". |

## Medicine Details:

**LITHIUM CARBONATE (Other drug)** **Reason:** Unspecifid affective psychosis
Tablet 500.0 Milligram Daily Oral
**Batch:** **Started:** 01/12/2003 **Stopped:**

**PARIET (Other drug)** **Reason:** Other diseases of esophagus
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/12/2002 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 2.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 01/03/2004 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 22/04/2004 | Blood pressure | | 23/03/2004 | 80/120 | |

## Additional Information:

Allergy to Avelox.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 196810 **Seq:** 1
**Reported:** 27/04/2004
**Hospitalisation:**
**Onset Date:** 30/10/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 54.00
**Age:** 56
**DOB:** 08/10/1947
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | Required Visit to Doctor | Excess sweating | To be decided (D/W Doctor) |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 225.0 Milligram Daily Oral

**Batch:** **Started:** 30/10/2003 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Other drugs: Monopril, Fosamax and Pravachol. Previously on Zoloft before Efexor - same side effects.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 196825 **Seq:** 1 **Gender:** F
**Reported:** 27/04/2004 **Weight:**
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome neona | Caused or prolonged inpatient hospitalisation | DoB: 02/01/2004 | |
| Maternal hypertension affecting f | Caused or prolonged inpatient hospitalisation | Withdrawal in neonate exposed during pregnancy. Maternal hypertension, delivery pre-term. | |
| Drug exposure during pregnancy | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**LABETALOL HYDROCHLORIDE (Suspected)** **Reason:** Essential benign hypertension
Tablet Dose Unspecified Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** Ongoing

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Venlafaxine taken for 15 months

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 196826 **Seq:** 1
**Reported:** 27/04/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:** 21/04/2004
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 56
**DOB:** 26/01/1948
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Circulatory collapse | Life [illegible] | Collapse, anxious, hyperventilation, undetectable phosphate levels and cardiac arrest. | ICU admission for 5 days, CPR, phosphate [illegible] |
| Anxiety | Life [illegible] | | |
| Blood phosphorus decreased | Life [illegible] | | |
| Cardiac arrest | Life [illegible] | | |
| Hyperventilation | Life [illegible] | | |

### Medicine Details:

**ALPRAZOLAM (Suspected)** **Reason:**
Tablet — Dose Unspecified — Oral
**Batch:** **Started:** **Stopped:** Ongoing

**OLANZAPINE (Suspected)** **Reason:**
Dose Unspecified
**Batch:** **Started:** **Stopped:** Ongoing

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule — 300.0 Milligram — Daily — Oral
**Batch:** **Started:** **Stopped:** Ongoing

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 27/04/2004 | Phosphate | 0.88 - 1.46 | 10/04/2004 | <0.3 | |

### Additional Information:

Patient hospitalised due to circulatory collapse. Other drug therapy taken: nilstat, aspirin, zyprexa, clexane. Phosphate level decreased with hyperventylation (anxiety), but not sufficient to explain phosphate levels <30.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 196959 **Seq:** 1 **Gender:** F
**Reported:** 21/04/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Homicidal ideation | | Attempted murder | |
| Thinking abnormal | | Increased suicidal thoughts and a constant mental battle between rational and irrational thoughts. | Patient reduced her intake of Efexor |
| Suicide attempt | | Patient twice tried to kill herself | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
300.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/2003 **Stopped:** 30/09/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient who two times tried to kill herself and two young daughters by gassing them in the family car in June 2003 has blamed antidepressants prescribed to her.
News article by O'Leary and Dortch, "Murder bid blamed on pill use", The West Australian, 20 April 2004. History: Bipolar II disorder, dysthymic disorder, family stress, marital problem. A past history of alcohol abuse and marijuana use.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 197157 **Seq:** 1 **Gender:** F
**Reported:** 10/05/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 04/05/2004 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation neonatal<br>Drug exposure during pregnancy<br>Hypertonia neonatal | | Jitteriness | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
450.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 197367 **Seq:** 1 **Gender:** M
**Reported:** 14/05/2004 **Weight:** 70.00
**Hospitalisation:** **Age:** 86
**Onset Date:** 23/03/2004 **DOB:** 30/03/1917
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypokalaemia | Caused or prolonged inpatient hospitalisation | Venlafaxine-induced myoclonus through pindolol augmentation in renal impairment. | Potassium supplement. Venlafaxine was returned to 225mg daily. |
| Convulsion | Caused or prolonged inpatient hospitalisation | | |
| Fall | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**PINDOLOL (Suspected)** **Reason:**
Tablet 15.0 Milligram Daily Oral
**Batch:** **Started:** 23/03/2004 **Stopped:** 14/04/2004

**FLUDROCORTISONE (Suspected)** **Reason:**
Tablet 0.2 Milligram Daily Oral
**Batch:** **Started:** 23/03/2004 **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** 23/03/2004 **Stopped:** 28/04/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 14/05/2004 | Potassium | | 23/03/2004 | 3.4mmol/L | |

### Additional Information:

Patient also taking Clopidogrel, Esomeprazole and Prednisolone.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 197367 **Seq:** 1
**Reported:** 14/05/2004
**Hospitalisation:**
**Onset Date:** 23/03/2004
**Outcome:** Recovered

**Gender:** M
**Weight:** 70.00
**Age:** 86
**DOB:** 30/03/1917
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myoclonus | Caused or prolonged inpatient hospitalisation | | |
| Orthostatic hypotension | Caused or prolonged inpatient hospitalisation | | |
| Syncope vasovagal | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**PINDOLOL (Suspected)** **Reason:**
Tablet 15.0 Milligram Daily Oral
**Batch:** **Started:** 23/03/2004 **Stopped:** 14/04/2004

**FLUDROCORTISONE (Suspected)** **Reason:**
Tablet 0.2 Milligram Daily Oral
**Batch:** **Started:** 23/03/2004 **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** 23/03/2004 **Stopped:** 28/04/2004

## Laboratory Investigations:

## Additional Information:

Patient also taking Clopidogrel, Esomeprazole and Prednisolone.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 197449 **Seq:** 1 **Gender:** F
**Reported:** 18/05/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 25
**Onset Date:** 15/03/2004 **DOB:** 29/09/1978
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state | Caused or prolonged inpatient hospitalisation | Confusion, incoherence, falling over, no hand-eye coordination - unable to feed herself. | Efexor-XR dose being tapered, Tramal stopped completely. |
| Balance disorder | Caused or prolonged inpatient hospitalisation | | |
| Coordination abnormal | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Abdominal pain
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**TRAMAL (Suspected)** **Reason:**
Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Efexor XR dose was alternating between 75mg/day and 150mg/day currently

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 197449 **Seq:** 1 **Gender:** F
**Reported:** 18/05/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 25
**Onset Date:** 15/03/2004 **DOB:** 29/09/1978
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fall | Caused or prolonged inpatient hospitalisation | | |
| Incoherent | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Abdominal pain
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**TRAMAL (Suspected)** **Reason:**
Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

Efexor XR dose was alternating between 75mg/day and 150mg/day currently

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 197450 **Seq:** 1 **Gender:** F
**Reported:** 18/05/2004 **Weight:** 60.00
**Hospitalisation:** **Age:** 66
**Onset Date:** 15/03/2004 **DOB:** 10/05/1937
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | Caused or prolonged inpatient hospitalisation | 4 episodes of seizure/loss of consciousness, associated with sweating. | Efexor-XR stopped completely. |
| Hyperhidrosis | Caused or prolonged inpatient hospitalisation | 4 episodes of seizure/loss of consciousness, associated with sweating. | |
| Loss of consciousness | Caused or prolonged inpatient hospitalisation | 4 episodes of seizure/loss of consciousness, associated with sweating. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/03/2004 **Stopped:** 16/03/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient's ECG normal.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 197507 **Seq:** 1
**Reported:** 21/05/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 78Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tardive dyskinesia | Caused or prolonged inpatient hospitalisation | Tardive dyskinesia | |

### Medicine Details:

**DIGOXIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**FRUSEMIDE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ASPIRIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**CLEXANE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient also taking Olanzapine, Digoxin, Frusemide, Aspirin and Clexane.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 197507 **Seq:** 1
**Reported:** 21/05/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 78Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **OLANZAPINE (Suspected)** | | | **Reason:** | | | |
| **Batch:** | **Started:** | | | **Stopped:** | | |
| **EFEXOR (Suspected)** | | | **Reason:** | | | |
| Tablet | 412.0 | Milligram | Daily | Oral | | |
| **Batch:** | **Started:** | L TERM | | **Stopped:** | Continuing | |

## Laboratory Investigations:

## Additional Information:

Patient also taking Olanzapine, Digoxin, Frusemide, Aspirin and Clexane.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 197553 **Seq:** 1 **Gender:** F
**Reported:** 24/05/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia<br>Abnormal behaviour<br>Dizziness<br>Hearing impaired<br>Malaise<br>Thinking abnormal | | Patient confined to bed for 2 weeks with dizziness, knocking in ears, malaise, incapability to function. Said the drug made her a 'raving lunatic'. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 01/05/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Efexor-XR was started on 150mg, tapered to 75mg, then 75mg every second day, then to half the granules in 75mg capsule before stopping.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 197668 **Seq:** 1
**Reported:** 27/05/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | Caused or prolonged inpatient hospitalisation | Seizure. | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Dose Unspecified

**Batch:** **Started:** S TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 197711 **Seq:** 1 **Gender:** F
**Reported:** 31/05/2004 **Weight:** 60.00
**Hospitalisation:** **Age:** 56
**Onset Date:** 21/07/2003 **DOB:** 06/10/1946
**Outcome:** Recovered 28/07/2003 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash | Required Visit to Doctor | Urticarial-like rash | Ceased Efexor-XR, treated with Antihistamines. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

**Batch:** **Started:** 17/07/2003 **Stopped:** 23/07/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 197820 **Seq:** 1 **Gender:** F
**Reported:** 03/06/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** 20/05/2004 **DOB:**
**Outcome:** Recovered without treatment 21/05/2004 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Blepharospasm | | Sustained upper eye lid retraction with inability to blink-lasted all day. | Nil treatment. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Tablet 75.0 Milligram 1 time Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 197949 **Seq:** 1
**Reported:** 08/06/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 55.00
**Age:** 48
**DOB:** 18/03/1956
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | Caused or prolonged inpatient hospitalisation | Suicidal, then became homicidal. | |
| Homicidal ideation | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
250.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 197958 **Seq:** 1 **Gender:** M
**Reported:** 08/06/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 30
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Serotonin syndrome | Required Visit to Doctor | Serotonin syndrome occurred when Efexor-XR dose was increased from 150mg/day to 300mg/day, and whilst on Tramal as as well. When Tramal was stopped, the apatient recovered. | Tramal stopped. |

### Medicine Details:

**TRAMAL (Interaction)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Interaction)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 198076 **Seq:** 1 **Gender:** F
**Reported:** 11/06/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 80
**Onset Date:** 16/03/2004 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Inappropriate antidiuretic hormon<br><br>Convulsion<br>Hyponatraemia | | SIADH suspected secondary to pneumonia; sodium level decreased causing one episode of seizure | Venlafaxine ceased. Strict fluid balance |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Tablet 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 16/03/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 11/06/2004 | Sodium | | 16/03/2004 | 118 | |
| 11/06/2004 | Sodium | | 17/03/2004 | 131 | |

### Additional Information:

Other drug therapy ergocalciferol, calcium salts, omeprazole, oxazepam

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 198598 **Seq:** 1 **Gender:** M
**Reported:** 30/06/2004 **Weight:** 90.00
**Hospitalisation:** **Age:** 60
**Onset Date:** 07/05/2004 **DOB:** 20/01/1944
**Outcome:** Recovered 24/06/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Asthenia<br>Disturbance in attention<br>Drug ineffective<br>Headache<br>Malaise<br>Paraesthesia | | During attempt to change treatment patient experienced a withdrawal reaction, inadequate efficacy and an increase in sexual dysfunction, generalised malaise, paraesthesia, weakness, headaches and poor concentration. | Changed to Avanza. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily Oral
**Batch:** **Started:** 15/11/2003 **Stopped:** 07/05/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Symptoms lasting for weeks. vastly in excess of expected withdrawal.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 198598 **Seq:** 1 **Gender:** M
**Reported:** 30/06/2004 **Weight:** 90.00
**Hospitalisation:** **Age:** 60
**Onset Date:** 07/05/2004 **DOB:** 20/01/1944
**Outcome:** Recovered 24/06/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sexual dysfunction | | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily Oral
**Batch:** **Started:** 15/11/2003 **Stopped:** 07/05/2004

### Laboratory Investigations:

### Additional Information:
Symptoms lasting for weeks. vastly in excess of expected withdrawal.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199087 **Seq:** 1 **Gender:** M
**Reported:** 16/07/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 57
**Onset Date:** 15/01/2004 **DOB:**
**Outcome:** Recovered 15/01/2004 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Required Visit to Doctor | Patient experienced hyponatraemia. | Ceased Venlafaxine and LMO follow up. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:** 13/01/2004 25 years

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 16/07/2004 | SAP = ALP | (135-145) | 11/12/2003 | 136 | |
| 16/07/2004 | SAP = ALP | (135-145) | 11/01/2004 | 129 | |
| 16/07/2004 | SAP = ALP | (135-145) | 15/01/2004 | 135 | |

### Additional Information:

Other drugs taken: Avapro, Quinbisul, Clopidogrel, Nitrazepam, Diltiazem CR and Meloxicam. All drugs taken prior to admission.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199111 **Seq:** 1
**Reported:** 19/07/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:** 13/07/2004
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 57
**DOB:** 26/09/1946
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Medication error | Caused or prolonged inpatient hospitalisation | Inadvertant concomitant use of Venlafaxine SR and Moclobemide, low blood pressure 90/60, hypotension, twitching of limbs, lethargy and loss of interest. | Venlafaxine and Moclobemide ceased by patient. |
| Decreased interest | Caused or prolonged inpatient hospitalisation | | |
| Hypotension | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
Dose Unspecified
**Batch:** **Started:** **Stopped:** 11 days

**MOCLOBEMIDE (Suspected)** **Reason:**
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 02/07/2004 **Stopped:** 13/07/2004 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Moclobemide dose was 300mg daily for 4 days then increased to 300mg bd. Other drugs taken: Serenace, Haloperidol, Effexor XR, Simvastatin, Cogentin, Tritace, Dilatrend and Cartia. Medical history: Brain injury 10 years ago, MI, CABG x 4 on day of infarct, depression, psych = paranoya, IHD and severe Liver dysfunction. Inadvertant concomitant use of Venlafaxine SR + Moclobemide for 11 days. Venlafaxine was meant to be ceased by patient .

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199111 **Seq:** 1
**Reported:** 19/07/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:** 13/07/2004
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 57
**DOB:** 26/09/1946
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Lethargy | Caused or prolonged inpatient hospitalisation | | |
| Muscle twitching | Caused or prolonged inpatient hospitalisation | | |
| Serotonin syndrome | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
Dose Unspecified
**Batch:** **Started:** **Stopped:** 11 days

**MOCLOBEMIDE (Suspected)** **Reason:**
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 02/07/2004 **Stopped:** 13/07/2004 0

### Laboratory Investigations:

### Additional Information:

Moclobemide dose was 300mg daily for 4 days then increased to 300mg bd. Other drugs taken: Serenace, Haloperidol, Effexor XR, Simvastatin, Cogentin, Tritace, Dilatrend and Cartia. Medical history: Brain injury 10 years ago, MI, CABG x 4 on day of infarct, depression, psych = paranoya, IHD and severe Liver dysfunction. Inadvertant concomitant use of Venlafaxine SR + Moclobemide for 11 days. Venlafaxine was meant to be ceased by patient .

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199131 **Seq:** 1
**Reported:** 19/07/2004
**Hospitalisation:**
**Onset Date:** 18/11/2003
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 83.00
**Age:** 59
**DOB:** 08/03/1944
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence | Required Visit to Doctor | Patient experienced somnolence - wants to sleep all of the time, day and night. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** 01/10/2003 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Other drugs taken: Karvea, Bicor, Lipitor Astrix 100. Medical history: Major heart attack in 02/2003. Efexor XR was started on a low dose on 22/10/03 and increased to 150mg/daily. Tapering off dose now.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199161 **Seq:** 1 **Gender:** F
**Reported:** 19/07/2004 **Weight:** 62.00
**Hospitalisation:** **Age:** 52Y
**Onset Date:** 15/03/2004 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hemihypertrophy<br>Oedema peripheral | | Hemihypertrophy, swelling of legs, | Ceased Efexor XR |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** 01/01/2003 **Stopped:** 30/11/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199463 **Seq:** 1 **Gender:** M
**Reported:** 28/07/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 30/11/2003 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Deep vein thrombosis | Required Visit to Doctor | DVT; obsessive behaviour, agitation and mood swings. | Changed to Risperdial for 6 weeks. Efexor restarted. Unspecified injections for 21 days after first DVT, and warfarin for 6 months after second DVT. |
| Abnormal behaviour | Required Visit to Doctor | | |
| Agitation | Required Visit to Doctor | | |
| Mood swings | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/2003 **Stopped:** Contin

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

A similar event was recorded in Nov-Dec 2003 when patient was also on Efexor XR. That event was treated by changing patient to Risperdal for 6 weeks.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199503 **Seq:** 1 **Gender:** F
**Reported:** 30/07/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 24
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Homicidal ideation | | Wanted to kill people, went into a frenzy and destroyed shed and wall. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**ZYPREXA (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199504 **Seq:** 1
**Reported:** 30/07/2004
**Hospitalisation:**
**Onset Date:** 15/05/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 24
**DOB:** 19/02/1980
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Disturbance in social behaviour<br>Drug ineffective<br>Suicidal ideation | | Suicidal, disturbed, raced around and wanted to provoke someone to kill her, drug ineffective, agitated. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199510 **Seq:** 1 **Gender:** M
**Reported:** 30/07/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 36
**Onset Date:** 15/11/2003 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | Wild suicide attempt - car, drugs and alcohol on 1st day on 225mg. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
225.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Was given Efexor again and made a suicide attemtp on ward by over dose.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 199531 **Seq:** 1 **Gender:** M
**Reported:** 30/07/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 84
**Onset Date:** 20/08/2003 **DOB:** 03/10/1918
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Reflexes abnormal | Caused or prolonged inpatient hospitalisation | Babinski sign positive | |
| Confusional state | | Confused and disorientated with disturbance of his sleep-wake cycle and intermittently aggressive | |
| Aggression | | | |
| Circadian rhythm sleep disorder | | | |
| Depressed level of consciousnes | | | |
| Disorientation | | | |
| Drug interaction | | | |

## Medicine Details:

**LINEZOLID (Interaction)** **Reason:** Otr&nos infec&parasit diseases

Tablet 1.0 Gram Daily Oral

**Batch:** **Started:** **Stopped:** 0

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:** Depression

Tablet 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Concomitant drug therapy: ciprofloxacin, rifampicin.
Serotonin Syndrome due to co-administration of Linezolid and Venlafaxine. Jones SL, Athan E, O'Brien D. Journal of Antimicrobial Chemotherapy 2004 Pages: 289-90.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 199531 **Seq:** 1
**Reported:** 30/07/2004
**Hospitalisation:**
**Onset Date:** 20/08/2003
**Outcome:** Recovered

**Gender:** M
**Weight:** 0.00
**Age:** 84
**DOB:** 03/10/1918
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertonia | | | |
| Myoclonus | | | |
| Pyrexia | | | |
| Serotonin syndrome | | | |
| Somnolence | | | |

## Medicine Details:

**LINEZOLID (Interaction)** **Reason:** Otr&nos infec&parasit diseases

Tablet 1.0 Gram Daily Oral

**Batch:** **Started:** **Stopped:** 0

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:** Depression

Tablet 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

## Laboratory Investigations:

## Additional Information:

Concomitant drug therapy: ciprofloxacin, rifampicin.
Serotonin Syndrome due to co-administration of Linezolid and Venlafaxine. Jones SL, Athan E, O'Brien D. Journal of Antimicrobial Chemotherapy 2004 Pages: 289-90.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199563 **Seq:** 1 **Gender:** F
**Reported:** 30/07/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 24
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br><br>Depression | | Went into a frenzy and destroyed shed and wall, depression. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199564 **Seq:** 1 **Gender:** M
**Reported:** 30/07/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 30
**Onset Date:** **DOB:** 20/08/1973
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Intentional self-injury | | Intentional self harm, cut himself | |

### Medicine Details:

**ZYPREXA (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**EFEXOR (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199608 **Seq:** 1 **Gender:** F
**Reported:** 03/08/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 61
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Life | Patient experienced severe hyponatraemia sodium levels at 111 mmol/L. | Patient required rescuscitation |

### Medicine Details:

**ATENOLOL (Other drug)** **Reason:** Essential benign hypertension
Tablet Dose Unspecified
**Batch:** **Started:** **Stopped:**

**DOXEPIN HYDROCHLORIDE (Other drug)** **Reason:** Depression
50.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**DIURETIC NOS (Suspected)** **Reason:**
Dose Unspecified
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 03/08/2004 | Sodium | | | | Sodium levels a t 111 mmol/L |

### Additional Information:

## Report Detail

**Case Number:** 199735 **Seq:** 1
**Reported:** 06/08/2004
**Hospitalisation:**
**Onset Date:** 10/05/2004
**Outcome:** Recovered

**Gender:** M
**Weight:** 60.00
**Age:** 79
**DOB:** 28/05/1924
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br><br>Coordination abnormal<br>Inappropriate antidiuretic hormon | | Hyponatraemia and Siadh. | Carbamazepine ceased, fluid restriction to 1L/day. |

## Medicine Details:

**TRAMADOL HYDROCHLORIDE (Other drug)** **Reason:** Pain
50.0 Milligram As necessary
**Batch:** **Started:** **Stopped:** 04/05/2004

**ROFECOXIB (Other drug)** **Reason:** Pain
25.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 08/05/2004

**OMEPRAZOLE (Other drug)** **Reason:** Other diseases of esophagus
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**CARBAMAZEPINE (Suspected)** **Reason:** Pain
100.0 Milligram Daily
**Batch:** **Started:** 07/05/2004 **Stopped:** 10/05/2004

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 06/08/2004 | Sodium | 137-145 mmol/L | 04/05/2004 | 136 | |
| 06/08/2004 | Sodium | 137-145 mmol/L | 10/05/2004 | 123 | |
| 06/08/2004 | Sodium | 137-145 mmol/L | 13/05/2004 | 126 | |
| 06/08/2004 | Sodium | 137-145 mmol/L | 14/05/2004 | 129 | |
| 06/08/2004 | Sodium | 137-145 mmol/L | 18/05/2004 | 135 | |

## Additional Information:

Other drug therapy: aspirin, multivitamin, paracetamol, alendronate, meloxicam, sorbitol.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 199735 **Seq:** 1
**Reported:** 06/08/2004
**Hospitalisation:**
**Onset Date:** 10/05/2004
**Outcome:** Recovered

**Gender:** M
**Weight:** 60.00
**Age:** 79
**DOB:** 28/05/1924
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | |
|---|---|---|---|
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | **Reason:** | Depression |
| | 75.0 Milligram | Daily | |
| **Batch:** | **Started:** 05/05/2004 | | **Stopped:** |
| **HYDROCHLOROTHIAZIDE (Suspected)** | | **Reason:** | Edema and dropsy |
| | 12.0 Milligram | Daily | |
| **Batch:** | **Started:** 07/05/2004 | | **Stopped:** 08/05/2004 |

## Laboratory Investigations:

## Additional Information:

Other drug therapy: aspirin, multivitamin, paracetamol, alendronate, meloxicam, sorbitol.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199852 **Seq:** 1
**Reported:** 10/08/2004
**Hospitalisation:**
**Onset Date:** 01/07/2004
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 85.00
**Age:** 72
**DOB:** 06/05/1932
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Gait disturbance | Required Visit to Doctor | Severe shuffling gait, stooped posture, absent arm swing, mild muscle rigidity in | Efexor XR ceased. |

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **CARTIA (Other drug)** | | | **Reason:** | | |
| Tablet | 100.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **COLOXYL WITH SENNA (Other drug)** | | | **Reason:** | Constipation | |
| Tablet | 4.0 | Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **DEXAMETHASONE (Other drug)** | | | **Reason:** | | |
| Tablet | 2.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **ENDONE (Other drug)** | | | **Reason:** | | |
| Tablet | 20.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient also taking Lucrin Depot 3 month injection, Maxolon, Methadone HCL, Movicol, Nexium, Physeptone, Seretide and Zometa.

## Report Detail

**Case Number:** 199852 **Seq:** 1
**Reported:** 10/08/2004
**Hospitalisation:**
**Onset Date:** 01/07/2004
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 85.00
**Age:** 72
**DOB:** 06/05/1932
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **KARVEA (Other drug)** | | | **Reason:** | | |
| Tablet | 150.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression | |
| Capsule, modified release | 75.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 30/04/2004 | | **Stopped:** | 19/07/2004 |

## Laboratory Investigations:

## Additional Information:

Patient also taking Lucrin Depot 3 month injection, Maxolon, Methadone HCL, Movicol, Nexium, Physeptone, Seretide and Zometa.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199857 **Seq:** 1
**Reported:** 10/08/2004
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 26/05/2004
**Outcome:** Unknown

**Gender:** M
**Weight:** 0.00
**Age:** 48
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression | Caused or prolonged inpatient hospitalisation | Became increasingly "cocky" at work and involved in conflicts with his superiors when dose of Efexor was increased to 225mg daily. Became hopeless, brittle in emotions and phoned "lifeline" when about to hang himself. Clear change noted by a close friend who knows him well. | Had to cease Efexor over 2-3 weeks, prescription for 37.5mg tabs allow him to do this. |
| Suicidal ideation | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

Tablet 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199929 **Seq:** 1 **Gender:** M
**Reported:** 12/08/2004 **Weight:** 55.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 02/08/2004 **DOB:**
**Outcome:** Recovered 05/08/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Musculoskeletal stiffness | Required Visit to Doctor | Patient experienced generalised muscle stiffness affecting gait and movement. Spastic appearance rigid with head pulled back | Cogentin. |
| Dystonia | Required Visit to Doctor | | |
| Gait disturbance | Required Visit to Doctor | | |
| Muscle rigidity | Required Visit to Doctor | | |

### Medicine Details:

**CITALOPRAM HYDROBROMIDE (Suspected)** **Reason:** Depression
Tablet Oral
**Batch:** **Started:** **Stopped:** 29/07/2004

**OLANZAPINE (Suspected)** **Reason:** Unspecified neurosis
10.0 Milligram Daily
**Batch:** **Started:** 22/07/2004 **Stopped:** 29/07/2004

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
38.0 Milligram Daily
**Batch:** **Started:** 30/07/2004 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 199930 **Seq:** 1 **Gender:** F
**Reported:** 12/08/2004 **Weight:** 64.20
**Hospitalisation:** **Age:** 43
**Onset Date:** 21/07/2004 **DOB:** 05/01/1961
**Outcome:** Recovered 28/07/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Thinking abnormal | Required Visit to Doctor | Abnormal thoughts regarding harming her | Efexor-XR withdrawn. |
| Violent ideation | Required Visit to Doctor | | |

### Medicine Details:

**LOETTE (Other drug)** **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 17/06/2004 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule, modified release 75.0 Milligram Daily Oral
**Batch:** **Started:** 03/06/2004 **Stopped:** 10/08/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200005 **Seq:** 1 **Gender:** M
**Reported:** 16/08/2004 **Weight:**
**Hospitalisation:** **Age:** 60
**Onset Date:** 22/07/2004 **DOB:** 08/03/1944
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal headache<br><br>Dizziness<br>Tinnitus | | Patient experienced withdrawal headaches, dizzy spells and tinnitus. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 20/07/2004 8 months

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

History: Sleep apnoea

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 200194 **Seq:** 1 **Gender:** F
**Reported:** 20/08/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 32
**Onset Date:** **DOB:** 25/01/1972
**Outcome:** Recovered 12/08/2004 **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br><br>Drug interaction<br>Headache<br>Nausea<br>Paraesthesia | | Dizziness, pins and needles/tingling in ankles, hands and fingers, slight headache, nausea | Cease Claramax |

## Medicine Details:

**EFEXOR-XR (Interaction)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** S TERM **Stopped:** 0

**Claramax (Interaction)** **Reason:** Hay fever
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 11/08/2004 **Stopped:** 11/08/2004 0

**LEVLEN ED (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Previously used Claratyne with no problems/together with the other antidepressants.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200212 **Seq:** 1 **Gender:** F
**Reported:** 20/08/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** **DOB:**
**Outcome:** Recovered without treatment **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vision blurred | | blurred vision | |
| Vision blurred | | inability to focus on objects or writing | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
150.0 Milligram 1 time Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200258 **Seq:** 1
**Reported:** 24/08/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 60.00
**Age:** 99U
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pneumonia | Caused or prolonged inpatient hospitalisation | Pneumonia and confusion. | Efexor XR ceased, Efexor |
| Confusional state | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**PREDNISONE (Other drug)** **Reason:**
Tablet 25.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule, modified release 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

200258 is a seq 01 of 200271 seq 02.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200271 **Seq:** 1 **Gender:** F
**Reported:** 24/08/2004 **Weight:** 60.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state | | Confusion | |

### Medicine Details:

**PREDNISONE (Other drug)** **Reason:**
Tablet 25.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

200271 is seq 02 of 200258 seq 01.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200292 **Seq:** 1 **Gender:** F
**Reported:** 25/08/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** 14/08/2004 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Neonatal disorder | | Baby showed abnormal neurological status from birth, increased tone poor response to stimulation. Improvement in first 4 days | Nil |
| Hyporeflexia | | Poor response to stimulation | |
| Hypertonia | | | Nil |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200467 **Seq:** 1 **Gender:** U
**Reported:** 01/09/2004 **Weight:** 70.00
**Hospitalisation:** **Age:** 42
**Onset Date:** 30/07/2004 **DOB:** 04/03/1962
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Weight increased | Required Visit to Doctor | Patient developed body weight increased. | Councelled and asked vascular surgeon's opinion. |

### Medicine Details:

**VIOXX (Other drug)** **Reason:**
25.0 Milligram As necessary Oral
**Batch:** **Started:** 03/07/2004 **Stopped:**

**METROGYL (Other drug)** **Reason:**
Tablet 1.0 Gram Daily Oral
**Batch:** **Started:** 11/07/2004 **Stopped:** 18/07/2004

**EFEXOR (Suspected)** **Reason:** Depression
Oral
**Batch:** **Started:** 09/10/2000 **Stopped:** 08/11/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200479 **Seq:** 1 **Gender:** U
**Reported:** 01/09/2004 **Weight:** 70.00
**Hospitalisation:** **Age:** 42
**Onset Date:** 30/07/2004 **DOB:** 04/03/1962
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Chillblains | Required Visit to Doctor | Patient developed feeling of general chills and chilbains to fingers. | Councelled and asked vascular surgeon for opinion. |

### Medicine Details:

**VIOXX (Other drug)** **Reason:**
25.0 Milligram As necessary Oral
**Batch:** **Started:** 03/07/2004 **Stopped:**

**METROGYL (Other drug)** **Reason:** Depression
Tablet 1.0 Gram Daily Oral
**Batch:** **Started:** 11/07/2004 **Stopped:** 18/07/2004

**EFEXOR (Suspected)** **Reason:** Depression
Oral
**Batch:** **Started:** 09/10/2000 **Stopped:** 08/11/2004

**EDRONAX (Suspected)** **Reason:** Depression
Tablet 8.0 Milligram Daily Oral
**Batch:** **Started:** 11/07/2004 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200588 **Seq:** 1 **Gender:** F
**Reported:** 06/09/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 78
**Onset Date:** 16/04/2004 **DOB:** 30/06/1925
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia | | Patient experienced a dystonic reaction 4 hours post first dose of Zopiclone - opisthotonus, oculogyric crisis, rigidity and jerky limb movements (patient conscious). | Benztropine 4mg (total) and Diazepam 5mg. Ceased Metoclopramide and changed to Dolaseteron. Increased Propofol with minor stimulation infusion to 3ml/hr |

### Medicine Details:

**ALENDRONATE SODIUM (Other drug)** **Reason:**
Tablet 70.0 Milligram Weekly Ophthalmic
**Batch:** **Started:** **Stopped:**

**MORPHINE SULPHATE (Other drug)** **Reason:**
Injection 2.0 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**SALBUTAMOL (Other drug)** **Reason:**
Inhalation 100.0 Microgram As necessary Oral
**Batch:** **Started:** **Stopped:**

**FRUSEMIDE (Other drug)** **Reason:**
Tablet 80.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient also taking Docusate and Senna tablets and Benefibre powder.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200588 **Seq:** 1 **Gender:** F
**Reported:** 06/09/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 78
**Onset Date:** 16/04/2004 **DOB:** 30/06/1925
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **OMEPRAZOLE (Other drug)** | | | **Reason:** | |
| Capsule | 20.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **ERGOCALCIFEROL (Other drug)** | | | **Reason:** | |
| Capsule | 25.0 | Microgram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **DIGOXIN (Other drug)** | | | **Reason:** | |
| Tablet | 125.0 | Microgram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **CHLORVESCENT (Other drug)** | | | **Reason:** | |
| Tablet | 2.0 | | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |

### Laboratory Investigations:

### Additional Information:
Patient also taking Docusate and Senna tablets and Benefibre powder.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200588 **Seq:** 1 **Gender:** F
**Reported:** 06/09/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 78
**Onset Date:** 16/04/2004 **DOB:** 30/06/1925
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **PARACETAMOL (Other drug)** | | | **Reason:** | |
| Tablet | 4.0 | Gram | Daily | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |
| **CIPROFLOXACIN (Other drug)** | | | **Reason:** | |
| Tablet | 500.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |
| **ENOXAPARIN (Other drug)** | | | **Reason:** | |
| Injection | 40.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **ASPIRIN (Other drug)** | | | **Reason:** | |
| Tablet | 100.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:
Patient also taking Docusate and Senna tablets and Benefibre powder.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200588 **Seq:** 1 **Gender:** F
**Reported:** 06/09/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 78
**Onset Date:** 16/04/2004 **DOB:** 30/06/1925
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **THYROXINE SODIUM (Other drug)** | | | **Reason:** | | |
| Tablet | 150.0 | Microgram | Alternate days | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **IMOVANE (Suspected)** | | | **Reason:** | Disturbance of sleep | |
| Tablet | 4.0 | Milligram | 1 time | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **MAXOLON (Suspected)** | | | **Reason:** | Nausea and vomiting | |
| Injection | 1.0 | Dose Unspecified | As necessary | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **EFEXOR (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 150.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:
Patient also taking Docusate and Senna tablets and Benefibre powder.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200661 **Seq:** 1 **Gender:** F
**Reported:** 08/09/2004 **Weight:** 60.00
**Hospitalisation:** **Age:** 44
**Onset Date:** 30/06/2004 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anger | Required Visit to Doctor | Agitative rage, verbally and physically aggressive, intolerant on withdrawal of Efexor XR | |
| Aggression | Required Visit to Doctor | | |
| Agitation | Required Visit to Doctor | | |
| Drug withdrawal syndrome | Required Visit to Doctor | | |

### Medicine Details:

**XANAX (Other drug)** **Reason:**
Tablet 3.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**DIAZEPAM (Other drug)** **Reason:**
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** 05/06/2001 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200701 **Seq:** 1 **Gender:** M
**Reported:** 09/09/2004 **Weight:** 75.00
**Hospitalisation:** **Age:** 48
**Onset Date:** 15/06/2004 **DOB:** 19/02/1956
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle tightness | Severe | The patient experienced severe muscle tension. Two hours after the dose he also had severe depression | Very slow dose reduction (using 5 or less granules from XR capsule) |
| Depression | Severe | | |
| Suicidal ideation | Severe | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
38.0 Milligram Daily Oral
**Batch:** **Started:** 07/05/2004 **Stopped:** 15/07/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200702 **Seq:** 1 **Gender:** M
**Reported:** 09/09/2004 **Weight:** 75.00
**Hospitalisation:** **Age:** 48
**Onset Date:** 15/06/2004 **DOB:** 19/02/1956
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Migraine<br><br>Drug withdrawal syndrome | | Migraine headaches when any dose reduction occured. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Oral
**Batch:** **Started:** 07/05/2004 **Stopped:** 15/07/2004 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 200721 **Seq:** 1
**Reported:** 10/09/2004
**Hospitalisation:**
**Onset Date:** 15/08/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 83.00
**Age:** 64
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fatigue<br>Abnormal dreams<br>Aggression<br>Bruxism<br>Headache<br>Irritability<br>Jaw disorder<br>Somnolence | | Fatigue, somnolence, aggressiveness, irritability, jaw clenching, nocturnal teeth grinding, bizarre dreaming and frontal headache | Tapered off Efexor XR. |

### Medicine Details:

**AVAPRO HCT 150/12.5 (Other drug)** **Reason:** Essential benign hypertension
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 05/02/2001 **Stopped:**

**LIPITOR (Other drug)** **Reason:** Othr&unspec metabolic diseases
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 07/12/1994 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 24/05/2004 **Stopped:** 06/09/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 201044 **Seq:** 1 **Gender:** M
**Reported:** 22/09/2004 **Weight:** 0.00
**Hospitalisation:** Admitted to hospital **Age:** 70Y
**Onset Date:** 09/09/2004 **DOB:**
**Outcome:** Recovered 16/09/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cerebrovascular accident | Required Visit to Doctor | Stroke. | |

### Medicine Details:

**PANADEINE FORTE (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified As necessary Oral
**Batch:** **Started:** 09/08/2004 **Stopped:**

**LIPEX (Other drug)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**LAMISIL (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 17/08/2004 **Stopped:**

**SINEMET (Other drug)** **Reason:**
Tablet 4.0 Dose Unspecified Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 201044 **Seq:** 1 **Gender:** M
**Reported:** 22/09/2004 **Weight:** 0.00
**Hospitalisation:** Admitted to hospital **Age:** 70Y
**Onset Date:** 09/09/2004 **DOB:**
**Outcome:** Recovered 16/09/2004 **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **SINEMET CR (Other drug)** | | | **Reason:** | | | |
| Tablet | 4.0 | Dose Unspecified | Daily | | Oral | |
| **Batch:** | **Started:** | L TERM | | **Stopped:** | | |
| **COMTAN (Other drug)** | | | **Reason:** | | | |
| Tablet | 800.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | L TERM | | **Stopped:** | | |
| **EFEXOR (Suspected)** | | | **Reason:** | | | |
| Tablet | 75.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** 09/09/2004 | | | **Stopped:** | 09/09/2004 | 0 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 201088 **Seq:** 1 **Gender:** F
**Reported:** 23/09/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 80Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic failure | Caused or prolonged inpatient hospitalisation | Hepatic failure, inr increased, confused, | Treated with IV Fluids, antibiotics, Vitamin K and oral lactulose, N-acetyl Cysterine |
| Confusional state | Caused or prolonged inpatient hospitalisation | | |
| Drug interaction | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**DIPYRIDAMOLE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PROCHLORPERAZINE MALEATE (Other drug)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**GLYCERYL TRINITRATE (Other drug)** **Reason:**
Drug delivery system, transde 50.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**FELODIPINE (Other drug)** **Reason:**
Tablet 5.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 23/09/2004 | ALT = SGPT | 0 - 40 U/L | | | Day 18 - 974 U/L<br>Day 23 - 1871 U/L<br>ALT returned to normal by day 35 |
| 23/09/2004 | AST = SGOT | 0 - 40 U/L | | | Day 18 - 506 U/L<br>Day 23 - 1178 U/L |
| 23/09/2004 | GGT = SGGT = | | | | Day 18 - 390 U/L<br>Day 23 - 473 U/L |
| 23/09/2004 | International | | | | INR reached 2.4 |

### Additional Information:

Internal Journal of Medicine 2004; 34: 441-448. Hepatotoxicity possibly due to paracetamol with carbamazepine. Authors: The risk of paracetamol toxicity may increase if it is given in combination with anticonvulsants which induce cytochrome P450 enzymes and can increase metabolism of paracetamol.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 201088 **Seq:** 1 **Gender:** F
**Reported:** 23/09/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 80Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| International normalised ratio inc | Caused or prolonged inpatient hospitalisation | | |
| Lethargy | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**ATENOLOL (Other drug)** **Reason:**
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**RAMIPRIL (Other drug)** **Reason:**
5.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**PARACETAMOL (Suspected)** **Reason:** Pain
Tablet 4.0 Gram Daily Oral
**Batch:** **Started:** **Stopped:** 0

**CARBAMAZEPINE (Suspected)** **Reason:**
400.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 23/09/2004 | Other data | | | | Hepatitis viral serology and autoantibody tests were negative. |
| 23/09/2004 | SAP = ALP | <110 U/L | | | Day 18 - 161<br>Day 23 - 224 U/L |

### Additional Information:

Internal Journal of Medicine 2004; 34: 441-448. Hepatotoxicity possibly due to paracetamol with carbamazepine. Authors: The risk of paracetamol toxicity may increase if it is given in combination with anticonvulsants which induce cytochrome P450 enzymes and can increase metabolism of paracetamol.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 201088 **Seq:** 1 **Gender:** F
**Reported:** 23/09/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 80Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | |
|---|---|---|---|
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | **Reason:** | |
| | 75.0 Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** |
| **METFORMIN HYDROCHLORIDE (Suspected)** | | **Reason:** | |
| | 2.0 Gram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** |
| **ATORVASTATIN (Suspected)** | | **Reason:** | |
| | 20.0 Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

### Additional Information:

Internal Journal of Medicine 2004; 34: 441-448. Hepatotoxicity possibly due to paracetamol with carbamazepine. Authors: The risk of paracetamol toxicity may increase if it is given in combination with anticonvulsants which induce cytochrome P450 enzymes and can increase metabolism of paracetamol.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 201264 **Seq:** 1 **Gender:** M
**Reported:** 24/09/2004 **Weight:** 93.50
**Hospitalisation:** **Age:** 48
**Onset Date:** 27/06/2003 **DOB:** 03/08/1954
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paranoia | Required Visit to Doctor | Paranoia and schizophreniform disorder. | Unknown. |
| Schizophreniform disorder | Required Visit to Doctor | | |

### Medicine Details:

**ZYPREXA (Other drug)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule, modified release 75.0 Milligram Daily Oral
**Batch:** **Started:** 20/03/2003 **Stopped:** 22/08/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 201334 **Seq:** 1
**Reported:** 28/09/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:** 20/09/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 89
**DOB:** 17/04/1915
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Hyponatremia. | |

### Medicine Details:

**CELEBREX (Suspected)** **Reason:** Other diseases of bone

Capsule 200.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression

Tablet 75.0 Milligram Daily Oral

**Batch:** **Started:** 17/09/2004 **Stopped:** 21/09/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 28/09/2004 | Sodium | | | | Sodium level dropped to 117 mmol/l 4 days after switching to efexor from zoloft. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 201429 **Seq:** 1 **Gender:** F
**Reported:** 01/10/2004 **Weight:** 60.00
**Hospitalisation:** **Age:** 21
**Onset Date:** 30/09/2004 **DOB:** 13/08/1983
**Outcome:** Recovered 01/10/2004 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination | Severe | | |
| Self injurious behaviour | Severe | | |
| Suicidal ideation | Severe | | |
| Suicide attempt | Severe | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Tablet 75.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**STILNOX (Suspected)** **Reason:**
Dose Unspecified 1 time Oral
**Batch:** **Started:** 30/09/2004 **Stopped:** 01/10/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 201690 **Seq:** 1 **Gender:** M
**Reported:** 13/10/2004 **Weight:**
**Hospitalisation:** **Age:** 28
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Trisomy 18 | | Male patient taking Efexor-XR, his unborn child was found to haveTrisomy 18 | |

### Medicine Details:

**INSULIN NOS (Other drug)** **Reason:** Diabetes mellitus

**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** L TERM **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 201782 **Seq:** 1 **Gender:** U
**Reported:** 18/10/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Electrocardiogram QT prolonged | | QT interval prolongation | |

### Medicine Details:

**OLANZAPINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 201814 **Seq:** 1 **Gender:** F
**Reported:** 18/10/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 46
**Onset Date:** **DOB:** 11/04/1958
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Aggression<br>Drug withdrawal syndrome<br>Nightmare<br>Suicidal ideation<br>Thinking abnormal | | The patient was taking Efexor-XR on alternate days. When Efexor was stopped, she experienced electric shocks started. The patient also had strange thoughts and nightmares, tingling in the fingers, wanted to commit suicide and harm other people. | |

### Medicine Details:

**VALIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 175.0 Milligram Weekly Oral
**Batch:** **Started:** **Stopped:** Contin

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202069 **Seq:** 1 **Gender:** M
**Reported:** 27/10/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 61
**Onset Date:** 15/03/2004 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Disorientation<br>Irritability | | Patient agitated, irritable and disorientated. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
112.0 Milligram Daily Oral
**Batch:** **Started:** 15/01/2004 **Stopped:**

**TRAMAL SR (Suspected)** **Reason:** Pain
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 15/03/2004 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

History: Patient also has Parkinson's Disease, with frontal lobe atrophy.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202083 **Seq:** 1 **Gender:** M
**Reported:** 27/10/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 81Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | Patient developed hyponatremia. | Ceased Venlafaxine. Na + returning to normal slowly. |

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **RAMIPRIL (Other drug)** | | | **Reason:** | |
| Tablet | 2.0 | Milligram | | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |
| **ATENOLOL (Other drug)** | | | **Reason:** | |
| Tablet | 50.0 | Milligram | | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |
| **CLOPIDOGREL (Other drug)** | | | **Reason:** | |
| Tablet | 75.0 | Milligram | | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |
| **SIMVASTATIN (Other drug)** | | | **Reason:** | |
| Tablet | 40.0 | Milligram | | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 27/10/2004 | Sodium | | 15/12/2003 | 134 | |
| 27/10/2004 | Sodium | | 17/12/2003 | 132 | |
| 27/10/2004 | Sodium | | 29/12/2003 | 128 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202083 **Seq:** 1
**Reported:** 27/10/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 81Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | Depression | | |
| Tablet | 75.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | 03/12/2003 | | **Stopped:** | 09/10/2004 | 0 |
| **OMEPRAZOLE (Suspected)** | | | **Reason:** | | | |
| Tablet | 4.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | | 0 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202154 **Seq:** 1 **Gender:** F
**Reported:** 29/10/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mitral valve prolapse | Required Visit to Doctor | Mitral valve prolapse | |

### Medicine Details:

**TELFAST (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Other suspected drug taken: Unspecified HRT.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202263 **Seq:** 1
**Reported:** 03/11/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 99U
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Status epilepticus | Caused or prolonged inpatient hospitalisation | Patient experienced seizures and subclinical status epilepsy. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient has a history of epilepsy.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202284 **Seq:** 1 **Gender:** F
**Reported:** 03/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 36
**Onset Date:** 15/01/2004 **DOB:** 03/01/1968
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anger | Required Visit to Doctor | | |
| Crying | Required Visit to Doctor | | |
| Depression | Required Visit to Doctor | | |
| Dizziness | Required Visit to Doctor | | |
| Drug withdrawal syndrome | Required Visit to Doctor | | |
| Nausea | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
225.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 202284 **Seq:** 1 **Gender:** F
**Reported:** 03/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 36
**Onset Date:** 15/01/2004 **DOB:** 03/01/1968
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | Required Visit to Doctor | | |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
225.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202473 **Seq:** 1
**Reported:** 11/11/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 53
**DOB:** 13/10/1951
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | Caused or prolonged inpatient hospitalisation | Suicide attempt by overdose. Ingested 28 x 150mg Efexor XR and Alcohol plus 4-6 tablets of Stelazine and was unconscious. | |
| Loss of consciousness | Caused or prolonged inpatient hospitalisation | | |
| Overdose | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**DIAZEPAM (Other drug)**
**Reason:**
**Batch:** **Started:** **Stopped:**

**LARGACTIL (Other drug)**
**Reason:**
**Batch:** **Started:** **Stopped:**

**STELAZINE (Suspected)**
**Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:** 09/02/2005 0

**ALCOHOL (Suspected)**
**Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient has a history of previous suicide attempts, sleeping disorder

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 202473 **Seq:** 1
**Reported:** 11/11/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 53
**DOB:** 13/10/1951
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule, modified release 150.0 Milligram Daily Oral

**Batch:** **Started:** 15/07/2004 **Stopped:**

## Laboratory Investigations:

## Additional Information:

Patient has a history of previous suicide attempts, sleeping disorder

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202519 **Seq:** 1
**Reported:** 12/11/2004
**Hospitalisation:**
**Onset Date:** 07/10/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 92.00
**Age:** 42
**DOB:** 09/10/1961
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cognitive disorder | Required Visit to Doctor | Patient developed cognitive dysfunction, severe nausea, vomiting, headache, mayalgia, (brain zaps shocks) - stomach "shocks", dizziness, mood disturbances and withdrawal syndrome | Efexor XR ceased. Prozac 20mg daily, Benadryl and Dramamine, Stemetil, Niacin and Valtarien given |
| Dizziness | Required Visit to Doctor | | |
| Drug withdrawal syndrome | Required Visit to Doctor | | |
| Eyelid sensory disorder | Required Visit to Doctor | | |
| Headache | Required Visit to Doctor | | |

### Medicine Details:

**PARIET (Other drug)** **Reason:** Other diseases of esophagus

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** L TERM **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Allergies to Sulfa - drugs.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 202519 **Seq:** 1
**Reported:** 12/11/2004
**Hospitalisation:**
**Onset Date:** 07/10/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 92.00
**Age:** 42
**DOB:** 09/10/1961
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mood swings | Required Visit to Doctor | | |
| Myalgia | Required Visit to Doctor | | |
| Nausea | Required Visit to Doctor | | |
| Vomiting | Required Visit to Doctor | | |

## Medicine Details:

**PARIET (Other drug)** **Reason:** Other diseases of esophagus

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** L TERM **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

## Laboratory Investigations:

## Additional Information:

Allergies to Sulfa - drugs.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202537 **Seq:** 1 **Gender:** M
**Reported:** 15/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 52Y
**Onset Date:** 26/10/2004 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Flushing | Required Visit to Doctor | Facial flushing and tinnitus every day commencing approx. 1 pm and continuing through to the end of the day. | |
| Tinnitus | Required Visit to Doctor | | |

### Medicine Details:

**DIAZEPAM (Suspected)** **Reason:** Anxiety neurosis
Tablet 1.0 Milligram Reducing Oral
**Batch:** **Started:** 01/05/2004 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 01/08/2004 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 202627 **Seq:** 1 **Gender:** F
**Reported:** 17/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 16
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Trismus<br>Fatigue<br>Musculoskeletal stiffness<br>Myalgia | | The patient experienced lockjaw and her jaw ached as a result of the tension created. The tension seemed to spread to her neck, into her shoulder blades and down her back. The treatment made her more tired. | Efexor XR ceased. She underwent physiotherapy for her jaw |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Neurasthenia
Capsule Oral
**Batch:** **Started:** **Stopped:** 0

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202631 **Seq:** 1 **Gender:** F
**Reported:** 17/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 16
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia<br><br>Drug withdrawal syndrome<br>Visual disturbance | | When Efexor XR was withdrawn the patient experienced horrendous insomnia and vision problems which took months to improve | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Neurasthenia
Capsule Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202658 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br><br>Akathisia<br>Suicide attempt | | Patient developed suicidal ideation, had 2 suicide attempts and suffered akathisia. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
250.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202660 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br>Aggression | | Patient had suicidal ideation and was | Discharged on Venlafaxine |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**OLANZAPINE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202661 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 63
**Onset Date:** **DOB:** 19/08/1941
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | | Suicidal ideation. | |

### Medicine Details:

**OLANZAPINE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ALCOHOL (Suspected)** **Reason:**
Oral Liquid Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202662 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Akathisia<br>Aggression | | Patient had psychosis, was violent and | Needed ECT. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202665 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 57
**Onset Date:** **DOB:** 07/12/1946
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Overdose | | Patient took overdose of Efexor. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
225.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**ALCOHOL (Suspected)** **Reason:**
Oral Liquid Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202667 **Seq:** 1 **Gender:** F
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 39
**Onset Date:** **DOB:** 11/03/1965
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Akathisia | | Patient suffered akathisia after ceasing | Efexor ceased. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
225.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202675 **Seq:** 1
**Reported:** 18/11/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Unknown

**Gender:** U
**Weight:** 0.00
**Age:** 46
**DOB:** 25/08/1958
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt<br>Overdose | | Sudden suicide attempt by overdose. | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202682 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 32
**Onset Date:** **DOB:** 06/06/1972
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt<br>Suicidal ideation | | Suicide attempt - hanging plan. | Discharged on Efexor x R |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202683 **Seq:** 1 **Gender:** F
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 24
**Onset Date:** **DOB:** 19/02/1980
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Homicidal ideation<br><br>Akathisia<br>Personality change<br>Suicidal ideation | | Patient suffered akathisia, suicidal ideation, personality change and homicidal ideation. | |

### Medicine Details:

**ZOLOFT (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202685 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 66
**Onset Date:** **DOB:** 24/12/1937
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | | Suicidal ideation. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
275.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**OLANZAPINE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**LITHIUM CARBONATE (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202687 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 32
**Onset Date:** **DOB:** 20/07/1972
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br>Homicidal ideation | | Suicidal and homicidal ideation. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**ALCOHOL (Suspected)** **Reason:**
Oral Liquid
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202690 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 34
**Onset Date:** **DOB:** 28/07/1970
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br>Suicide attempt | | Suicidal ideation and suicide attempt. | |

### Medicine Details:

**OLANZAPINE (Suspected)** **Reason:**
15.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 202691 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br>Homicidal ideation | | Suicidal and homicidal ideation. | |

## Medicine Details:

**QUETIAPINE (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**FLUOXETINE HYDROCHLORIDE (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:**

**HALOPERIDOL (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202699 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 22
**Onset Date:** **DOB:** 20/11/1981
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Overdose<br><br>Serotonin syndrome | | Patient overdosed on Efexor and Zoloft and had Serotonergic syndrome. | Discharged on Olanzapine. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**ZOLOFT (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202701 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 24
**Onset Date:** **DOB:** 22/10/1980
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Homicidal ideation<br><br>Agitation | | Patient experienced homicidal ideation, homicidal attempts, frenzy and was destructive | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
4.0 Dose Unspecified Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202716 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 29
**Onset Date:** **DOB:** 03/07/1975
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Overdose | | Patient overdosed. | Discharged on 450mg Efexor. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202718 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 49
**Onset Date:** **DOB:** 28/05/1955
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | | Suicidal ideation. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202724 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 37
**Onset Date:** **DOB:** 08/08/1967
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | | Suicidal ideation. | Left on Venlafaxine 150mg. |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202725 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Depression | | Patient was agitated and depressed. | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202729 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | | Suicidal ideation. | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202731 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt<br>Suicidal ideation | | Suicidal ideation and suicide attempt. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
225.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202739 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | 2 suicide attempts. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
225.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202746 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 43
**Onset Date:** **DOB:** 05/09/1961
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety<br><br>Depression<br>Suicidal ideation | | Patient suffered anxiety, was depressed and had suicidal ideation. | |

### Medicine Details:

**OLANZAPINE (Suspected)** **Reason:**
Tablet 5.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202747 **Seq:** 1
**Reported:** 18/11/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** U
**Weight:** 0.00
**Age:** 25
**DOB:** 03/03/1979
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | | Suicidal ideation. | Discharged on Efexor 150mg. |

### Medicine Details:

**CANNABIS PREPARATION (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 09/03/2003

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202750 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 27
**Onset Date:** 28/10/2004 **DOB:** 02/05/1977
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Homicidal ideation<br>Suicidal ideation | | Homicidal ideation and suicidal ideation. | |

### Medicine Details:

**ZUCLOPENTHIXOL ACETATE (Suspected)** **Reason:**
Injection
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
450.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202759 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br>Suicide attempt | | Suicidal ideation and suicide attempt. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202760 **Seq:** 1
**Reported:** 18/11/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** U
**Weight:** 0.00
**Age:** 27
**DOB:** 26/12/1976
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | Suicide attempt. | Discharged on 150mg Efexor. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202761 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 62
**Onset Date:** 04/08/2003 **DOB:** 16/08/1940
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | Suicide attempt. | |

### Medicine Details:

**XANAX (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:** 0

**ZYPREXA (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**Benzodiazepine NOS (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202763 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br>Suicide attempt | | Suicidal ideation and 2 suicide attempts. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202764 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 24
**Onset Date:** **DOB:** 22/10/1980
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Akathisia | | Patient experienced akathisia. | |

### Medicine Details:

**OLANZAPINE (Suspected)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
38.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202766 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 29
**Onset Date:** **DOB:** 03/07/1975
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | Suicide attempt. | Sent home on Efexor 15mg. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
450.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202767 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 43
**Onset Date:** 05/02/2004 **DOB:** 17/07/1960
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Akathisia<br><br>Suicidal ideation<br>Suicide attempt | | Patient experienced akathisia, suicidal ideation and suicide attempt. | |

### Medicine Details:

**PROZAC (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 202781 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression | | Patient became violent. | |

## Medicine Details:

**OLANZAPINE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ZUCLOPENTHIXOL ACETATE (Suspected)** **Reason:**
Injection
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202782 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 41
**Onset Date:** **DOB:** 20/08/1963
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br>Suicide attempt | | Suicidal ideation and suicide attempt. | |

### Medicine Details:

**MIRTAZAPINE (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**ZYPREXA (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202798 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Overdose | | Patient overdosed. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**ZOLOFT (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202800 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 49
**Onset Date:** **DOB:** 11/04/1955
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Akathisia<br><br>Suicidal ideation<br>Suicide attempt | | Chronic akathisia for 6 years, suicidal ideation with multiple suicide attempts and suicidal attempt in withdrawal phase. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202805 **Seq:** 1 **Gender:** U
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 55
**Onset Date:** **DOB:** 27/05/1949
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | | Suicidal ideation. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202814 **Seq:** 1 **Gender:** M
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Death, maybe drug **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Completed suicide | | Completed suicide. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**RISPERIDONE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202815 **Seq:** 1 **Gender:** M
**Reported:** 18/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Death, maybe drug **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Akathisia<br><br>Completed suicide | | Patient experienced suicide attempt, akathisia and completed suicide. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**FLUVOXAMINE MALEATE (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202832 **Seq:** 1 **Gender:** U
**Reported:** 19/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | Suicidal ideation and suicide attempt. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202833 **Seq:** 1 **Gender:** U
**Reported:** 19/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | Suicide attempt. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202834 **Seq:** 1 **Gender:** U
**Reported:** 19/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | Suicidal ideation and suicide attempt. | |

### Medicine Details:

**MIRTAZAPINE (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**ZYPREXA (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 202839 **Seq:** 1
**Reported:** 19/11/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** U
**Weight:** 0.00
**Age:** 99U
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Homicidal ideation | Caused or prolonged inpatient hospitalisation | Homicidal and suicidal ideation, violent and akathisia. | |
| Aggression | Caused or prolonged inpatient hospitalisation | | |
| Akathisia | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**ZYPREXA (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 202839 **Seq:** 1
**Reported:** 19/11/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** U
**Weight:** 0.00
**Age:** 99U
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**ZYPREXA (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 202840 **Seq:** 1
**Reported:** 19/11/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** U
**Weight:** 0.00
**Age:** 99U
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Akathisia | Caused or prolonged inpatient hospitalisation | Akathisia and violent. | |
| Aggression | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:**

Oral

**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202843 **Seq:** 1 **Gender:** U
**Reported:** 19/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Homicidal ideation<br><br>Aggression<br>Akathisia<br>Suicidal ideation | | Homicidal ideation, violent, akathisia and suicidal ideation. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**ZUCLOPENTHIXOL ACETATE (Suspected)** **Reason:**
Injection
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202849 **Seq:** 1 **Gender:** U
**Reported:** 19/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Akathisia | | Akathisia. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202854 **Seq:** 1 **Gender:** U
**Reported:** 19/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | Suicide attempt. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**CLOZAPINE (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202857 **Seq:** 1 **Gender:** U
**Reported:** 19/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression<br><br>Suicide attempt | | After withdrawal of Efexor the patient became violent and attempted suicide. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202859 **Seq:** 1
**Reported:** 19/11/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** U
**Weight:** 0.00
**Age:** 99U
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | Caused or prolonged inpatient hospitalisation | After withdrawal of Efexor the patient attempted suicide. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 202861 **Seq:** 1 **Gender:** U
**Reported:** 19/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | Patient experienced chronic suicidal ideation, suicide attempt and akathisia. | |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202869 **Seq:** 1 **Gender:** U
**Reported:** 19/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br>Akathisia<br>Homicidal ideation | | Suicidal, homicidal ideation and akathisia. | |

### Medicine Details:

**ALCOHOL (Suspected)** **Reason:**
Oral Liquid Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202964 **Seq:** 1 **Gender:** F
**Reported:** 23/11/2004 **Weight:** 60.00
**Hospitalisation:** **Age:** 49
**Onset Date:** 09/11/2004 **DOB:** 03/04/1955
**Outcome:** Recovered 17/11/2004 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination<br>Gait disturbance<br>Nausea<br>Tinnitus<br>Tremor<br>Xanthopsia | | Patient experienced hallucinations, nausea seeing yellow, buzzing ears, shaky and unsteady walking | Stopped Efexor |

### Medicine Details:

**NULAX FRUIT LAXATIVE (Other drug)** **Reason:** Constipation
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily Oral
**Batch:** **Started:** 09/11/2004 **Stopped:** 11/11/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202966 **Seq:** 1 **Gender:** M
**Reported:** 23/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 53
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pancreatitis acute | Required Visit to Doctor | Patient went missing from an unspecified institution and was found 24 hours later with hypothermia and acute pancreatitis. | |
| Hyponatraemia | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 202987 **Seq:** 1
**Reported:** 23/11/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:** 05/11/2004
**Outcome:** Recovered

**Gender:** M
**Weight:** 75.00
**Age:** 39
**DOB:** 24/08/1965
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | Caused or prolonged inpatient hospitalisation | Severe headache. | Analgesia and hospitalised for |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** 17/09/2004 **Stopped:** 17/11/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203087 **Seq:** 1
**Reported:** 26/11/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/04/2004
**Outcome:** Unknown

**Gender:** M
**Weight:** 0.00
**Age:** 55
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | Caused or prolonged inpatient hospitalisation | Patient would get the shakes and would fall out of bed. | |

### Medicine Details:

**RIVOTRIL (Other drug)** **Reason:**
30.0 Milligram
**Batch:** **Started:** **Stopped:**

**LOSEC (Other drug)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule, modified release 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203088 **Seq:** 1 **Gender:** F
**Reported:** 26/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 24
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | Required Visit to Doctor | Aggravation of epileptic fits. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule, modified release 300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203101 **Seq:** 1 **Gender:** F
**Reported:** 26/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** 22/11/2004 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome neona | Caused or prolonged inpatient hospitalisation | Mother on Venlafaxine 150mg daily during pregnancy, increased to 225mg daily, for depression. Baby developed clinical evidence of withdrawal on day 1 of life (DoB: 21/11/2004) with severe jitteriness, tachypnoea, low grade temperature and vomiting. | Phenobarbitone |
| Feeling jittery | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
225.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203101 **Seq:** 1 **Gender:** F
**Reported:** 26/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** 22/11/2004 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pyrexia | Caused or prolonged inpatient hospitalisation | | |
| Tachypnoea | Caused or prolonged inpatient hospitalisation | | |
| Vomiting | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**

225.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203102 **Seq:** 1 **Gender:** F
**Reported:** 26/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome neona | Required Specialist Consultation | Mother on venlafaxine (effexor) 225mg through the pregnancy for depression on advice of psychiatrist. Baby exhibited evidence of withdrawal at 24 hrs of age (DoB: 01/06/2004) with marked jitteriness. | Phenobarbitone |
| Drug exposure during pregnancy | Required Specialist Consultation | | |
| Feeling jittery | Required Specialist Consultation | | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
225.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Baby subsequently went on to breast feed well. No other cause for jitters found and phenobarb weaned off on day 9.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203119 **Seq:** 1
**Reported:** 29/11/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 51.00
**Age:** 25
**DOB:** 07/05/1979
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Amenorrhoea<br><br>Galactorrhoea | | Patient experienced amenorrhea and | Switched to Olanzapine and then Abilify. |

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **OLANZAPINE (Other drug)** | | **Reason:** | | | |
| **Batch:** | **Started:** 01/05/2004 | | **Stopped:** 08/07/2004 | 0 | |
| **HALOPERIDOL (Other drug)** | | **Reason:** | | | |
| **Batch:** | **Started:** 01/08/2004 | | **Stopped:** | 0 | |
| **ALPRAZOLAM (Other drug)** | | **Reason:** | | | |
| **Batch:** | **Started:** 01/05/2004 | | **Stopped:** 15/05/2004 | 0 | |
| **AMISULPRIDE (Suspected)** | | **Reason:** | | | |
| | | | Oral | | |
| **Batch:** | **Started:** | | **Stopped:** | | |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203119 **Seq:** 1
**Reported:** 29/11/2004
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 51.00
**Age:** 25
**DOB:** 07/05/1979
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule, modified release 75.0 Milligram Daily Oral

**Batch:** **Started:** 07/01/2004 **Stopped:** Contin

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203122 **Seq:** 1 **Gender:** F
**Reported:** 29/11/2004 **Weight:** 0.00
**Hospitalisation:** **Age:** 25
**Onset Date:** 14/10/2004 **DOB:** 07/05/1979
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Heart disease congenital<br><br>Drug exposure during pregnancy<br>Kidney malformation<br>Limb malformation<br>Trisomy 21 | | Heart disease congenital, kidney malformation, limb malformation. | Abortion, pregnancy |

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **OLANZAPINE (Other drug)** | | **Reason:** | | | |
| **Batch:** | **Started:** | 01/05/2004 | **Stopped:** | 08/07/2004 | 0 |
| **HALOPERIDOL (Other drug)** | | **Reason:** | | | |
| **Batch:** | **Started:** | 01/08/2004 | **Stopped:** | | 0 |
| **DICLOXACILLIN SODIUM (Other drug)** | | **Reason:** | | | |
| **Batch:** | **Started:** | 10/04/2004 | **Stopped:** | 03/06/2004 | 0 |
| **ALPRAZOLAM (Other drug)** | | **Reason:** | | | |
| **Batch:** | **Started:** | 01/05/2004 | **Stopped:** | 15/05/2004 | 0 |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 29/11/2004 | Other data | | | | At 16 weeks an ultrasound revealed heart (absense of right ventricle) and renal tract abnormalities (left hydronephrosis) and the patient decided to terminate the pregnancy at 19 weeks. This was the patient's second pregancy with no developmental problems with the first child. Amniocentesis revealed no chromosome abnormalities. Follow-up: The foetal heart showed only three chambers with absence of the right ventricle. Only one outflow tract was seen. Foetal heart beat was 129 bpm. There was a marked hydronephrosis of the left kidney. Right ... |

### Additional Information:

Gravidity 3, parity 1.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203122 **Seq:** 1
**Reported:** 29/11/2004
**Hospitalisation:**
**Onset Date:** 14/10/2004
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 25
**DOB:** 07/05/1979
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **Abilify (Suspected)** | | | **Reason:** | Unspecified schizophrenia | | |
| Tablet | 15.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | 21/06/2004 | | **Stopped:** | 24/08/2004 | 0 |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | | | |
| Capsule, modified release | 75.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | 07/01/2004 | | **Stopped:** | | 0 |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | ... renal outline was difficult to identify, but the kidney was probably short being at about the fifth percentile measuring 16 mm long. There was a prominant tubular structure in the abdomen which was probably a dilated left ureter. There was absence of the middle phalanx of the little finger of the foetal right hand. |

### Additional Information:

Gravidity 3, parity 1.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203186 **Seq:** 1
**Reported:** 01/12/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/01/2004
**Outcome:** Unknown

**Gender:** M
**Weight:** 82.00
**Age:** 60
**DOB:** 05/03/1943
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | Life | The patient developed bad trembling, high anxiety, chills, impaired vision, sweating, depression, bad dreams, headaches, low libido and hallucinations | Hospitalisation for 3 days. |
| Anxiety | Life | | |
| Chills | Life | | |
| Depression | Life | | |
| Hallucination | Life | | |
| Headache | Life | | |
| Hyperhidrosis | Life | | |
| Loss of libido | Life | | |
| Nightmare | Life | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**LOVAN (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**Lexapro (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**DOTHEP (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203186 **Seq:** 1
**Reported:** 01/12/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/01/2004
**Outcome:** Unknown

**Gender:** M
**Weight:** 82.00
**Age:** 60
**DOB:** 05/03/1943
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Visual disturbance | Life | | |

### Medicine Details:

**VERAPAMIL HYDROCHLORIDE (Suspected)** **Reason:** Headache
Tablet 80.0 Milligram Daily Oral
**Batch:** **Started:** 15/10/2003 **Stopped:**

**ZOLOFT (Suspected)** **Reason:**
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203334 **Seq:** 1 **Gender:** F
**Reported:** 07/12/2004 **Weight:** 90.00
**Hospitalisation:** **Age:** 66
**Onset Date:** 02/12/2003 **DOB:** 29/07/1937
**Outcome:** Recovered 11/04/2004 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Chest pain | Required Visit to Doctor | Chest pain, similar to cardiac pain. | Cease Efexor-XR |

### Medicine Details:

**VERAPAMIL HYDROCHLORIDE (Other drug)** **Reason:**
Tablet 160.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**TEGRETOL (Other drug)** **Reason:**
Tablet 500.0 Milligram Oral
**Batch:** **Started:** 18/07/2003 **Stopped:** 13/10/2004

**ZOTON (Other drug)** **Reason:**
Capsule 30.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**PARACETAMOL (Other drug)** **Reason:**
500.0 Milligram As necessary
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 07/12/2004 | Other data | | | | L x with no cardiac cause detected. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203334 **Seq:** 1 **Gender:** F
**Reported:** 07/12/2004 **Weight:** 90.00
**Hospitalisation:** **Age:** 66
**Onset Date:** 02/12/2003 **DOB:** 29/07/1937
**Outcome:** Recovered 11/04/2004 **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **MURELAX (Other drug)** | | | **Reason:** | | |
| Tablet | 15.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | | |
| Capsule | 70.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | 18/07/2003 | | **Stopped:** | 13/10/2004 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203420 **Seq:** 1 **Gender:** F
**Reported:** 13/12/2004 **Weight:** 70.00
**Hospitalisation:** **Age:** 25
**Onset Date:** 29/11/2004 **DOB:** 05/09/1979
**Outcome:** Recovered 06/12/2004 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mydriasis | Required Visit to Doctor | Severe mydriasis, photophobia commencing after 5-7 days. | Drug stopped. |
| Photophobia | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily Oral
**Batch:** **Started:** 19/11/2004 S TERM **Stopped:** 01/12/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203573 **Seq:** 1
**Reported:** 15/12/2004
**Hospitalisation:**
**Onset Date:** 15/06/2004
**Outcome:** Death, maybe drug

**Gender:** M
**Weight:** 0.00
**Age:** 39
**DOB:** 20/11/1964
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Completed suicide | | Completed suicide. | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203612 **Seq:** 1
**Reported:** 16/12/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:** 17/08/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 56.00
**Age:** 33
**DOB:** 20/02/1971
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vomiting | Caused or prolonged inpatient hospitalisation | Vomiting, some dehydration, looking terrible, weak, tremor, was dizzy with blurred vision | Efexor ceased. Observation. |
| Asthenia | Caused or prolonged inpatient hospitalisation | | |
| Dehydration | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**BUPRENORPHINE HYDROCHLORIDE (Suspected)** **Reason:**
12.0 Milligram
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient had 20+ cups of coffee/pay with little food.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 203612 **Seq:** 1
**Reported:** 16/12/2004
**Hospitalisation:** Admitted to hospital
**Onset Date:** 17/08/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 56.00
**Age:** 33
**DOB:** 20/02/1971
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness | Caused or prolonged inpatient hospitalisation | | |
| Tremor | Caused or prolonged inpatient hospitalisation | | |
| Vision blurred | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**BUPRENORPHINE HYDROCHLORIDE (Suspected)** **Reason:**
12.0 Milligram
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

## Laboratory Investigations:

## Additional Information:

Patient had 20+ cups of coffee/pay with little food.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203821 **Seq:** 1 **Gender:** F
**Reported:** 24/12/2004 **Weight:** 150.00
**Hospitalisation:** Admitted to hospital **Age:** 38
**Onset Date:** 18/11/2004 **DOB:** 23/10/1966
**Outcome:** Recovered 18/11/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Grand mal convulsion | Caused or prolonged inpatient hospitalisation | Grand mall seizure - one episode only lasted about 1-2 minutes. | IV Midazolam given. |

### Medicine Details:

**TRAMADOL HYDROCHLORIDE (Interaction)** **Reason:** Other disturbance of sensation
**Batch:** **Started:** 12/11/2004 **Stopped:** 12/11/2004 0

**DICLOFENAC SODIUM (Interaction)** **Reason:**
**Batch:** **Started:** 12/11/2004 **Stopped:** 18/11/2004

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** 0

**PARACETAMOL (Other drug)** **Reason:**
As necessary Oral
**Batch:** **Started:** 12/11/2004 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was in-patient in the hospital post confinement and has had postdural puncture headache.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203909 **Seq:** 1
**Reported:** 04/01/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** M
**Weight:** 0.00
**Age:** 99U
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arrhythmia | Caused or prolonged inpatient hospitalisation | Patient experienced irregular heartbeat and spleen damage. | Cardioconversion twice. |
| Spleen disorder | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**DIAMICRON MR (Other drug)** **Reason:** Diabetes mellitus
**Batch:** **Started:** **Stopped:**

**BETALOC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**LOSEC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ZYLOPRIM (Other drug)** **Reason:** Gout
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203909 **Seq:** 1
**Reported:** 04/01/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** M
**Weight:** 0.00
**Age:** 99U
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **DIABEX (Other drug)** | | | **Reason:** | Diabetes mellitus | |
| Tablet | 1500.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression | |
| Capsule, modified release | 75.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | S TERM | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 203971 **Seq:** 1 **Gender:** U
**Reported:** 06/01/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Death, maybe drug **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Completed suicide | | The patient committed suicide whilst on | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204149 **Seq:** 1 **Gender:** F
**Reported:** 12/01/2005 **Weight:** 65.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 30/11/2004 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia | Required Visit to Doctor | The patient experienced insomnia often, psychedelic dreams and nightmares. She suffered severe withdrawal symptoms when tapering off | Changed to Fluoxetine. |
| Drug withdrawal syndrome | Required Visit to Doctor | | |
| Nightmare | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204157 **Seq:** 1
**Reported:** 12/01/2005
**Hospitalisation:**
**Onset Date:** 16/12/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 76.00
**Age:** 63
**DOB:** 25/08/1941
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea<br>Abdominal discomfort<br>Chills<br>Hyperhidrosis<br>Hypoaesthesia<br>Vomiting | | The patient experienced nausea, sweating/shivers, numbness, gastro-intestinal upset and dry retching after taking one tablet of Efexor XR | |

### Medicine Details:

**OGEN (Other drug)** **Reason:**
Tablet Oral
**Batch:** **Started:** L TERM **Stopped:**

**OROXINE (Other drug)** **Reason:**
Tablet Oral
**Batch:** **Started:** L TERM **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Tablet 75.0 Milligram 1 time Oral
**Batch:** **Started:** 16/12/2004 **Stopped:** 16/12/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204173 **Seq:** 1
**Reported:** 13/01/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 02/10/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 78Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | The patient experienced hyponatraemia and vomiting. | Slow IV N/S and fluid restriction. Ceased Avapro HCT and Efexor |
| Vomiting | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**OMEPRAZOLE (Other drug)** **Reason:**
20.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**VIOXX (Other drug)** **Reason:** Osteoarthritis
Oral
**Batch:** **Started:** **Stopped:** 01/10/2004

**PARACETAMOL (Other drug)** **Reason:**
6.0 Dose Unspecified Oral
**Batch:** **Started:** **Stopped:**

**CHLORSIG (Other drug)** **Reason:**
Eye Drops Intraocular
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 13/01/2005 | Serum osmolality | | 03/10/2004 | 239 | |
| 13/01/2005 | Serum osmolality | | 09/10/2004 | 291 | |
| 13/01/2005 | Serum osmolality | | 10/10/2004 | 283 | |
| 13/01/2005 | Sodium | | 03/10/2004 | 112 mmol/L | |
| 13/01/2005 | Sodium | | 04/10/2004 | 121 | |
| 13/01/2005 | Sodium | | 06/10/2004 | 128 | |
| 13/01/2005 | Sodium | | 07/10/2004 | 130 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204173 **Seq:** 1
**Reported:** 13/01/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 02/10/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 78Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **FOSAMAX (Other drug)** | | | **Reason:** | Osteoporosis | |
| | 70.0 | Milligram | Weekly | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **AVAPRO HCT 150/12.5 (Suspected)** | | | **Reason:** | Essential benign hypertension | |
| Tablet | 1.0 | Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** | 25/09/2004 | | **Stopped:** | 02/10/2004 |
| **EFEXOR (Suspected)** | | | **Reason:** | Anxiety neurosis | |
| | 38.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 25/09/2004 | | **Stopped:** | 02/10/2004 |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 13/01/2005 | Sodium | | 08/10/2004 | 131 | |
| 13/01/2005 | Sodium | | 09/10/2004 | 134 | |
| 13/01/2005 | Sodium | | 10/10/2004 | 134 | |
| 13/01/2005 | Urine Sodium | | 06/10/2004 | 7 | |
| 13/01/2005 | Urine osmolality | | 03/10/2004 | 526 | |
| 13/01/2005 | Urine osmolality | | 06/10/2004 | 522 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204210 **Seq:** 1 **Gender:** M
**Reported:** 13/01/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 78
**Onset Date:** 15/11/2004 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia<br><br>Fatigue<br>Feeling hot | | Patient had been unable to sleep because the cream had made his skin hot. Also noted tiredness and wants to lie in bed. | |

### Medicine Details:

**THEOPHYLLINE (Other drug)** **Reason:**
Tablet, modified release 600.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**SERETIDE ACCUHALER NOS (Other drug)** **Reason:**
Inhalation 4.0 Dose Unspecified Inhalation
**Batch:** **Started:** **Stopped:**

**CALTRATE (Other drug)** **Reason:**
600.0 Milligram
**Batch:** **Started:** **Stopped:**

**FOSAMAX (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204210 **Seq:** 1 **Gender:** M
**Reported:** 13/01/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 78
**Onset Date:** 15/11/2004 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **EFEXOR (Suspected)** | | | | **Reason:** | Depression |
| | | | | | Oral |
| **Batch:** | **Started:** | 15/11/2004 | | **Stopped:** | |
| **ELOCON (Suspected)** | | | | **Reason:** | Otr ecz&der due otr&unsp cause |
| Cream | 1.0 | Dose Unspecified | Daily | | Topical |
| **Batch:** | **Started:** | 12/11/2004 | | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204369 **Seq:** 1 **Gender:** F
**Reported:** 18/01/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 24
**Onset Date:** 15/12/2004 **DOB:** 16/07/1980
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br><br>Nausea<br>Visual disturbance | | Possible withdrawal effects: nausea, vision abnormal . | Took dose of Efexor-XR |

### Medicine Details:

**LEVLEN ED (Other drug)** **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/11/2004 **Stopped:** 15/12/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Suspected drug positive rechallenge.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204429 **Seq:** 1 **Gender:** M
**Reported:** 22/01/2005 **Weight:** 80.00
**Hospitalisation:** **Age:** 25
**Onset Date:** 28/04/2004 **DOB:** 02/06/1978
**Outcome:** Death, maybe drug 28/04/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Completed suicide | | The patient took his life at the gap. | |

### Medicine Details:

**SODIUM VALPROATE (Other drug)** **Reason:** Depression
2.0 Gram Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule, modified release 300.0 Milligram Daily Oral
**Batch:** **Started:** 02/02/2004 **Stopped:**

**CIPRAMIL (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 05/01/2004 **Stopped:** 02/02/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204577 **Seq:** 1
**Reported:** 25/01/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 60.00
**Age:** 80
**DOB:** 28/05/1924
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Joint stiffness | Caused or prolonged inpatient hospitalisation | The patient experienced joint stiffness. He was unable to get out of bed to walk. | Venlafaxine and Methadone ceased. Oxycodone 5mg prn 4/24 was commenced. |

### Medicine Details:

**METHADONE HYDROCHLORIDE (Other drug)** **Reason:** Pain
1.0 Milligram
**Batch:** **Started:** 05/05/2004 **Stopped:**

**ALENDRONATE SODIUM (Other drug)** **Reason:** Osteoporosis
70.0 Milligram
**Batch:** **Started:** **Stopped:**

**SORBITOL (Other drug)** **Reason:** Constipation
60.0 Millilitre
**Batch:** **Started:** **Stopped:**

**OMEPRAZOLE (Other drug)** **Reason:** Other diseases of esophagus
20.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

## Report Detail

**Case Number:** 204577 **Seq:** 1
**Reported:** 25/01/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 60.00
**Age:** 80
**DOB:** 28/05/1924
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **ASPIRIN (Other drug)** | | | **Reason:** | | | |
| | 100.0 | Milligram | | Daily | | |
| **Batch:** | **Started:** | | L TERM | | **Stopped:** | |
| **CENTRUM TABLETS (Other drug)** | | | **Reason:** | | | |
| Tablet | 1.0 | Dose Unspecified | | Daily | | Oral |
| **Batch:** | **Started:** | | L TERM | | **Stopped:** | |
| **PARACETAMOL (Other drug)** | | | **Reason:** | | | |
| | 3.0 | Gram | | Daily | | |
| **Batch:** | **Started:** | | L TERM | | **Stopped:** | |
| **COLOXYL WITH SENNA (Other drug)** | | | **Reason:** | Constipation | | |
| Tablet | 6.0 | Dose Unspecified | | Daily | | Oral |
| **Batch:** | **Started:** | | L TERM | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204577 **Seq:** 1
**Reported:** 25/01/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 60.00
**Age:** 80
**DOB:** 28/05/1924
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204690 **Seq:** 1 **Gender:** F
**Reported:** 27/01/2005 **Weight:** 79.00
**Hospitalisation:** **Age:** 50
**Onset Date:** **DOB:** 28/04/1954
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia | | The patient experienced marked nausea and vomiting preceded by tingling in the arms within 15 minutes of taking Efexor 75 slow release | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram 1 time
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204786 **Seq:** 1
**Reported:** 01/02/2005
**Hospitalisation:**
**Onset Date:** 27/10/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 99U
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness | Required Visit to Doctor | After one capsule patient felt a little strange, a sort of light headedness, revolted by the thought of food, excessive sweating, nausea, dizziness, disorientation and possibel collapse twice resulting in an injured foot. | |
| Circulatory collapse | Required Visit to Doctor | | |
| Disorientation | Required Visit to Doctor | | |
| Dizziness | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Oral
**Batch:** **Started:** 27/10/2004 **Stopped:** 27/10/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204786 **Seq:** 1 **Gender:** F
**Reported:** 01/02/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** 27/10/2004 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | Required Visit to Doctor | | |
| Nausea | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Oral
**Batch:** **Started:** 27/10/2004 **Stopped:** 27/10/2004

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204892 **Seq:** 1 **Gender:** M
**Reported:** 04/02/2005 **Weight:** 47.00
**Hospitalisation:** Admitted to hospital **Age:** 61
**Onset Date:** 08/01/2005 **DOB:** 03/05/1943
**Outcome:** Recovered 12/01/2005 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | Caused or prolonged inpatient hospitalisation | Severe headache, blurred vision, nausea and vomiting, "severe shakes", tachycardia. Reaction lasted 4 hours. | Required ambulance and hospitalisation, for 2 hours (observation). |
| Nausea | Caused or prolonged inpatient hospitalisation | | |
| Tachycardia | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**NEXIUM (Other drug)** **Reason:** Other diseases of esophagus
Tablet 40.0 Milligram Oral
**Batch:** **Started:** 17/12/2004 **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 08/01/2005 **Stopped:** 08/01/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204892 **Seq:** 1 **Gender:** M
**Reported:** 04/02/2005 **Weight:** 47.00
**Hospitalisation:** Admitted to hospital **Age:** 61
**Onset Date:** 08/01/2005 **DOB:** 03/05/1943
**Outcome:** Recovered 12/01/2005 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | Caused or prolonged inpatient hospitalisation | | |
| Vision blurred | Caused or prolonged inpatient hospitalisation | | |
| Vomiting | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**NEXIUM (Other drug)** **Reason:** Other diseases of esophagus
Tablet 40.0 Milligram Oral
**Batch:** **Started:** 17/12/2004 **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 08/01/2005 **Stopped:** 08/01/2005

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 204988 **Seq:** 1 **Gender:** M
**Reported:** 07/02/2005 **Weight:** 90.00
**Hospitalisation:** **Age:** 28
**Onset Date:** 13/12/2004 **DOB:** 22/06/1976
**Outcome:** Recovered 13/12/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Supraventricular tachycardia | Life | Patient developed supraventricular | Verapamil 5mg. |

### Medicine Details:

**CO-PHENYLCAINE (Interaction)** **Reason:**
Spray 5.0 Millilitre 1 time Nasal
**Batch:** **Started:** **Stopped:**

**ADRENALINE (Interaction)** **Reason:**
1.0 Milligram 1 time
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205080 **Seq:** 1 **Gender:** F
**Reported:** 09/02/2005 **Weight:** 74.00
**Hospitalisation:** **Age:** 51
**Onset Date:** 26/01/2005 **DOB:** 21/12/1953
**Outcome:** Recovered without treatment 01/02/2005 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension | Required Visit to Doctor | Severe anxiety and irritability. Rapid heart rate. Elevated blood pressure - c. 200/95. Headache | Stopped taking medication - personal decision; No further use of medication |
| Anxiety | Required Visit to Doctor | | |
| Irritability | Required Visit to Doctor | | |
| Tachycardia | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram 1 time Oral
**Batch:** B78 **Started:** 25/01/2005 **Stopped:** 27/01/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205158 **Seq:** 1
**Reported:** 10/02/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 24/10/2004
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 81
**DOB:** 04/01/1923
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pitting oedema | Caused or prolonged inpatient hospitalisation | The patient experienced a pitting lower leg [illegible] | Patient was started on Lasix (as oedema was thought to be secondary to CCF), Warfarin and Clexane given |

### Medicine Details:

**AVANZA (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**LASIX (Suspected)** **Reason:** Edema and dropsy
**Batch:** **Started:** **Stopped:** 0

**WARFARIN SODIUM (Suspected)** **Reason:** Edema and dropsy
Tablet Oral
**Batch:** **Started:** **Stopped:** 0

**CLEXANE (Suspected)** **Reason:** Edema and dropsy
Injection
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Pre-existing conditions: anaemia, hypercholesterolaemia, dementia and hypertension.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205158 **Seq:** 1
**Reported:** 10/02/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 24/10/2004
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 81
**DOB:** 04/01/1923
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **EFEXOR-XR (Suspected)** | | | **Reason:** Depression | |
| Tablet | 75.0 Milligram | | Daily | Oral |
| **Batch:** | **Started:** 21/10/2004 | | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:

Pre-existing conditions: anaemia, hypercholesterolaemia, dementia and hypertension.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205197 **Seq:** 1
**Reported:** 11/02/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 50
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Liver function test abnormal | Caused or prolonged inpatient hospitalisation | The patient experienced worsening of liver function tests. | |

### Medicine Details:

**SEROQUEL (Suspected)** **Reason:**

Tablet 200.0 Milligram Daily Oral

**Batch:** **Started:** L TERM **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**

75.0 Milligram Daily

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 11/02/2005 | Other data | | | | Liver scan was normal. |

### Additional Information:

History: Liver function test abnormal. Anormal liver function tests prior to hospital admissin, which has worsened after his co-medication was switched from Citalopram to Venlafaxine.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205299 **Seq:** 1 **Gender:** U
**Reported:** 16/02/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cardiomyopathy | | Patient experienced cardiomyopathy. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule, modified release 150.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205303 **Seq:** 1
**Reported:** 16/02/2005
**Hospitalisation:** Required a specialist consultation
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 58
**DOB:** 27/10/1946
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic function abnormal | Required Specialist Consultation | Patient experienced hepatitis. | |
| Liver function test abnormal | Required Specialist Consultation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

Capsule, modified release 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

"Reporter does not believe hepatitis was a result of Efexor. Efexor was stopped on an unknown date and patient started on Aurorix. Patient couldn't tolerate Aurorix so it was stopped and Avanza initiated.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205307 **Seq:** 1
**Reported:** 16/02/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Patient experienced hyponatraemia. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule, modified release Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205393 **Seq:** 1 **Gender:** F
**Reported:** 17/02/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** 27/12/2004 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nightmare<br><br>Drug ineffective<br>Somnolence<br>Suicidal ideation | | Recurrent nightmares, suicidal thoughts, feeling bombed. | Cut dose down to 75mg. |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 14/12/2004 **Stopped:** 05/01/2005 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205398 **Seq:** 1 **Gender:** M
**Reported:** 18/02/2005 **Weight:** 0.00
**Hospitalisation:** Admitted to hospital **Age:** 89
**Onset Date:** 14/02/2005 **DOB:** 13/03/1915
**Outcome:** Recovered 16/02/2005 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Patient was started on Efexor 25mg SR for depression during a recent hospital visit. Discharged on 11/2/05. On 14/2/05 got out of bed in morning, felt dizzy and collapsed to the floor. Was taken to hospital where he was found ot be hyponatremic (122mmol). | Withdrawal of medication |
| Circulatory collapse | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

| | | | |
|---|---|---|---|
| **PANADOL (Other drug)** | | **Reason:** | |
| Tablet | | As necessary | Oral |
| **Batch:** | **Started:** | **Stopped:** | |
| **SOMAC (Other drug)** | | **Reason:** | |
| Tablet | | Daily | Oral |
| **Batch:** | **Started:** | **Stopped:** | |
| **AVAPRO (Other drug)** | | **Reason:** | |
| Tablet | | Daily | Oral |
| **Batch:** | **Started:** | **Stopped:** | |
| **EFEXOR-XR (Suspected)** | | **Reason:** | |
| Tablet | | Daily | Oral |
| **Batch:** | **Started:** 11/02/2005 | **Stopped:** | 14/02/2005 |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 18/02/2005 | Sodium | | | | Na back up to 138mmol by 16/2/05 |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205398 **Seq:** 1 **Gender:** M
**Reported:** 18/02/2005 **Weight:** 0.00
**Hospitalisation:** Admitted to hospital **Age:** 89
**Onset Date:** 14/02/2005 **DOB:** 13/03/1915
**Outcome:** Recovered 16/02/2005 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**PANADOL (Other drug)** **Reason:**
Tablet As necessary Oral
**Batch:** **Started:** **Stopped:**

**SOMAC (Other drug)** **Reason:**
Tablet Daily Oral
**Batch:** **Started:** **Stopped:**

**AVAPRO (Other drug)** **Reason:**
Tablet Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Tablet Daily Oral
**Batch:** **Started:** 11/02/2005 **Stopped:** 14/02/2005

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205406 **Seq:** 1
**Reported:** 21/02/2005
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 60
**DOB:** 05/11/1944
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Psychotic disorder | Required Visit to Doctor | The patient developed psychotic depression whilst on 150mg daily from which she fully recovered. She then 'gradually deteriorated'. Efexor-XR was increased and she experienced worsened depression, suicidal ideation, Parkinsonism-type shaking, constant mouth movement, lip biting, flushing, perspiring, intermittent sleep disturbances and 'funny sensations' in the legs when | |
| Depression | Required Visit to Doctor | | |
| Flushing | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** Continuing.

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205406 **Seq:** 1
**Reported:** 21/02/2005
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 60
**DOB:** 05/11/1944
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | Required Visit to Doctor | | |
| Parkinsonism | Required Visit to Doctor | | |
| Sleep disorder | Required Visit to Doctor | | |
| Suicidal ideation | Required Visit to Doctor | | |
| Tardive dyskinesia | Required Visit to Doctor | | |
| Tremor | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** Continuing.

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205567 **Seq:** 1
**Reported:** 25/02/2005
**Hospitalisation:**
**Onset Date:** 11/02/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 77.00
**Age:** 33
**DOB:** 12/03/1971
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Neutropenia | | The patient had a decrease in neutrophil count and white blood cell count. | |

### Medicine Details:

**CLOZARIL (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 15/09/2004 **Stopped:** 11/02/2005 0

**LAMICTAL (Suspected)** **Reason:**
Tablet 25.0 Milligram Daily Oral
**Batch:** **Started:** 15/01/2005 **Stopped:** 12/02/2005

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 20/01/2005 **Stopped:** 12/02/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 25/02/2005 | White blood cells | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205655 **Seq:** 1 **Gender:** F
**Reported:** 01/03/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 69Y
**Onset Date:** 03/02/2005 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypotension<br><br>Fall<br>Syncope | | 02/02/05- Blood pressure of 100/60.<br>03/02/05- Systolic blood pressure of 70, and faint | |

### Medicine Details:

**SINEMET (Other drug)** **Reason:**
Tablet 3.0 Oral
**Batch:** **Started:** **Stopped:**

**DILTIAZEM HYDROCHLORIDE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**SIMVASTATIN (Other drug)** **Reason:**
Tablet 40.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**MADOPAR (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205655 **Seq:** 1
**Reported:** 01/03/2005
**Hospitalisation:**
**Onset Date:** 03/02/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 69Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **PREMARIN (Other drug)** | | | **Reason:** | | | |
| Tablet | 0.0 | Milligram | | Oral | | |
| **Batch:** | **Started:** | | | **Stopped:** | | |
| **CLOPIDOGREL (Other drug)** | | | **Reason:** | | | |
| Tablet | 75.0 | Milligram | Daily | Oral | | |
| **Batch:** | **Started:** | | | **Stopped:** | 0 | |
| **EDRONAX (Suspected)** | | | **Reason:** | Depression | | |
| Tablet | 4.0 | Milligram | Daily | Oral | | |
| **Batch:** | **Started:** | 31/01/2005 | | **Stopped:** | Continuing | |
| **PRESSIN (Suspected)** | | | **Reason:** | | | |
| Tablet | 6.0 | Milligram | Daily | Oral | | |
| **Batch:** | **Started:** | 01/03/2000 | | **Stopped:** | 28/02/2005 | 0 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205655 **Seq:** 1
**Reported:** 01/03/2005
**Hospitalisation:**
**Onset Date:** 03/02/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 69Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** 01/03/2001 **Stopped:** 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205734 **Seq:** 1
**Reported:** 03/03/2005
**Hospitalisation:**
**Onset Date:** 07/12/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 70.00
**Age:** 39
**DOB:** 25/08/1965
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Disorientation | Required Visit to Doctor | Patient felt that they were in another world, had no drive, wanted to sleep, sweaty palms, tears, became very depressed, feelings of being unsafe, dizziness, yawning, weight gain | Weaned off Efexor to half tab every 2 days. |
| Anxiety | Required Visit to Doctor | | |
| Apathy | Required Visit to Doctor | | |
| Depression | Required Visit to Doctor | | |
| Dizziness | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

75.0 Milligram Daily

**Batch:** **Started:** 01/12/2004 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205734 **Seq:** 1
**Reported:** 03/03/2005
**Hospitalisation:**
**Onset Date:** 07/12/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 70.00
**Age:** 39
**DOB:** 25/08/1965
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fatigue | Required Visit to Doctor | | |
| Hyperhidrosis | Required Visit to Doctor | | |
| Tearfulness | Required Visit to Doctor | | |
| Weight increased | Required Visit to Doctor | | |
| Yawning | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 01/12/2004 **Stopped:** 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205735 **Seq:** 1
**Reported:** 03/03/2005
**Hospitalisation:**
**Onset Date:** 07/12/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 70.00
**Age:** 39
**DOB:** 25/08/1965
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Required Visit to Doctor | Withdrawal symptoms, very dizzy, upset stomach, feel queezy, can't eat much, ache all over even teeth, senses became very sharp/smell, touch, easily startled, find it hard to relax, cried uncontrollabley. | Advised to take half tablet Efexor every 36 hours. |
| Agitation | Required Visit to Doctor | | |
| Crying | Required Visit to Doctor | | |
| Dizziness | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
19.0 Milligram Alternate days
**Batch:** **Started:** 01/12/2004 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205735 **Seq:** 1
**Reported:** 03/03/2005
**Hospitalisation:**
**Onset Date:** 07/12/2004
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 70.00
**Age:** 39
**DOB:** 25/08/1965
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia | Required Visit to Doctor | | |
| Nausea | Required Visit to Doctor | | |
| Stomach discomfort | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
19.0 Milligram Alternate days
**Batch:** **Started:** 01/12/2004 **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205865 **Seq:** 1
**Reported:** 09/03/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 25/02/2005
**Outcome:** Recovered

**Gender:** F
**Weight:** 85.00
**Age:** 17
**DOB:** 03/11/1987
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | Life | First suicide attempt 4 days after being prescribed antidepressant for first time. | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Capsule 38.0 Milligram Daily Oral

**Batch:** **Started:** 21/02/2005 **Stopped:** 25/02/2005 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

3 years of suicidal ideation.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 205889 **Seq:** 1 **Gender:** M
**Reported:** 09/03/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 66Y
**Onset Date:** 15/01/2005 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea | Required Visit to Doctor | January 05 patient put on Efexor XR 75mg for 10 days, felt nauseous and "zombie like" | Efexor XR stopped after 10 |
| Depersonalisation | Required Visit to Doctor | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/01/2005 **Stopped:** 25/01/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Report 205891 is the second sequence to this report.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206033 **Seq:** 1
**Reported:** 15/03/2005
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Syncope<br><br>Suicidal ideation | | The patient fainted after taking Efexor-XR 150mg bd for 3 weeks. She was also suicidal | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 300.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206070 **Seq:** 1 **Gender:** M
**Reported:** 16/03/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** **DOB:**
**Outcome:** Death, maybe drug **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Completed suicide | | The patient committed suicide 48 hours after starting Efexor-XR. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Heavy marijuana user, past Aropaxz treatment.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206106 **Seq:** 1 **Gender:** M
**Reported:** 16/03/2005 **Weight:** 103.90
**Hospitalisation:** **Age:** 77
**Onset Date:** 20/02/2005 **DOB:** 13/09/1927
**Outcome:** Recovered 01/03/2005 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Inappropriate antidiuretic hormon | | Patient developed SIADH. | |

### Medicine Details:

**PLAVIX (Other drug)** **Reason:** Transient cereb isch no hypert
**Batch:** **Started:** **Stopped:** 0

**COVERSYL (Other drug)** **Reason:** Essential benign hypertension
**Batch:** **Started:** **Stopped:**

**ATENOLOL (Other drug)** **Reason:** Essential benign hypertension
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 14/02/2005 **Stopped:** 20/02/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206106 **Seq:** 1 **Gender:** M
**Reported:** 16/03/2005 **Weight:** 103.90
**Hospitalisation:** **Age:** 77
**Onset Date:** 20/02/2005 **DOB:** 13/09/1927
**Outcome:** Recovered 01/03/2005 **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **INDAPAMIDE HEMIHYDRATE (Suspected)** | | | | **Reason:** | Essential benign hypertension |
| Tablet | 1.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | 20/02/2005 |
| **OMEPRAZOLE (Suspected)** | | | | **Reason:** | Otr disorders stomach function |
| | 20.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | 22/02/2005 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206129 **Seq:** 1
**Reported:** 17/03/2005
**Hospitalisation:**
**Onset Date:** 10/02/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 53.00
**Age:** 71
**DOB:** 23/07/1933
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tardive dyskinesia | | Patient developed lip smacking, involuntary teeth grinding, probable tardive dyskinesia. | Stop Efexor over next 10 days-reducing dose. |

### Medicine Details:

**COVERSYL PLUS (Other drug)** **Reason:** Essential benign hypertension
Tablet 1.0 Dose Unspecified Oral
**Batch:** **Started:** 15/04/2004 **Stopped:**

**ORUDIS SR (Other drug)** **Reason:**
200.0 Milligram
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 20/12/2004 **Stopped:** 15/03/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Started soon after increasing Efexor from 75 to 150mg.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206247 **Seq:** 1
**Reported:** 23/03/2005
**Hospitalisation:**
**Onset Date:**
**Outcome:** Recovered

**Gender:** M
**Weight:** 80.00
**Age:** 34
**DOB:** 30/08/1970
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Therapy regimen changed | Life | Dose had been increased from 150mg to 225mg one week prior to admission | Kept in intensive care, Venlafaxine ceased, changed to Lovan |
| Encephalopathy | Life | The patient developed a severe headache with coitus and was brought to hospital where he was observed to have a seizure. It seems likely that his hypertension was related to Venlafaxine and this appears to have caused an encephalopathy and associated seizures. | Venlafaxine ceased, changed to Lovan. |
| Convulsion | Life | | |
| Headache | Life | | |
| Hypertension | Life | | |

### Medicine Details:

**LIPITOR (Other drug)** **Reason:** Othr&unspec metabolic diseases
Tablet 80.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**LOSEC (Other drug)** **Reason:** Other diseases of esophagus
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
225.0 Milligram Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 23/03/2005 | Magnetic | | | | Some non specific changes seen involving the cortex. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206499 **Seq:** 1 **Gender:** M
**Reported:** 02/04/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 51Y
**Onset Date:** 07/03/2005 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal convulsions | Life | The patient fitted about two weeks after withdrawal of Valproate. | |

### Medicine Details:

**OROXINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**LOSEC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**TEMAZE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**Memantine Hydrochloride (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The reporter suspected that the fitting was the result of too rapid withdrawal of valproate and intriduction of memantine.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 206499 **Seq:** 1 **Gender:** M
**Reported:** 02/04/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 51Y
**Onset Date:** 07/03/2005 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **EFEXOR (Suspected)** | | | **Reason:** | | |
| | | | | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **EPILIM (Suspected)** | | | **Reason:** | Otr spec symp psychopathol nec | |
| Tablet | 800.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

The reporter suspected that the fitting was the result of too rapid withdrawal of valproate and intriduction of memantine.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206557 **Seq:** 1 **Gender:** F
**Reported:** 02/04/2005 **Weight:** 90.00
**Hospitalisation:** **Age:** 27
**Onset Date:** 16/03/2005 **DOB:** 06/05/1977
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Affect lability | Incapacity/disability | Patient experienced emotional, weepy, panic attacks, shaky and stressed, unable to cope | Advised to cease Celebrex and contact GP immediately. |
| Stress | Incapacity/disability | | |
| Tremor | Incapacity/disability | | |

### Medicine Details:

**EFEXOR (Interaction)** **Reason:**
Tablet, modified release 150.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/2003 **Stopped:**

**CELEBREX (Interaction)** **Reason:**
Capsule 200.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Stable on Efexor SR 150mg for 2 years, commenced Celebrex 200mg 2 daily and noticed immediate recurrence of symptoms.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206579 **Seq:** 1 **Gender:** F
**Reported:** 04/04/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 24
**Onset Date:** **DOB:** 17/10/1980
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Obsessive-compulsive disorder | Incapacity/disability | The patient noticed white coloured granules in her stools, her obsessive compulsive disorder increased 'tenfold', she had panic attacks, her anxiety level became unbearable and her depression escalated and included suicidal thoughts. She stated that the reason for her deterioration in health was because she had found that her medication was getting flushed down the toilet instead of being digested into her system and drawn into her blood stream, thus forfeiting its | |
| Abnormal faeces | Incapacity/disability | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Obsessive compulsive neurosis

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 206579 **Seq:** 1 **Gender:** F
**Reported:** 04/04/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 24
**Onset Date:** **DOB:** 17/10/1980
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety | Incapacity/disability | | |
| Condition aggravated | Incapacity/disability | | |
| Depression | Incapacity/disability | | |
| Drug ineffective | Incapacity/disability | | |
| Panic attack | Incapacity/disability | | |
| Suicidal ideation | Incapacity/disability | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Obsessive compulsive neurosis

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206668 **Seq:** 1 **Gender:** F
**Reported:** 05/04/2005 **Weight:** 76.00
**Hospitalisation:** **Age:** 46
**Onset Date:** **DOB:** 15/10/1958
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br><br>Hyperhidrosis<br>Mood swings<br>Poor quality sleep | | The patient experienced a withdrawal reaction from Efexor XR. She experienced marked mood swings, sweats, night waking and poor sleep. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

These are reactions from Efexor XR withdrawal.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206719 **Seq:** 1 **Gender:** F
**Reported:** 07/04/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 29
**Onset Date:** 13/02/2003 **DOB:** 04/02/1974
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug interaction | Caused or prolonged inpatient hospitalisation | The patient was admitted to hospital with rhabdomyolysis secondary to seizures. | The patient was resuscitated, intubated, ventilated and required inotropes. Valproate, Venlafaxine and Quetiapine were ceased. |
| Neuroleptic malignant syndrome | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

| | | | |
|---|---|---|---|
| **PANADOL (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **SANDOMIGRAN (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **MERSYNDOL (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **DIAZEPAM (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

A drug interaction between Stilnos, Quetiapine, Valproate and Venlafaxine was suspected. Valproate, Venlafaxine and Quetipaine were withdraw. Valproate and Venlafaxine were subsequenctly restarted without adverse event.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206719 **Seq:** 1 **Gender:** F
**Reported:** 07/04/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 29
**Onset Date:** 13/02/2003 **DOB:** 04/02/1974
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **PROMETHAZINE HYDROCHLORIDE (Other drug)** | | | **Reason:** | | | |
| **Batch:** | **Started:** | | | **Stopped:** | | |
| **SALBUTAMOL (Other drug)** | | | **Reason:** | | | |
| **Batch:** | **Started:** | | | **Stopped:** | | |
| **STILNOX (Suspected)** | | | **Reason:** | Convulsions | | |
| Tablet | | | | | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | | 0 |
| **QUETIAPINE (Suspected)** | | | **Reason:** | | | |
| Tablet | 150.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | 13/02/2003 | |

### Laboratory Investigations:

### Additional Information:

A drug interaction between Stilnos, Quetiapine, Valproate and Venlafaxine was suspected. Valproate, Venlafaxine and Quetipaine were withdraw. Valproate and Venlafaxine were subsequenctly restarted without adverse event.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206719 **Seq:** 1
**Reported:** 07/04/2005
**Hospitalisation:**
**Onset Date:** 13/02/2003
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 29
**DOB:** 04/02/1974
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **SODIUM VALPROATE (Suspected)** | | | **Reason:** | Convulsions | |
| Tablet | 1.0 | Gram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | 0 |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | | |
| | 150.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | 0 |

### Laboratory Investigations:

### Additional Information:

A drug interaction between Stilnos, Quetiapine, Valproate and Venlafaxine was suspected. Valproate, Venlafaxine and Quetipaine were withdraw. Valproate and Venlafaxine were subsequenctly restarted without adverse event.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 206907 **Seq:** 1 **Gender:** M
**Reported:** 11/04/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 51
**Onset Date:** 07/04/2005 **DOB:** 13/10/1953
**Outcome:** Recovered with sequelae 11/04/2005 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Circulatory collapse | Life | Patient has been taking venlafaxine XR 300 mg mane, for 3 years. Inadvertently consumed moclobemide 300 mg tablets (2 or 3, according to patient). Noted to collapse and experience clonus approximately 20 minutes later. Taken to hospital, where required intubation and ICU | Intubation and ventilation in ICU for 24 hours, supportive care. Cessation of moclobemide. Withheld venlafaxine for four days. |
| Clonus | Life | | |
| Hypoxia | Life | | |
| Medication error | Life | | |

### Medicine Details:

**EFEXOR-XR (Interaction)** **Reason:**
Capsule 300.0 Milligram 1 time Oral
**Batch:** **Started:** 01/04/2002 **Stopped:** 0

**MOCLOBEMIDE (Interaction)** **Reason:**
Tablet 600.0 Milligram 1 time Oral
**Batch:** **Started:** 07/04/2005 **Stopped:** 07/04/2005 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207014 **Seq:** 1 **Gender:** M
**Reported:** 14/04/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vision blurred<br>Angle closure glaucoma<br>Intraocular pressure increased<br>Ocular discomfort<br>Therapy regimen changed | | The patient experienced aggravated right visual blurring and visual discomfort overngiht. Symptoms were occurring about every other day. Intraocular pressures were 69 mmHg (right eye) and 62 mmHg (left eye). Gonioscopy revealed lateral completely closed angles. | Given IV Mannitol 100g over 40 minutes, oral Acetazolamide 500mg, topical Timolol 0.5%, Apraclonidine 1% and Pilocarpine 2%. Bilateral laser peripheral iridotomies were performed. Venlafaxine |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 14/04/2005 | Other data | | | | Ultrasound biomicroscopy showed bilateral supraciliary effusions and anterior chamber shallowing (Box 1). Manifest refraction (ie, manual subjective measurement of refractive error) at this time revealed a myopic shift of about 3 dioptres in each eye. |

### Additional Information:

Bilateral acute angle closure caused by supraciliary effusions asociated with Venlafaxine intake. Maria Hannah Pia de Guzman, Sureka Thiagalingam, Poh Yan Ong and Ivan Goldberg. MJA 2005; 182 (3): 121-123.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207131 **Seq:** 1 **Gender:** F
**Reported:** 18/04/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 62Y
**Onset Date:** 26/07/2004 **DOB:**
**Outcome:** Recovered 27/07/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Severe hyponatraemia leading to cerebral oedema and decreased conscious state. | Venlafaxine was ceased and treatment was cautiously started with Mirtazapine and Olanzapine with good effect. Slow sodium replacement. |
| Brain oedema | Caused or prolonged inpatient hospitalisation | | |
| Depressed level of consciousnes | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**ATENOLOL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ZOPICLONE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**SLOW-K (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**XALATAN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 18/04/2005 | Sodium | | | | Sodium - 110mmol. |

### Additional Information:

Report 207128 is the first sequence to this report

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207131 **Seq:** 1 **Gender:** F
**Reported:** 18/04/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 62Y
**Onset Date:** 26/07/2004 **DOB:**
**Outcome:** Recovered 27/07/2004 **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **DIAZEPAM (Other drug)** | | | **Reason:** | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 38.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 22/07/2004 | | **Stopped:** | 26/07/2004 |
| **CHLORTHALIDONE (Suspected)** | | | **Reason:** | Polyuria | |
| Tablet | 25.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | 26/07/2004 |

### Laboratory Investigations:

### Additional Information:
Report 207128 is the first sequence to this report

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207224 **Seq:** 1
**Reported:** 19/04/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 14/01/2005
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 53
**DOB:** 13/10/1951
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Overdose | Caused or prolonged inpatient hospitalisation | The patient overdosed with Efexor XR and Panadol. When Efexor XR was stopped she experienced withdrawal effects - really bad headaches, shaking and she 'couldn't function', so it was restarted. She had tried to taper Efexor XR in the past, but experienced bad headaches. She also had headaches when she forgot to take a dose. | Efexor XR ceased whilst in [illegible] |
| Drug withdrawal syndrome | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**PANADOL (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 15/07/2004 **Stopped:**

**STELAZINE (Suspected)** **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:** 09/02/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Prior to Efexor-XR, patient was on paroxetine, which did not help with depression. Patient advised she finds Efexor-XR helped, but life stresses "just get too much sometimes".

## Report Detail

**Case Number:** 207224 **Seq:** 1
**Reported:** 19/04/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 14/01/2005
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 53
**DOB:** 13/10/1951
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | Caused or prolonged inpatient hospitalisation | | |
| Tremor | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**PANADOL (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 15/07/2004 **Stopped:**

**STELAZINE (Suspected)** **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:** 09/02/2005

## Laboratory Investigations:

## Additional Information:

Prior to Efexor-XR, patient was on paroxetine, which did not help with depression. Patient advised she finds Efexor-XR helped, but life stresses "just get too much sometimes".

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207335 **Seq:** 1
**Reported:** 21/04/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 09/03/2005
**Outcome:** Recovered

**Gender:** M
**Weight:** 0.00
**Age:** 55
**DOB:** 19/04/1949
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tardive dyskinesia | Caused or prolonged inpatient hospitalisation | The patient experienced relapse psychosis, worsening of tardive dyskinesia and neutrophilia, vomiting, diarrhoea and leucocytosis and elevated liver enzymes. He may have been non-compliant with Clozaril treatment. | Clozaril dosage increased from 400mg/day to 450mg/day. Started electro-convulsive therapy |
| Diarrhoea | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**QUETIAPINE (Suspected)** **Reason:**
Tablet 100.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**VALIUM (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**CLOZARIL (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207335 **Seq:** 1
**Reported:** 21/04/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 09/03/2005
**Outcome:** Recovered

**Gender:** M
**Weight:** 0.00
**Age:** 55
**DOB:** 19/04/1949
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic enzyme increased | Caused or prolonged inpatient hospitalisation | | |
| Leukocytosis | Caused or prolonged inpatient hospitalisation | | |
| Neutrophilia | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**QUETIAPINE (Suspected)** **Reason:**
Tablet 100.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**VALIUM (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**CLOZARIL (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207335 **Seq:** 1
**Reported:** 21/04/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 09/03/2005
**Outcome:** Recovered

**Gender:** M
**Weight:** 0.00
**Age:** 55
**DOB:** 19/04/1949
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vomiting | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**QUETIAPINE (Suspected)** **Reason:**
Tablet 100.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**VALIUM (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**CLOZARIL (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207525 **Seq:** 1
**Reported:** 02/05/2005
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 10/03/2005
**Outcome:** Recovered

**Gender:** M
**Weight:** 70.00
**Age:** 21
**DOB:** 28/08/1983
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mydriasis<br><br>Ejaculation delayed | | The patient developed dilated pupils and ejaculation delay. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** 17/02/2005 **Stopped:** 14/04/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207595 **Seq:** 1
**Reported:** 04/05/2005
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depression suicidal | Treated in outpatient department only | Suicidal, discontinuation symptoms since tapering Venlafaxine, headaches, trembling, tingling and electric shocks, insomnia, nervousness, dizziness | Efexor tapered off then ceased. Treated with 2 to 3 Nurofen Plus tablets and 2 to 3 Panadol tablets (all taken at once). |
| Drug withdrawal syndrome | Treated in outpatient department only | | |
| Headache | Treated in outpatient department only | | |

### Medicine Details:

**VALIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NEULACTIL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NUROFEN PLUS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PANADOL (Other drug)** **Reason:** Headache
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207595 **Seq:** 1
**Reported:** 04/05/2005
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **EFEXOR (Suspected)** | | | **Reason:** | Depression |
| Tablet | 37.5 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 15/12/2004 | | **Stopped:** | |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression |
| Capsule | 75.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 15/12/2004 | | **Stopped:** | 14/04/2005 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207634 **Seq:** 1
**Reported:** 05/05/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 08/02/2005
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 85
**DOB:** 17/11/1919
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Hyponatraemia (Na 128). | Ceased Efexor-XR |

### Medicine Details:

| | | | |
|---|---|---|---|
| **MIRTAZAPINE (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **ASPIRIN (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **FOLIC ACID (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **RISPERIDONE (Other drug)** | | **Reason:** | Anxiety neurosis |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 05/05/2005 | Sodium | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207634 **Seq:** 1
**Reported:** 05/05/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 08/02/2005
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 85
**DOB:** 17/11/1919
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **OESTRIOL (Other drug)** | | | **Reason:** | Menopausal symptoms | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **ACTONEL (Other drug)** | | | **Reason:** | Other diseases of bone | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **AMOXYCILLIN-POTASSIUM CLAVULANATE (Other drug)** | | | **Reason:** | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 75.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | 09/02/2005 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207648 **Seq:** 1 **Gender:** M
**Reported:** 06/05/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 52
**Onset Date:** **DOB:** 09/05/1952
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Malaise<br><br><br><br><br><br><br>Asthenia<br>Back pain<br>Dysstasia | | Within half an hour of taking the first Efexor XR capsule, the patient was sick in the stomach, then laid down and fell asleep. Within 2 hours he had difficulty urinating. After the second capsule, he slept for two days. After the third capsule, he fell into a deep sleep and took 5-6 days to recover and about two weeks before he could 'return to normal'. He also experienced severe weakness in the back, arms and legs, found it hard to stand and his back pain worsened | Efexor XR ceased and restarted on 12/04/2005 at night |

### Medicine Details:

**DILOSYN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**INDERAL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**LOSEC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207648 **Seq:** 1 **Gender:** M
**Reported:** 06/05/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 52
**Onset Date:** **DOB:** 09/05/1952
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysuria<br>Hypersomnia<br>Systemic lupus erythematosus | | | |

### Medicine Details:

**DILOSYN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**INDERAL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**LOSEC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207724 **Seq:** 1 **Gender:** U
**Reported:** 11/05/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Haemorrhagic stroke | Life | Patient suffered a haemorrhagic stroke. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule, modified release Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207725 **Seq:** 1 **Gender:** U
**Reported:** 11/05/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Haemorrhagic stroke | Life | Patient expereinced a haemorrhagic | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule, modified release Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207763 **Seq:** 1 **Gender:** M
**Reported:** 12/05/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 63Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depression<br><br>Sexual dysfunction | | Patient expereinced sexual dysfunction and severe depression. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
225.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207896 **Seq:** 1 **Gender:** M
**Reported:** 17/05/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 76Y
**Onset Date:** 01/03/2005 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | Caused or prolonged inpatient hospitalisation | The patient became agitated, drowsy, vomited, experienced hallucinations, confusion, haematemesis and malaena. | Mirtazapine ceased. |
| Confusional state | Caused or prolonged inpatient hospitalisation | | |
| Haematemesis | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**ATORVASTATIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**METOPROLOL TARTRATE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**FOSINOPRIL-HYDROCHLOROTHIAZIDE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**OMEPRAZOLE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Admission notes indicate patient was often already confused with occasional hallucinations and patient has history of peptic ulcer. Efexor XR 75mg daily recently ceased (according to pharmacy last despensed 06/02/05, unsure of when patient stopped taking it).

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 207896 **Seq:** 1
**Reported:** 17/05/2005
**Hospitalisation:**
**Onset Date:** 01/03/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 76Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination | Caused or prolonged inpatient hospitalisation | | |
| Melaena | Caused or prolonged inpatient hospitalisation | | |
| Somnolence | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**CALTRATE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**FOLIC ACID (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**MIXTARD 30/70 (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**AMLODIPINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

Admission notes indicate patient was often already confused with occasional hallucinations and patient has history of peptic ulcer. Efexor XR 75mg daily recently ceased (according to pharmacy last despensed 06/02/05, unsure of when patient stopped taking it).

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 207896 **Seq:** 1 **Gender:** M
**Reported:** 17/05/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 76Y
**Onset Date:** 01/03/2005 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vomiting | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**ACTILAX (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**OSTELIN 1000 (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**MIRTAZAPINE (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** 28/02/2005 **Stopped:**

**WARFARIN SODIUM (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

Admission notes indicate patient was often already confused with occasional hallucinations and patient has history of peptic ulcer. Efexor XR 75mg daily recently ceased (according to pharmacy last despensed 06/02/05, unsure of when patient stopped taking it).

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 207896 **Seq:** 1
**Reported:** 17/05/2005
**Hospitalisation:**
**Onset Date:** 01/03/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 76Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**

75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

Admission notes indicate patient was often already confused with occasional hallucinations and patient has history of peptic ulcer. Efexor XR 75mg daily recently ceased (according to pharmacy last despensed 06/02/05, unsure of when patient stopped taking it).

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207913 **Seq:** 1 **Gender:** F
**Reported:** 17/05/2005 **Weight:** 39.00
**Hospitalisation:** **Age:** 62
**Onset Date:** 04/04/2005 **DOB:** 07/05/1942
**Outcome:** Recovered 12/04/2005 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agranulocytosis | Life | The patient developed agranulocytosis - her neutrophil count dropped to zero. | Neupogen given. |

### Medicine Details:

**SERETIDE ACCUHALER NOS (Other drug)** **Reason:** Asthma
**Batch:** **Started:** **Stopped:**

**ASPIRIN (Other drug)** **Reason:** Acute,ill-def cerebrovascular disease w/o hyperte
100.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**MIRTAZAPINE (Suspected)** **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 30/01/2005 **Stopped:** 04/04/2005

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 16/02/2005 **Stopped:** 04/04/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 17/05/2005 | Bone marrow | | | | Consistent with drug effect. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 207913 **Seq:** 1 **Gender:** F
**Reported:** 17/05/2005 **Weight:** 39.00
**Hospitalisation:** **Age:** 62
**Onset Date:** 04/04/2005 **DOB:** 07/05/1942
**Outcome:** Recovered 12/04/2005 **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **OLANZAPINE (Suspected)** | | | **Reason:** | Depression |
| | 5.0 Milligram | Daily | | |
| **Batch:** | **Started:** 22/02/2005 | | **Stopped:** | 04/04/2005 |
| **LOSEC (Suspected)** | | | **Reason:** | |
| | 20.0 Milligram | Daily | | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | 04/04/2005 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 208256 **Seq:** 1 **Gender:** F
**Reported:** 30/05/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 68
**Onset Date:** **DOB:** 19/09/1936
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus<br>Balance disorder<br>Serotonin syndrome<br>Somnolence<br>Urticaria | Required Visit to Doctor | Patient experienced itching, drowsiness, poor balance within 3 days, followed by extensive hives, serotonin syndrome suspected | Ceased Tramadol and use of Phenergan within 3 weeks. |

### Medicine Details:

**EFEXOR (Interaction)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 03/11/2004 **Stopped:** 18/03/2005 0

**TRAMAL SR (Interaction)** **Reason:** Cervicalgia
Tablet 200.0 Milligram Daily Oral
**Batch:** **Started:** 17/03/2005 **Stopped:** 18/03/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 208441 **Seq:** 1
**Reported:** 03/06/2005
**Hospitalisation:**
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 25
**DOB:** 30/11/1979
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | The patient made a suicide attempt. | |

## Medicine Details:

**CIPRAMIL (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**ZYPREXA (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Report 208442 is the second sequence to this report.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 208445 **Seq:** 1
**Reported:** 03/06/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 20
**DOB:** 20/02/1985
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression | Caused or prolonged inpatient hospitalisation | After four days on single dose Efexor the patient became violent, smashed her house, took four Temazepam tablets and drank a bottle of port. She complained for several days of serious voice hallucinations, she was obviously psychotic and suicidal. | |
| Hallucination, auditory | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**

Oral

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Report 208446 is the second sequence to this report. Past history of half a dozen suicide attempts and intermittent suicidal ideation.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 208445 **Seq:** 1
**Reported:** 03/06/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 20
**DOB:** 20/02/1985
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Psychotic disorder | Caused or prolonged inpatient hospitalisation | | |
| Suicidal ideation | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:**

Oral

**Batch:** **Started:** **Stopped:** 0

## Laboratory Investigations:

## Additional Information:

Report 208446 is the second sequence to this report. Past history of half a dozen suicide attempts and intermittent suicidal ideation.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 208454 **Seq:** 1
**Reported:** 03/06/2005
**Hospitalisation:**
**Onset Date:**
**Outcome:** Unrelated death

**Gender:** M
**Weight:** 0.00
**Age:** 32
**DOB:** 13/06/1972
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | Death | The patient was violently suicidal with multiple suicidal acts whilst on Efexor. He developed voice hallucinations, which were treated with Seroquel. This led to an overdose of suicidal intention and delirium. | Treated with Chlorpromazine. |
| Delirium | Death | | |
| Suicide attempt | Death | | |

### Medicine Details:

**SEROQUEL (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
300.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient drank a bottle of vodka, fell over aspirated and died. Not a suicide but a death.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 208455 **Seq:** 1 **Gender:** M
**Reported:** 03/06/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 28
**Onset Date:** **DOB:** 29/05/1977
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Psychotic disorder | Caused or prolonged inpatient hospitalisation | The patient experienced drug-induced psychosis during gradual withdrawal from Efexor. He went through a period of homicidal ideation | Treated with Clozaril. |
| Homicidal ideation | Caused or prolonged inpatient hospitalisation | | |
| Mania | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**Benzodiazepine NOS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
37.5 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 208457 **Seq:** 1 **Gender:** F
**Reported:** 03/06/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | Caused or prolonged inpatient hospitalisation | The patient experienced suicidal ideation whilst on Efexor. | Efexor increased. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 208459 **Seq:** 1 **Gender:** F
**Reported:** 03/06/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 56
**Onset Date:** **DOB:** 27/05/1949
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety | Caused or prolonged inpatient hospitalisation | The patient presented with anxiety, panic attacks and suicidal ideation. | |
| Panic attack | Caused or prolonged inpatient hospitalisation | | |
| Suicidal ideation | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
1 time
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 208470 **Seq:** 1 **Gender:** U
**Reported:** 03/06/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Death, maybe drug **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Intentional overdose | Death | Patient died after overdose. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 208813 **Seq:** 1 **Gender:** U
**Reported:** 20/06/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug exposure during pregnancy<br><br>Status epilepticus | | The patient had taken Venlafaxine during pregnancy. The neonate had status epilepticus. | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Neonate had status epilepticus.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 209092 **Seq:** 1 **Gender:** F
**Reported:** 24/06/2005 **Weight:** 60.00
**Hospitalisation:** Admitted to hospital **Age:** 74
**Onset Date:** 18/05/2005 **DOB:** 23/05/1930
**Outcome:** Recovered 26/05/2005 **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | The patient developed severe hyponatraemia with vomiting and weakness after 2 doses of Efexor XR | |
| Asthenia | Caused or prolonged inpatient hospitalisation | | |
| Vomiting | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**KLIOVANCE (Other drug)** **Reason:** Menopausal symptoms
**Batch:** **Started:** L TERM **Stopped:**

**ACTONEL (Other drug)** **Reason:** Osteoporosis
**Batch:** **Started:** L TERM **Stopped:**

**Seretide 500/50 Accuhaler (Other drug)** **Reason:** Asthma
**Batch:** **Started:** L TERM **Stopped:**

**SPIRIVA (Other drug)** **Reason:** Otr respiratory systm diseases
**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 24/06/2005 | Sodium | | | | S. Na 123 |

## Additional Information:

## Report Detail

**Case Number:** 209092 **Seq:** 1 **Gender:** F
**Reported:** 24/06/2005 **Weight:** 60.00
**Hospitalisation:** Admitted to hospital **Age:** 74
**Onset Date:** 18/05/2005 **DOB:** 23/05/1930
**Outcome:** Recovered 26/05/2005 **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **DEXAMPHETAMINE SULPHATE (Suspected)** | | | **Reason:** | Behavior disorders of childhod |
| | 10.0 Milligram | Weekly | | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression |
| Capsule | 75.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 16/05/2005 | | **Stopped:** | 17/05/2005 |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209199 **Seq:** 1
**Reported:** 28/06/2005
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 14/05/2005
**Outcome:** Unknown

**Gender:** M
**Weight:** 118.00
**Age:** 61
**DOB:** 29/06/1943
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vertigo<br><br><br>Blindness<br>Orthostatic hypotension<br>Photophobia<br>Visual disturbance | | The patient experienced vertigo, postural hypotension, visual disturbances, loss of vision and light sensitivity. | Ceased medications. |

### Medicine Details:

**TAZAC (Other drug)** **Reason:** Other diseases of esophagus
150.0 Milligram
**Batch:** **Started:** **Stopped:**

**AVAPRO (Other drug)** **Reason:** Essential benign hypertension
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 0

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Oral
**Batch:** **Started:** 11/05/2005 **Stopped:** 10/06/2005 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209276 **Seq:** 1 **Gender:** M
**Reported:** 29/06/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 40
**Onset Date:** 12/01/2005 **DOB:** 10/07/1964
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary retention | | urinary retention (due to venlafaxine) | venlafaxine ceased, reboxitine 4mg/day commenced 11/01/2005 |

### Medicine Details:

**DIAZEPAM (Other drug)** **Reason:**
Milligram As necessary Oral
**Batch:** **Started:** 06/01/2005 **Stopped:**

**OLANZAPINE (Other drug)** **Reason:**
Milligram As necessary Oral
**Batch:** **Started:** 06/01/2005 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
225.0 Milligram Daily Oral
**Batch:** **Started:** 06/01/2005 **Stopped:** 12/01/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209295 **Seq:** 1 **Gender:** M
**Reported:** 30/06/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 26Y
**Onset Date:** 22/04/2005 **DOB:**
**Outcome:** Death, maybe drug 22/04/2005 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | Death | Patient experienced suicidal ideation and completed suicide | |
| Completed suicide | Death | | |
| Drug ineffective | Death | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209479 **Seq:** 1 **Gender:** M
**Reported:** 05/07/2005 **Weight:** 70.00
**Hospitalisation:** **Age:** 39
**Onset Date:** **DOB:** 28/04/1966
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Stomach discomfort<br><br>Dyspepsia | | The patient developed a severe stomach upset and heartburn after taking Efexor. | Took subsequent dose after [illegible] |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 20/06/2004 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209498 **Seq:** 1 **Gender:** F
**Reported:** 06/07/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 38
**Onset Date:** **DOB:** 08/07/1966
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vomiting | | expereinced night seats, vomiting and tiredness. she was grumpy from feeling tired at work | |
| Night sweats | | experienced night sweats within the first month of taking efexor XR 225mg, resolved when within 7 to 10 days of reducing dose to 150mg | |
| Therapy regimen changed | | gradaul increase in dose form 75mg to | |
| Fatigue | | | |

### Medicine Details:

**SEROQUEL (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** 15/04/2005 **Stopped:** Continuing

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Current conditions: Schizophrenia.Psychotic disorder, Smoker, Overweight

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209509 **Seq:** 1
**Reported:** 06/07/2005
**Hospitalisation:** Required a specialist consultation
**Onset Date:** 15/02/2004
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 34Y
**DOB:**
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vision blurred | Caused or prolonged inpatient hospitalisation | Two weeks after commencing Efexor XR the patient developed blurred vision and loss of concentration/memory lapses. The dosage was increased two weeks later. At nine weeks she could not rise from bed and her vision was worse. | Efexor XR ceased. |
| Amnesia | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** 15/02/2004 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209509 **Seq:** 1
**Reported:** 06/07/2005
**Hospitalisation:** Required a specialist consultation
**Onset Date:** 15/02/2004
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 34Y
**DOB:**
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Disturbance in attention | Caused or prolonged inpatient hospitalisation | | |
| Fatigue | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** 15/02/2004 **Stopped:** 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209532 **Seq:** 1
**Reported:** 06/07/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | Caused or prolonged inpatient hospitalisation | Efexor exacerbated her symptoms of depression (hyper-vigilance, sleeplessness, dysphoria and panic). After one particularly nasty episode of panic I "took a fistful of sleeping pills" (suicide | |
| Condition aggravated | Caused or prolonged inpatient hospitalisation | | |
| Dysphoria | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Tablet Oral
**Batch:** **Started:** **Stopped:**

**PROZAC (Suspected)** **Reason:** Depression
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209532 **Seq:** 1
**Reported:** 06/07/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypervigilance | Caused or prolonged inpatient hospitalisation | | |
| Insomnia | Caused or prolonged inpatient hospitalisation | | |
| Panic attack | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Tablet Oral
**Batch:** **Started:** **Stopped:**

**PROZAC (Suspected)** **Reason:** Depression
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209694 **Seq:** 1 **Gender:** F
**Reported:** 11/07/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 34
**Onset Date:** **DOB:** 22/03/1971
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension<br>Dizziness<br>Drug exposure during pregnancy<br>Drug ineffective<br>Nausea | | The patient received Efexor XR therapy throughout her pregnancy. She experienced hypertension and nausea while pregnant. In addition she experienced dizziness while taking 75mg daily and Efexor XR was not effective on 150mg daily. She delivered the infant via | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient was a 'casual drinker'. Her infant was born 3 weeks premature, had six digits on the left hand, required resuscitation and was admitted to ICU.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209697 **Seq:** 1
**Reported:** 11/07/2005
**Hospitalisation:**
**Onset Date:** 26/05/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 32
**DOB:** 22/03/1971
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Birth trauma | Caused or prolonged inpatient hospitalisation | The patient received Efexor XR therapy throughout her pregnancy. Her infant was 'born three weeks premature', experienced a 'difficult birth', and had 6 digits on the left hand. In addition, the infant's physician suspected Horner's syndrome. | |
| Drug exposure during pregnancy | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Maternal indication for Efexor XR was depression and post-traumatic stress disorder. Efexor XR was started in 1999 at 150mg daily for 12 months before the patient 'tapered to 75mg/day'. The patient took 75mg daily until October 2003, after which the dose was increased to 150mg daily for a duration of two months, when the dose was decreased back to 75mg daily. Therapy continued.

## Report Detail

**Case Number:** 209697 **Seq:** 1
**Reported:** 11/07/2005
**Hospitalisation:**
**Onset Date:** 26/05/2003
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 32
**DOB:** 22/03/1971
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Horner's syndrome | Caused or prolonged inpatient hospitalisation | | |
| Polydactyly | Caused or prolonged inpatient hospitalisation | | |
| Premature baby | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

## Laboratory Investigations:

## Additional Information:

Maternal indication for Efexor XR was depression and post-traumatic stress disorder. Efexor XR was started in 1999 at 150mg daily for 12 months before the patient 'tapered to 75mg/day'. The patient took 75mg daily until October 2003, after which the dose was increased to 150mg daily for a duration of two months, when the dose was decreased back to 75mg daily. Therapy continued.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209706 **Seq:** 1 **Gender:** F
**Reported:** 11/07/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | Incapacity/disability | Patient experienced bad withdrawals symptoms, sweating, disorientation, mood swings and depression. | |
| Depression | Incapacity/disability | | |
| Disorientation | Incapacity/disability | | |
| Drug withdrawal syndrome | Incapacity/disability | | |
| Mood swings | Incapacity/disability | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Suspected drug positive rechallenge.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209759 **Seq:** 1 **Gender:** M
**Reported:** 12/07/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 21
**Onset Date:** 05/06/2005 **DOB:** 17/09/1983
**Outcome:** Death, maybe drug 05/06/2005 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Completed suicide | Death | The patient committed suicide on 5 June | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient had initiated therapy with Efexor XR "over a couple of weeks ago". History: Asthma.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209805 **Seq:** 1 **Gender:** M
**Reported:** 13/07/2005 **Weight:** 0.00
**Hospitalisation:** Admitted to hospital **Age:** 72
**Onset Date:** 26/06/2005 **DOB:** 13/03/1933
**Outcome:** Recovered 26/06/2005 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Patient experienced low sodium due to venlafaxine, high potassium to perindopril. | Ceased venlafaxine and perindopril and given Normal Saline and Resonium 15g start. |
| Hyperkalaemia | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**OXYCONTIN (Other drug)** **Reason:**
20.0 Milligram
**Batch:** **Started:** **Stopped:**

**COLOXYL WITH SENNA (Other drug)** **Reason:**
Tablet 4.0 Dose Unspecified Oral
**Batch:** **Started:** **Stopped:**

**LACTULOSE (Other drug)** **Reason:**
60.0 Millilitre
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 26/06/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 13/07/2005 | Potassium | | 26/06/2005 | 5.3 | |
| 13/07/2005 | Potassium | | 29/06/2005 | 4.8 | |
| 13/07/2005 | Sodium | | 26/06/2005 | 126 | |
| 13/07/2005 | Sodium | | 29/06/2005 | 132 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209805 **Seq:** 1 **Gender:** M
**Reported:** 13/07/2005 **Weight:** 0.00
**Hospitalisation:** Admitted to hospital **Age:** 72
**Onset Date:** 26/06/2005 **DOB:** 13/03/1933
**Outcome:** Recovered 26/06/2005 **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**PERINDOPRIL (Suspected)** **Reason:**

Tablet 4.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 26/06/2005

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 209811 **Seq:** 1 **Gender:** M
**Reported:** 13/07/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 29
**Onset Date:** **DOB:** 27/05/1976
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension | | The patient experienced hypertension and possible drug interaction whilst on Clopine treatment. Patient presented with high blood pressure of (140/105). Baseline blood pressure was (140/70). | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**AMISULPRIDE (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**CLOPINE (Suspected)** **Reason:**
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** 08/06/2004 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210030 **Seq:** 1
**Reported:** 21/07/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 31/03/2005
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 54Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Caused or prolonged inpatient hospitalisation | The patient experienced withdrawal syndrome. She developed agitation, mania, shaking, nightmares, foot tapping and amnesia | Given Diazepam. |
| Agitation | Caused or prolonged inpatient hospitalisation | | |
| Akathisia | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**OMEGA-3 MARINE TRIGLYCERIDES (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NEURONTIN (Other drug)** **Reason:** Otr&unsp vertebrogen pain synd
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Unspecifid affective psychosis
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 12/12/2002 **Stopped:** 31/03/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210030 **Seq:** 1
**Reported:** 21/07/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 31/03/2005
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 54Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Amnesia | Caused or prolonged inpatient hospitalisation | | |
| Mania | Caused or prolonged inpatient hospitalisation | | |
| Nightmare | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**OMEGA-3 MARINE TRIGLYCERIDES (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NEURONTIN (Other drug)** **Reason:** Otr&unsp vertebrogen pain synd
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Unspecifid affective psychosis
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 12/12/2002 **Stopped:** 31/03/2005

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210030 **Seq:** 1
**Reported:** 21/07/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 31/03/2005
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 54Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**OMEGA-3 MARINE TRIGLYCERIDES (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NEURONTIN (Other drug)** **Reason:** Otr&unsp vertebrogen pain synd
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Unspecifid affective psychosis
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 12/12/2002 **Stopped:** 31/03/2005

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210062 **Seq:** 1
**Reported:** 21/07/2005
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 07/06/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 62.00
**Age:** 21
**DOB:** 25/10/1983
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Visual disturbance | | Patient took Efexor XR in the morning, that night noticed while driving rear lights had a hazy blue/purple colour around it in peripheral vision, not during the day unless very bright glare. After affect of bright light lasts long time. Still present despite ceasing- sees bright red dot. | Efexor XR ceased. |

### Medicine Details:

**LEVLEN ED (Other drug)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:** 06/06/2005

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 07/06/2005 **Stopped:** 28/06/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210069 **Seq:** 1
**Reported:** 25/07/2005
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 01/06/2005
**Outcome:** Recovered

**Gender:** F
**Weight:** 50.00
**Age:** 33
**DOB:** 23/01/1972
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Therapy regimen changed<br><br>Arthralgia<br>Pain in extremity | | Patient developed painful hands and painful knees, one week after commencing 75mg venfafaxine slow release, worsening of symptoms after increase to 150mg. | Ceased Venlafaxine |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210108 **Seq:** 1
**Reported:** 26/07/2005
**Hospitalisation:**
**Onset Date:** 08/07/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 90.00
**Age:** 51
**DOB:** 17/08/1953
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Balance disorder | | Episode dysequilibrium and nausea not related to tinnitus or hearing changes. | |
| Tinnitus | | Gaze-evoked tinnitus - appearance of tinnitus on laterel gaze only - not on vertical gaze | Observation. |
| Nausea | | | |

### Medicine Details:

**OMEPRAZOLE (Other drug)** **Reason:** Other diseases of esophagus
20.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 15/10/2004 **Stopped:** 07/07/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210134 **Seq:** 1 **Gender:** M
**Reported:** 27/07/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 69Y
**Onset Date:** 03/07/2005 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Therapy regimen changed<br><br>Gravitational oedema | | The patient developed pitting oedema on the distal third right and left leg, which coincided with increased dose of Quetiapine and commencement of Venlafaxine. | Dose of Quetiapine was reduced to 150mg. |

### Medicine Details:

**MADOPAR (Other drug)** **Reason:**
3.0 Dose Unspecified Oral
**Batch:** **Started:** **Stopped:** 24/06/2005

**BENZHEXOL HYDROCHLORIDE (Other drug)** **Reason:**
6.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**ASPIRIN (Other drug)** **Reason:**
100.0 Milligram
**Batch:** **Started:** **Stopped:**

**ALPRAZOLAM (Other drug)** **Reason:**
2.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210134 **Seq:** 1 **Gender:** M
**Reported:** 27/07/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 69Y
**Onset Date:** 03/07/2005 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **CITALOPRAM HYDROBROMIDE (Other drug)** | | | **Reason:** | |
| | 20.0 Milligram | | | |
| **Batch:** | **Started:** | | **Stopped:** | 28/06/2005 |
| **COLOXYL WITH SENNA (Other drug)** | | | **Reason:** | |
| | 2.0 Dose Unspecified | | | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **QUETIAPINE (Suspected)** | | | **Reason:** | |
| Tablet | 200.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | **Stopped:** | 24/06/2005 |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | |
| Capsule | 75.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 01/07/2005 | | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210191 **Seq:** 1
**Reported:** 27/07/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 30Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Overdose | Caused or prolonged inpatient hospitalisation | Patient "overdosed with 2 packets of 150mg capsule" of Efexor XR. | Resuscitated, admitted to ICU. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210213 **Seq:** 1 **Gender:** F
**Reported:** 28/07/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 41
**Onset Date:** 20/06/2005 **DOB:** 04/04/1964
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tardive dyskinesia | | The patient developed mild tardive | |

### Medicine Details:

**CIPRAMIL (Other drug)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**SEROQUEL (Suspected)** **Reason:** Unspecified psychosis
Tablet 600.0 Milligram Daily Oral
**Batch:** **Started:** S TERM **Stopped:** 0

**OLANZAPINE (Suspected)** **Reason:**
5.0 Milligram Daily Oral
**Batch:** **Started:** 11/09/2004 **Stopped:** 29/09/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210342 **Seq:** 1 **Gender:** F
**Reported:** 03/08/2005 **Weight:** 55.00
**Hospitalisation:** **Age:** 75
**Onset Date:** **DOB:** 17/07/1930
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia<br><br><br><br>Agitation<br>Tremor | | Sudden onset of shakiness, more agitation and severe dystonia in upper limbs, having been on Risperidone up to 2mg which has been reduced to 1mg nocte. Had previously had a course of Risperidone 2mg without any signs of dystonia. | Benztropine for dystonia. |

### Medicine Details:

**RISPERIDONE (Suspected)** **Reason:** Otr spec symp psychopathol nec
1.0 Milligram Daily
**Batch:** **Started:** 04/07/2005 **Stopped:** 12/07/2005

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
225.0 Milligram Daily
**Batch:** **Started:** 05/07/2005 **Stopped:** 07/07/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Report 210347 is the second sequence to this report.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210347 **Seq:** 1
**Reported:** 03/08/2005
**Hospitalisation:**
**Onset Date:** 06/07/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 55.00
**Age:** 74
**DOB:** 17/07/1930
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | Hyponatraemia on and off during 2005. Noted again on 06/07/05 after Venlafaxine restarted (making slow recovery since). | Cease Vanlafaxine added salt tablets and restrict fluids. |

### Medicine Details:

**RISPERIDONE (Interaction)** **Reason:** Otr spec symp psychopathol nec
1.0 Milligram Daily
**Batch:** **Started:** 04/07/2005 **Stopped:** 12/07/2005

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:** Depression
225.0 Milligram Daily
**Batch:** **Started:** 05/07/2005 **Stopped:** 07/07/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Report 210342 is the first sequence to this report.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210404 **Seq:** 1
**Reported:** 04/08/2005
**Hospitalisation:**
**Onset Date:** 15/01/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 53
**DOB:** 27/04/1951
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Psoriasis | Caused or prolonged inpatient hospitalisation | Patient experienced worsening psoriasis with bleeding, blood cholesterol increased, no menstruation, facial flushing, teeth clenching/grinding, "grinding made teeth fillings fall out", purple discolouration of skin on feet, peeling of both feet, "bad circulation", candida, agitation, patient also experienced hypermania and biting of tongue, while tapering Efexor. | |
| Drug withdrawal syndrome | Caused or prolonged inpatient hospitalisation | patient expereinced forgetfulness while taking Efeoxr, hypomania while tapering and was suicidal after stopping therapy | |

### Medicine Details:

| | | | |
|---|---|---|---|
| **NEURONTIN (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **VALIUM (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **XANAX (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **PARIET (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient's concurrent illnesses include psoriasis (both parents also have psoriasis, hypertension and pain. The patient was 'medically retired' due to psychiatric problems which she has had since she was 12 years old. The patient has a past history of major back surgery during which time, she tested positive for 'staph and helicabacter' infections. The patient was previously hospitalised with psoriasis while taking Prozac and experienced mania while taking Cortisone. The patient has a familial history of hypercholesterolaemia and her father has bipolar disorder.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 210404 **Seq:** 1
**Reported:** 04/08/2005
**Hospitalisation:**
**Onset Date:** 15/01/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 53
**DOB:** 27/04/1951
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | Caused or prolonged inpatient hospitalisation | | |
| Amenorrhoea | Caused or prolonged inpatient hospitalisation | | |
| Blood cholesterol increased | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**RENITEC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**DI-GESIC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PETHIDINE HYDROCHLORIDE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**VITAMINS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

The patient's concurrent illnesses include psoriasis (both parents also have psoriasis, hypertension and pain. The patient was 'medically retired' due to psychiatric problems which she has had since she was 12 years old. The patient has a past history of major back surgery during which time, she tested positive for 'staph and helicabacter' infections. The patient was previously hospitalised with psoriasis while taking Prozac and experienced mania while taking Cortisone. The patient has a familial history of hypercholesterolaemia and her father has bipolar disorder.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 210404 **Seq:** 1
**Reported:** 04/08/2005
**Hospitalisation:**
**Onset Date:** 15/01/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 53
**DOB:** 27/04/1951
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Bruxism | Caused or prolonged inpatient hospitalisation | | |
| Candidiasis | Caused or prolonged inpatient hospitalisation | | |
| Dermatitis exfoliative | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** L TERM **Stopped:** 15/04/2005 0

**SEROQUEL (Suspected)** **Reason:**

Tablet 50.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** Continuing.

## Laboratory Investigations:

## Additional Information:

The patient's concurrent illnesses include psoriasis (both parents also have psoriasis, hypertension and pain. The patient was 'medically retired' due to psychiatric problems which she has had since she was 12 years old. The patient has a past history of major back surgery during which time, she tested positive for 'staph and helicabacter' infections. The patient was previously hospitalised with psoriasis while taking Prozac and experienced mania while taking Cortisone. The patient has a familial history of hypercholesterolaemia and her father has bipolar disorder.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 210404 **Seq:** 1
**Reported:** 04/08/2005
**Hospitalisation:**
**Onset Date:** 15/01/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 53
**DOB:** 27/04/1951
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Flushing | Caused or prolonged inpatient hospitalisation | | |
| Haemorrhage subcutaneous | Caused or prolonged inpatient hospitalisation | | |
| Mania | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**NEURONTIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**VALIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**XANAX (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PARIET (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

The patient's concurrent illnesses include psoriasis (both parents also have psoriasis, hypertension and pain. The patient was 'medically retired' due to psychiatric problems which she has had since she was 12 years old. The patient has a past history of major back surgery during which time, she tested positive for 'staph and helicabacter' infections. The patient was previously hospitalised with psoriasis while taking Prozac and experienced mania while taking Cortisone. The patient has a familial history of hypercholesterolaemia and her father has bipolar disorder.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 210404 **Seq:** 1
**Reported:** 04/08/2005
**Hospitalisation:**
**Onset Date:** 15/01/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 53
**DOB:** 27/04/1951
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Memory impairment | Caused or prolonged inpatient hospitalisation | | |
| Poor peripheral circulation | Caused or prolonged inpatient hospitalisation | | |
| Skin discolouration | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**RENITEC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**DI-GESIC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PETHIDINE HYDROCHLORIDE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**VITAMINS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

The patient's concurrent illnesses include psoriasis (both parents also have psoriasis, hypertension and pain. The patient was 'medically retired' due to psychiatric problems which she has had since she was 12 years old. The patient has a past history of major back surgery during which time, she tested positive for 'staph and helicabacter' infections. The patient was previously hospitalised with psoriasis while taking Prozac and experienced mania while taking Cortisone. The patient has a familial history of hypercholesterolaemia and her father has bipolar disorder.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 210404 **Seq:** 1
**Reported:** 04/08/2005
**Hospitalisation:**
**Onset Date:** 15/01/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 53
**DOB:** 27/04/1951
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tongue biting | Caused or prolonged inpatient hospitalisation | | |
| Tooth disorder | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** L TERM **Stopped:** 15/04/2005 0

**SEROQUEL (Suspected)** **Reason:**

Tablet 50.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** Continuing.

## Laboratory Investigations:

## Additional Information:

The patient's concurrent illnesses include psoriasis (both parents also have psoriasis, hypertension and pain. The patient was 'medically retired' due to psychiatric problems which she has had since she was 12 years old. The patient has a past history of major back surgery during which time, she tested positive for 'staph and helicabacter' infections. The patient was previously hospitalised with psoriasis while taking Prozac and experienced mania while taking Cortisone. The patient has a familial history of hypercholesterolaemia and her father has bipolar disorder.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210424 **Seq:** 1
**Reported:** 05/08/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 23/12/2004
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 52
**DOB:** 13/07/1952
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Inappropriate antidiuretic hormon | Caused or prolonged inpatient hospitalisation | The patient experienced hyponatraemia, fine tremor, nausea, vomiting and diarrhoea and was diagnosed with SIADH. | Venlafaxine ceased. Given Metoclopramide. |
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**MELOXICAM (Other drug)** **Reason:**
15.0 Milligram
**Batch:** **Started:** **Stopped:**

**PREMARIN (Other drug)** **Reason:**
625.0 Microgram
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 20/12/2004 **Stopped:** 23/12/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 05/08/2005 | Other data | | | | Osmolarity 232. |
| 05/08/2005 | Sodium | | | | Na 116. |
| 05/08/2005 | Urine Sodium | | | | Urine Na 82. |
| 05/08/2005 | Urine osmolality | | | | Urine Osm 731. |

### Additional Information:

Report 210426 is the second sequence to this report.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210506 **Seq:** 1
**Reported:** 08/08/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 28
**DOB:** 07/01/1977
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypomania | Caused or prolonged inpatient hospitalisation | Patient received Efexor XR therapy and experienced an episode of hypomania. His symptoms were reported as feelings of emptiness, loss of memory and loss of motivation. | Dose of Efexor XR was increased gradually from 225mg to 525mg daily. Also treated with Seroquel and |
| Therapy regimen changed | Caused or prolonged inpatient hospitalisation | patiend self medicated ranging from 600mg to 900mg, he experienced hot flushes and feeling cloudy | |
| Depression | Caused or prolonged inpatient hospitalisation | patient experienced depression and decided to stop seroquel and epilim without medical advice | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 225.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210506 **Seq:** 1
**Reported:** 08/08/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 28
**DOB:** 07/01/1977
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Caused or prolonged inpatient hospitalisation | patient experienced electric shock, dizziness, tiredness, and somnolence on withdrawal of efexor | |
| Drug ineffective | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 225.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210528 **Seq:** 1 **Gender:** M
**Reported:** 09/08/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Intentional overdose<br>Suicidal ideation | | Intentional overdose and suicidal ideation. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 600.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient increased the Efexor XR dose to 600mg/day then 900mg/day and experienced feelings of elation. When the dose was tapered, the patient experienced relapse of depression and suicical ideation.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210578 **Seq:** 1
**Reported:** 11/08/2005
**Hospitalisation:** Hospitalisation prolonged
**Onset Date:** 01/01/2005
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 49
**DOB:** 17/06/1955
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Encephalopathy | Caused or prolonged inpatient hospitalisation | Drug-induced encephalopathy with paranoid features where the combination of a tricyclic antidepressant and SNRI was implicated as the major cause. | Patient was transferred to Royal Melbourne Hospital |
| Paranoia | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:**
Capsule 225.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**NORTRIPTYLINE HYDROCHLORIDE (Interaction)** **Reason:**
Tablet 175.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**GABAPENTIN (Other drug)** **Reason:**
1200.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**AMANTADINE HYDROCHLORIDE (Other drug)** **Reason:**
Capsule 200.0 Milligram Oral
**Batch:** **Started:** **Stopped:** 13/01/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210578 **Seq:** 1
**Reported:** 11/08/2005
**Hospitalisation:** Hospitalisation prolonged
**Onset Date:** 01/01/2005
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 49
**DOB:** 17/06/1955
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **LAMOTRIGINE (Other drug)** | | | **Reason:** | | |
| Tablet | 200.0 | Milligram | | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **COPAXONE (Other drug)** | | | **Reason:** | | |
| Injection | | | Daily | | Subcutaneous |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **METHYSERGIDE MALEATE (Other drug)** | | | **Reason:** | | |
| Tablet | 3.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | 13/01/2005 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210704 **Seq:** 1 **Gender:** M
**Reported:** 15/08/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 52Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Micturition urgency<br><br>Ejaculation disorder | | Patient experienced urinary urency, urgent need to urinate 6 times a day, bladder not full, wakes frequently during the night. Spontaneous ejuculation after 6 weeks treament, occurred just as wet dream when using Efexor in 2001. This time has had 2 x spontanous ejuculation, no sense of orgasm, no wet dream. | Decreased Efexor dose. |

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression | |
| Capsule | 150.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | 15/12/2000 | | **Stopped:** | 15/06/2001 |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression | |
| Capsule | 75.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | 15/06/2001 | | **Stopped:** | 15/12/2001 |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | | |
| Capsule | 150.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | 15/01/2005 | | **Stopped:** | 01/03/2005 0 |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | | |
| Capsule | 75.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | 01/03/2005 | | **Stopped:** | |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210832 **Seq:** 1 **Gender:** F
**Reported:** 17/08/2005 **Weight:** 61.00
**Hospitalisation:** **Age:** 51
**Onset Date:** **DOB:** 09/08/1954
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Neutropenia | | The patient experienced suspected | Efexor XR ceased. |

### Medicine Details:

**MODURETIC (Other drug)** **Reason:**
1.0 Dose Unspecified
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 21/06/2004 **Stopped:** 25/07/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210842 **Seq:** 1 **Gender:** F
**Reported:** 17/08/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 23
**Onset Date:** 15/07/2005 **DOB:** 27/08/1981
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myoclonus | Incapacity/disability | Patient was experiencing myoclonic jerks (up to a couple of times each day) approximately 1 year and 11 months after commencing Clozaril. Patient had also gained 30kg of weight. | |
| Weight increased | Incapacity/disability | | |

### Medicine Details:

**CLOZARIL (Interaction)** **Reason:** Unspecified neurosis

Tablet 550.0 Milligram Daily Oral

**Batch:** **Started:** 07/09/2003 **Stopped:**

**EFEXOR-XR (Interaction)** **Reason:**

Capsule 225.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210895 **Seq:** 1
**Reported:** 18/08/2005
**Hospitalisation:**
**Onset Date:** 15/05/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 80.00
**Age:** 45
**DOB:** 26/02/1960
**Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Galactorrhoea | | The patient experienced galactorrhoea whilst taking Efexor XR in 2001. He started taking Efexor again in March 2005 and the symptoms recurred. | Efexor XR dosage reduced to 150mg daily. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 225.0 Milligram Daily Oral

**Batch:** **Started:** 15/03/2005 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Suspected drug positive rechallenge.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 210977 **Seq:** 1
**Reported:** 22/08/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 10/08/2005
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 77
**DOB:** 31/08/1927
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Serotonin syndrome | Caused or prolonged inpatient hospitalisation | The patient experienced suspected Serotonin Syndrome. | Ceased Lithium and |

### Medicine Details:

| | | | |
|---|---|---|---|
| **SINEMET (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **TAMOXIFEN CITRATE (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **OROXINE (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **TEMAZEPAM (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 210977 **Seq:** 1
**Reported:** 22/08/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 10/08/2005
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 77
**DOB:** 31/08/1927
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **MOVICOL (Other drug)** | | | **Reason:** | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **COLOXYL WITH SENNA (Other drug)** | | | **Reason:** | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **LITHICARB (Suspected)** | | | **Reason:** | |
| Tablet | 250.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211024 **Seq:** 1 **Gender:** M
**Reported:** 24/08/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tachycardia | | Heart pounding, throat constriction and increased fluid in the lungs. | |
| Feeling hot and cold | | The patient experienced uncontrollable hot and cold sweats. | Ceased Efexor. |
| Pulmonary oedema | | | |
| Throat tightness | | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Tablet 37.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**DILATREND (Suspected)** **Reason:**
Tablet 3.3 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient History: heart attack.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211141 **Seq:** 1 **Gender:** F
**Reported:** 26/08/2005 **Weight:** 60.00
**Hospitalisation:** **Age:** 42
**Onset Date:** 24/05/2005 **DOB:** 23/01/1963
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vomiting<br><br><br>Anxiety<br>Muscle twitching<br>Sneezing | | Patient experienced vomiting, anxiety, Facial twitching, sneezing, within half an hour of first dose, continued 2 hours, recurred with each subsequent dose. | Ceased Efexor. |

### Medicine Details:

**KARVEA (Other drug)** **Reason:**
Tablet 150.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
75.0 Milligram Daily
**Batch:** **Started:** 24/05/2005 **Stopped:** 31/07/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211202 **Seq:** 1
**Reported:** 30/08/2005
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 13/07/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 86.00
**Age:** 19
**DOB:** 06/03/1986
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mydriasis | | Patient developed mydriasis of both eyes. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 12/07/2005 **Stopped:**

**Yasmin (Suspected)** **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 15/05/2003 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211373 **Seq:** 1 **Gender:** M
**Reported:** 05/09/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 58Y
**Onset Date:** 01/05/2005 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia<br><br>Arthralgia | | Patient experienced generalised myalgias, severe arthralgias in wrists, hips, knees and ankles and groin pain. | Ceased Lipitor and Efexor. |

### Medicine Details:

**EPILIM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**IMOVANE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**BRICANYL TURBUHALER (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**CALTRATE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 05/09/2005 | ALT = SGPT | | 04/05/2005 | 127 | |
| 05/09/2005 | ALT = SGPT | | 06/05/2005 | 93 | |
| 05/09/2005 | ALT = SGPT | | 12/05/2005 | 50 | |
| 05/09/2005 | ALT = SGPT | | 20/05/2005 | 47 | |
| 05/09/2005 | ALT = SGPT | | 15/06/2005 | 35 | |
| 05/09/2005 | Creatine | | 04/05/2005 | 1451 | |
| 05/09/2005 | Creatine | | 06/05/2005 | 646 | |

### Additional Information:

Patient was on Lopid since at least 2001 until July 2003 when it was ceased due to myalgia. Anafranil and Prothiaden caused some agitation.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211373 **Seq:** 1 **Gender:** M
**Reported:** 05/09/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 58Y
**Onset Date:** 01/05/2005 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | |
|---|---|---|---|
| **CODALGIN FORTE (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **NEXIUM (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **NORVASC (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **NOTEN (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 05/09/2005 | Creatine | | 12/05/2005 | 90 | |
| 05/09/2005 | Creatine | | 20/05/2005 | 1299 | |
| 05/09/2005 | Creatine | | 23/05/2005 | 298 | |
| 05/09/2005 | Creatine | | 26/05/2005 | 241 | |
| 05/09/2005 | Creatine | | 30/05/2005 | 195 | |
| 05/09/2005 | Creatine | | 15/06/2005 | 109 | |

### Additional Information:

Patient was on Lopid since at least 2001 until July 2003 when it was ceased due to myalgia. Anafranil and Prothiaden caused some agitation.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211373 **Seq:** 1 **Gender:** M
**Reported:** 05/09/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 58Y
**Onset Date:** 01/05/2005 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | |
|---|---|---|---|
| **QUINATE (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **RECTOGESIC (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **Seretide 250/50 Accuhaler (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **VOLTAREN (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

### Additional Information:

Patient was on Lopid since at least 2001 until July 2003 when it was ceased due to myalgia. Anafranil and Prothiaden caused some agitation.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 211373 **Seq:** 1 **Gender:** M
**Reported:** 05/09/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 58Y
**Onset Date:** 01/05/2005 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **LIPITOR (Suspected)** | | | **Reason:** | |
| Tablet | 80.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **EFEXOR (Suspected)** | | | **Reason:** | |
| Tablet | 150.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **TOLVON (Suspected)** | | | **Reason:** | |
| Tablet | 40.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |

## Laboratory Investigations:

## Additional Information:

Patient was on Lopid since at least 2001 until July 2003 when it was ceased due to myalgia. Anafranil and Prothiaden caused some agitation.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211389 **Seq:** 1
**Reported:** 06/09/2005
**Hospitalisation:**
**Onset Date:** 03/01/2005
**Outcome:** Recovered

**Gender:** M
**Weight:** 75.00
**Age:** 90
**DOB:** 26/06/1914
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | Incapacity/disability | | |

### Medicine Details:

**GLIPIZIDE (Other drug)** **Reason:** Diabetes mellitus
Tablet 2.5 Milligram 2 times Oral
**Batch:** unknown **Started:** **Stopped:** 0

**METFORMIN HYDROCHLORIDE (Other drug)** **Reason:** Diabetes mellitus
Tablet 500.0 Milligram 2 times Oral
**Batch:** unknown **Started:** **Stopped:**

**TEMAZEPAM (Other drug)** **Reason:** Specific disorders of sleep
Tablet 10.0 Milligram 1 time Oral
**Batch:** unknown **Started:** **Stopped:** 0

**QUINAPRIL HYDROCHLORIDE (Other drug)** **Reason:** Essential benign hypertension
Tablet 20.0 Milligram 1 time Oral
**Batch:** unknown **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211389 **Seq:** 1
**Reported:** 06/09/2005
**Hospitalisation:**
**Onset Date:** 03/01/2005
**Outcome:** Recovered

**Gender:** M
**Weight:** 75.00
**Age:** 90
**DOB:** 26/06/1914
**Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **PRAVASTATIN SODIUM (Other drug)** | | | | **Reason:** | Othr&unspec metabolic diseases | | |
| Tablet | | 40.0 | Milligram | 1 time | | Oral | |
| **Batch:** | unknown | **Started:** | | | **Stopped:** | | 0 |
| **ASPIRIN (Other drug)** | | | | **Reason:** | Prophylaxis | | |
| Tablet | | 100.0 | Milligram | 1 time | | Oral | |
| **Batch:** | unknown | **Started:** | | | **Stopped:** | | |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | | **Reason:** | Depression | | |
| Capsule | | 37.5 | Milligram | 1 time | | Oral | |
| **Batch:** | unknown | **Started:** | 03/01/2005 | | **Stopped:** | 06/01/2005 | 0 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211433 **Seq:** 1 **Gender:** F
**Reported:** 06/09/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br><br>Agitation<br>Tremor | | Patient experienced suicidal ideation, severe psychomotor agitation and visible tremors<br>Severe psychomotor agitation | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The dose regimen was 75mg /d and then 150mg/daily.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211505 **Seq:** 1
**Reported:** 07/09/2005
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 18/08/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 60.00
**Age:** 38
**DOB:** 07/03/1967
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Erythema<br><br>Motion sickness<br>Nausea<br>Pruritus<br>Skin exfoliation<br>Tremor | | The patient experienced redness, itch, scaling skin, nausea, motion sickness and tremor. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** 17/08/2005 **Stopped:** 21/08/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient had prolonged INR and bruising on Zoloft.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211523 **Seq:** 1
**Reported:** 08/09/2005
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 15/04/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 50
**DOB:** 09/08/1954
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Neuropathy peripheral | | Patient developed peripheral neuropathy symptoms during therapy with Efexor. | |

### Medicine Details:

**MODURETIC (Other drug)** **Reason:** Essential benign hypertension
Tablet Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Oral
**Batch:** **Started:** 15/07/2004 **Stopped:** 15/07/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211545 **Seq:** 1
**Reported:** 09/09/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 51Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myocardial infarction | Caused or prolonged inpatient hospitalisation | The patient experienced a heart attack, (myocardial infarction). | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis

Capsule 225.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211696 **Seq:** 1
**Reported:** 15/09/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/05/2004
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 45Y
**DOB:**
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Palpitations | Caused or prolonged inpatient hospitalisation | The patient experienced palpitations, angina and shortness of breath six weeks after switching to Efexor. Three weeks later she experienced suspected myocardial infarction, chest pain and her heart rate was 130. | Atenolol to reduce heart rate. Ceased Efexor. |
| Angina pectoris | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 211696 **Seq:** 1
**Reported:** 15/09/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/05/2004
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 45Y
**DOB:**
**Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyspnoea | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211781 **Seq:** 1
**Reported:** 20/09/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 09/08/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 58.00
**Age:** 38
**DOB:** 29/05/1967
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia | Caused or prolonged inpatient hospitalisation | The patient experienced severe discontinuation symptoms of Efexor XR despite tapering. She developed severe muscle pain, migraines, agitation and increasing suicidality. | |
| Agitation | Caused or prolonged inpatient hospitalisation | | |
| Drug withdrawal syndrome | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**Yasmin (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**BRICANYL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ZANTAC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NASONEX AQUEOUS NASAL SPRAY (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211781 **Seq:** 1
**Reported:** 20/09/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 09/08/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 58.00
**Age:** 38
**DOB:** 29/05/1967
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Migraine | Caused or prolonged inpatient hospitalisation | | |
| Suicidal ideation | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 375.0 Milligram Daily Oral

**Batch:** **Started:** L TERM **Stopped:** 09/08/2005

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211785 **Seq:** 1
**Reported:** 20/09/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 11/09/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 80.00
**Age:** 84
**DOB:** 26/02/1921
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | The patient experienced hyponatraemia eight days after starting Efexor. He was also confused. | Cease all Sodium decreasing medications. |
| Confusional state | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**IRBESARTAN (Other drug)** **Reason:** Essential benign hypertension
Tablet 300.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**RANITIDINE (Other drug)** **Reason:** Other diseases of esophagus
150.0 Milligram
**Batch:** **Started:** **Stopped:**

**MOBIC (Other drug)** **Reason:** Pain
7.5 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211785 **Seq:** 1
**Reported:** 20/09/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 11/09/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 80.00
**Age:** 84
**DOB:** 26/02/1921
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**INDAPAMIDE HEMIHYDRATE (Suspected)** **Reason:** Essential benign hypertension

Tablet 1.5 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211866 **Seq:** 1 **Gender:** F
**Reported:** 22/09/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 54Y
**Onset Date:** 15/08/2005 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Constipation | Incapacity/disability | The patient developed severe constipation, her muscles (particularly gluteus) became very tight, she had aches and pains in the body, a metallic taste in the mouth and a very strong smell to her urine. | Efexor XR ceased. |
| Dysgeusia | Incapacity/disability | | |
| Muscle rigidity | Incapacity/disability | | |
| Myalgia | Incapacity/disability | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** 15/08/2005 **Stopped:** 15/09/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 211868 **Seq:** 1
**Reported:** 22/09/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 18/08/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 43
**DOB:** 07/07/1962
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anger | Caused or prolonged inpatient hospitalisation | Patient experienced an angry episode leading to cruelty to his girlfriend's dog. | |

### Medicine Details:

| | | | |
|---|---|---|---|
| **CLONAZEPAM (Other drug)** | | **Reason:** | Unspecifid affective psychosis |
| **Batch:** | **Started:** | | **Stopped:** |
| **SODIUM VALPROATE (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **CHLORPROMAZINE HYDROCHLORIDE (Other drug)** | | **Reason:** | Unspecifid affective psychosis |
| **Batch:** | **Started:** | | **Stopped:** |
| **LAMOTRIGINE (Other drug)** | | **Reason:** | Unspecifid affective psychosis |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Study D1447C00126.

## Report Detail

**Case Number:** 211868 **Seq:** 1
**Reported:** 22/09/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 18/08/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 43
**DOB:** 07/07/1962
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **SEROQUEL (Suspected)** | | | **Reason:** | Unspecifid affective psychosis |
| Tablet | 800.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 23/06/2005 | | | **Stopped:** 0 |

## Laboratory Investigations:

## Additional Information:

Study D1447C00126.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 212013 **Seq:** 1 **Gender:** U
**Reported:** 27/09/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cerebrovascular accident | | The patient experienced a stroke while receiving Efexor XR. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 212122 **Seq:** 1 **Gender:** F
**Reported:** 04/10/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Caused or prolonged inpatient hospitalisation | The patient experienced lack of effect and discontinuation symptoms, which included suicidal ideation, agitation and headaches. | |
| Agitation | Caused or prolonged inpatient hospitalisation | | |
| Drug ineffective | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 212122 **Seq:** 1 **Gender:** F
**Reported:** 04/10/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | Caused or prolonged inpatient hospitalisation | | |
| Suicidal ideation | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 212166 **Seq:** 1
**Reported:** 05/10/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 19/07/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 54Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash | Caused or prolonged inpatient hospitalisation | The patient developed a rash over the arms, legs, back and chest which was pruritic and itchy, bruising and thrombocytopenia with platelet count of 0.7 | Prednisolone 75 mg daily. |
| Contusion | Caused or prolonged inpatient hospitalisation | | |
| Thrombocytopenia | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**OMEPRAZOLE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**DIAZEPAM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NITRAZEPAM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**SALBUTAMOL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient also taking Alendronate.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 212166 **Seq:** 1
**Reported:** 05/10/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 19/07/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 54Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **FLIXOTIDE (Other drug)** | | | | **Reason:** | | | |
| **Batch:** | **Started:** | | | | **Stopped:** | | |
| **Glucosamine Nos (Other drug)** | | | | **Reason:** | | | |
| **Batch:** | **Started:** | | | | **Stopped:** | | |
| **CELECOXIB (Suspected)** | | | | **Reason:** | | | |
| Capsule | 200.0 | Milligram | | Daily | | Oral | |
| **Batch:** | **Started:** | | L TERM | | **Stopped:** | 20/07/2005 | 0 |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | | **Reason:** | | | |
| | 112.5 | Milligram | | Daily | | | |
| **Batch:** | **Started:** | 15/06/2005 | S TERM | | **Stopped:** | 20/07/2005 | 0 |

### Laboratory Investigations:

### Additional Information:
Patient also taking Alendronate.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 212166 **Seq:** 1
**Reported:** 05/10/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 19/07/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 54Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **SULFASALAZINE (Suspected)** | | | **Reason:** | |
| | 1.0 Gram | Daily | | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | 20/07/2005 |
| **TRIMETHOPRIM (Suspected)** | | | **Reason:** | |
| | 1.0 Dose Unspecified | Daily | | |
| **Batch:** | **Started:** | 14/07/2005 | **Stopped:** | 20/07/2005 |

## Laboratory Investigations:

## Additional Information:

Patient also taking Alendronate.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 212265 **Seq:** 1 **Gender:** F
**Reported:** 05/10/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Incapacity/disability | Twenty-four hours after the last dose of Efexor, patient experienced dizziness, nausea, vomiting "could not sit up and was confined to lying down", general feelig of unwell, cold shivers, brain zaps and anxiety after stopping Efexor. | Treatment included the administration of Stemzine and an unspecified antianxiety agent. Efexor discontinued. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Tablet 600.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 212283 **Seq:** 1 **Gender:** F
**Reported:** 06/10/2005 **Weight:** 88.00
**Hospitalisation:** **Age:** 19
**Onset Date:** 08/09/2005 **DOB:** 29/10/1985
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state | | Pateint experienced confusion. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 05/09/2005 **Stopped:** 14/09/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 212481 **Seq:** 1
**Reported:** 12/10/2005
**Hospitalisation:**
**Onset Date:** 01/06/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 39
**DOB:** 01/04/1966
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vision blurred | Incapacity/disability | The patient experienced blurred vision, tunnel vision and tinnitus. | Efexor XR ceased. |
| Tinnitus | Incapacity/disability | | |
| Tunnel vision | Incapacity/disability | | |

### Medicine Details:

**PANADEINE FORTE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 01/03/2005 **Stopped:** 29/07/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 212626 **Seq:** 1 **Gender:** F
**Reported:** 17/10/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Infantile apnoeic attack<br><br>Drug withdrawal syndrome neona | | Neonatal apnoeic attack, the baby did not breath for the first 10 minutes. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
150.0 Milligram Oral
**Batch:** **Started:** 15/06/2004 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The reporter delivered a baby to a women who was treated with Efexor XR (drug exposure during pregnancy). The baby did not breath for the first 10 minutes (neonatal apnoeic attack) but has recovered. The reporter considered the "apnoea secondary to venlafaxine use".

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 212835 **Seq:** 1 **Gender:** F
**Reported:** 25/10/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 10/06/2005 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation neonatal<br><br>Drug withdrawal syndrome neona | | The patient was taking Efexor during pregnancy. The dose had been reduced from 150mg to 75mg when pregnancy was confirmed. Her baby was jittery in the hands, arms and face at birth. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

On review at 4 months - normal development. Jittery almost resolved.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 212895 **Seq:** 1 **Gender:** F
**Reported:** 26/10/2005 **Weight:** 0.00
**Hospitalisation:** Required a visit to the doctor **Age:** 19
**Onset Date:** **DOB:** 24/10/1986
**Outcome:** Recovered 07/10/2005 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Neutropenia | | The patient experienced neutropaenia. | Venlafaxine ceased. |

### Medicine Details:

**DIANE-35 ED (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Oral
**Batch:** **Started:** 25/11/2004 **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
**Batch:** **Started:** 08/04/2005 **Stopped:** 07/10/2005

**ALPRAZOLAM (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** 27/08/2004 **Stopped:** 15/10/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 26/10/2005 | Neutrophils | | 23/05/1996 | 1.59 | |
| 26/10/2005 | Neutrophils | | 27/09/2005 | 1.78 | |
| 26/10/2005 | Neutrophils | | 29/09/2005 | 1.78 | |
| 26/10/2005 | Neutrophils | | 07/10/2005 | 1.74 | |
| 26/10/2005 | Neutrophils | | 17/10/2005 | 6.42 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213105 **Seq:** 1 **Gender:** F
**Reported:** 04/11/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br><br>Abdominal pain upper<br>Anorexia<br>Diarrhoea | | The patient experienced suicidal thoughts, loss of appetite, "extreme" diarrhoea and stomach cramps | |

### Medicine Details:

**OROXINE (Other drug)** **Reason:**
100.0 Microgram
**Batch:** **Started:** **Stopped:**

**OMEPRAZOLE (Other drug)** **Reason:**
20.0 Milligram
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 29/09/2005 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 213109 **Seq:** 1
**Reported:** 04/11/2005
**Hospitalisation:**
**Onset Date:** 25/10/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 62
**DOB:** 19/07/1943
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Disorientation<br>Anorexia<br>Anxiety<br>Eye rolling<br>Fatigue<br>Pallor | | The patient became disoriented, her eyes were rolling back, could only focus briefly, was more tired than usual, was pale, anorexic, felt "dreadful all over" and experienced anxiety. | Oxygen. |

## Medicine Details:

**ATROVENT (Other drug)** **Reason:** Asthma
**Batch:** **Started:** **Stopped:**

**AVAPRO (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**SOMAC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**DIDROCAL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient also taking Ventolin, Prednisolone, Seretide and Panadeine.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213109 **Seq:** 1
**Reported:** 04/11/2005
**Hospitalisation:**
**Onset Date:** 25/10/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 62
**DOB:** 19/07/1943
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **OVESTIN (Other drug)** | | | **Reason:** | |
| | | | | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **KLIOVANCE (Other drug)** | | | **Reason:** | |
| | | | | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **CIPROXIN (Suspected)** | | | **Reason:** | |
| | | 1.0 Dose Unspecified As necessary | | |
| **Batch:** | **Started:** | 24/10/2005 | **Stopped:** | 25/10/2005 |
| **EFEXOR (Suspected)** | | | **Reason:** | |
| | | 1.0 Dose Unspecified As necessary | | Oral |
| **Batch:** | **Started:** | 24/10/2005 | **Stopped:** | 25/10/2005 |

### Laboratory Investigations:

### Additional Information:

Patient also taking Ventolin, Prednisolone, Seretide and Panadeine.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213162 **Seq:** 1
**Reported:** 07/11/2005
**Hospitalisation:**
**Onset Date:** 23/03/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 87
**DOB:** 21/11/1917
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Liver function test abnormal | | Patient experienced abnormal liver function | Discontinuation of Amiodarone. |

### Medicine Details:

**COLOXYL WITH SENNA (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**URAL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**FLORINEF (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PANADEINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 07/11/2005 | ALT = SGPT | (less than 45) | 01/03/2005 | 13 | |
| 07/11/2005 | ALT = SGPT | (less than 45) | 22/03/2005 | 47 | |
| 07/11/2005 | ALT = SGPT | (less than 45) | 30/03/2005 | 95 | |
| 07/11/2005 | ALT = SGPT | (less than 45) | 24/04/2005 | 25 | |
| 07/11/2005 | AST = SGOT | (less than 40) | 01/03/2005 | 20 | |
| 07/11/2005 | AST = SGOT | (less than 40) | 22/03/2005 | 57 | |
| 07/11/2005 | AST = SGOT | (less than 40) | 30/03/2005 | 30 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 213162 **Seq:** 1
**Reported:** 07/11/2005
**Hospitalisation:**
**Onset Date:** 23/03/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 87
**DOB:** 21/11/1917
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **HEPARIN SODIUM (Other drug)** | | | **Reason:** | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **AVANZA (Suspected)** | | | **Reason:** | |
| Tablet | 60.0 Milligram | | | Oral |
| **Batch:** | **Started:** 23/03/2005 | | | **Stopped:** |
| **DILTAHEXAL (Suspected)** | | | **Reason:** | |
| | | | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **CORDARONE X (Suspected)** | | | **Reason:** | Otr&nos disord of heart rhythm |
| Tablet | 100.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 07/11/2005 | AST = SGOT | (less than 40) | 24/04/2005 | 27 | |
| 07/11/2005 | Albumin | (33-47) | 01/03/2005 | 37 | |
| 07/11/2005 | Albumin | (33-47) | 22/03/2005 | 32 | |
| 07/11/2005 | Albumin | (33-47) | 30/03/2005 | 28 | |
| 07/11/2005 | Albumin | (33-47) | 24/04/2005 | 35 | |
| 07/11/2005 | Bilirubin | (less than 20) | 01/03/2005 | 15 | |
| 07/11/2005 | Bilirubin | (less than 20) | 22/03/2005 | 25 | |

## Additional Information:

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## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213162 **Seq:** 1
**Reported:** 07/11/2005
**Hospitalisation:**
**Onset Date:** 23/03/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 87
**DOB:** 21/11/1917
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **EFEXOR (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 150.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **PRAVACHOL (Suspected)** | | | **Reason:** | Othr&unspec metabolic diseases | |
| Tablet | 10.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 07/11/2005 | Bilirubin | (less than 20) | 24/04/2005 | 8 | |
| 07/11/2005 | Bilirubin | (less than 20) | 30/03/2005 | 20 | |
| 07/11/2005 | GGT = SGGT = | (less than 50) | 01/03/2005 | 83 | |
| 07/11/2005 | GGT = SGGT = | (less than 50) | 24/04/2005 | 156 | |
| 07/11/2005 | GGT = SGGT = | (less than 50) | 30/03/2005 | 85 | |
| 07/11/2005 | GGT = SGGT = | (less than 50) | 22/03/2005 | 92 | |
| 07/11/2005 | Haemoglobin | (24-45) | 01/03/2005 | 33 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
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Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213162 **Seq:** 1
**Reported:** 07/11/2005
**Hospitalisation:**
**Onset Date:** 23/03/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 87
**DOB:** 21/11/1917
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**COLOXYL WITH SENNA (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**URAL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**FLORINEF (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PANADEINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 07/11/2005 | Haemoglobin | (24-45) | 22/03/2005 | 30 | |
| 07/11/2005 | Haemoglobin | (24-45) | 24/04/2005 | 33 | |
| 07/11/2005 | Haemoglobin | (24-45) | 30/03/2005 | 29 | |
| 07/11/2005 | Lactate | (110-250) | 01/03/2005 | 395 | |
| 07/11/2005 | Lactate | (110-250) | 22/03/2005 | 316 | |
| 07/11/2005 | Lactate | (110-250) | 24/04/2005 | 270 | |
| 07/11/2005 | Lactate | (110-250) | 30/03/2005 | 321 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213162 **Seq:** 1
**Reported:** 07/11/2005
**Hospitalisation:**
**Onset Date:** 23/03/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 87
**DOB:** 21/11/1917
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**HEPARIN SODIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**AVANZA (Suspected)** **Reason:**
Tablet 60.0 Milligram Oral
**Batch:** **Started:** 23/03/2005 **Stopped:**

**DILTAHEXAL (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**CORDARONE X (Suspected)** **Reason:** Otr&nos disord of heart rhythm
Tablet 100.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 07/11/2005 | Other data | (40-100) | 01/03/2005 | 143 | Alk Phosphatase |
| 07/11/2005 | Other data | (40-100) | 22/03/2005 | 187 | Alk Phosphatase |
| 07/11/2005 | Other data | (40-100) | 30/03/2005 | 161 | Alk Phosphatase |
| 07/11/2005 | Other data | (40-100) | 24/04/2005 | 250 | Alk Phosphatase |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213162 **Seq:** 1
**Reported:** 07/11/2005
**Hospitalisation:**
**Onset Date:** 23/03/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 87
**DOB:** 21/11/1917
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **EFEXOR (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 150.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **PRAVACHOL (Suspected)** | | | **Reason:** | Othr&unspec metabolic diseases | |
| Tablet | 10.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213383 **Seq:** 1 **Gender:** M
**Reported:** 14/11/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 68Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | Incapacity/disability | Patient experienced sweating, and lethargy in the morning. When patient began taking 450mg/daily, he felt high, became verbally abusive, experienced an arterial problem in the brain, "hardening of an artery", drug effect decreased and short term memory loss. | Efexor XR ceased. Started on Lithium. Efexor XR restarted. |
| Amnesia | Incapacity/disability | | |
| Euphoric mood | Incapacity/disability | | |
| Hostility | Incapacity/disability | | |

### Medicine Details:

**NEULACTIL (Other drug)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**LIPITOR (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**OMEPRAZOLE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**TEGRETOL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Concurrent conditions: Bipolar I disorder, alcoholic, hypercholesterolaemia and dyspepsia.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213383 **Seq:** 1 **Gender:** M
**Reported:** 14/11/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 68Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Lethargy | Incapacity/disability | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 300.0 Milligram Daily Oral

**Batch:** **Started:** 15/08/2003 **Stopped:**

### Laboratory Investigations:

### Additional Information:

Concurrent conditions: Bipolar I disorder, alcoholic, hypercholesterolaemia and dyspepsia.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213565 **Seq:** 1 **Gender:** F
**Reported:** 17/11/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 48Y
**Onset Date:** 08/08/2005 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatitis fulminant | Caused or prolonged inpatient hospitalisation | Fulminant hepatitis likely caused by [illegible] | Patient intubated and sedated, NGT, NAC and Folinic Acid. Cholestyramine 8g/tds to help with removal of Arava from GIT. Stopped all anti-rheumatoid medications, and psychotropic medications |

### Medicine Details:

| | | | |
|---|---|---|---|
| **FOLIC ACID (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **CENTRUM TABLETS (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **OSTELIN 1000 (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **NEXIUM (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 17/11/2005 | ALT = SGPT | <34 u/l | 04/08/2005 | 2621 | |
| 17/11/2005 | ALT = SGPT | <34 u/l | 10/08/2005 | 1583 | |
| 17/11/2005 | ALT = SGPT | <34 u/l | 23/08/2005 | 1431 | |
| 17/11/2005 | Bilirubin | <18 mcmol/L | 04/08/2005 | 27 | |
| 17/11/2005 | Bilirubin | <18 mcmol/L | 10/08/2005 | 50 | |
| 17/11/2005 | Bilirubin | <18 mcmol/L | 23/08/2005 | 33 | |
| 17/11/2005 | GGT = SGGT = [illegible] | <38 u/l | 04/08/2005 | 118 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213565 **Seq:** 1
**Reported:** 17/11/2005
**Hospitalisation:**
**Onset Date:** 08/08/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 48Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**MONOPLUS NOS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**AMOXIL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**METHOTREXATE (Suspected)** **Reason:**
20.0 Milligram Weekly Oral
**Batch:** **Started:** **Stopped:** 09/08/2005

**ALPRAZOLAM (Suspected)** **Reason:**
Tablet 5.0 Milligram As necessary Oral
**Batch:** **Started:** **Stopped:** 09/08/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 17/11/2005 | GGT = SGGT = | <38 u/l | 23/08/2005 | 153 | |
| 17/11/2005 | GGT = SGGT = | <38 u/l | 10/08/2005 | 104 | |
| 17/11/2005 | International | | | | INR - 4.5. |
| 17/11/2005 | SAP = ALP | 32-91 u/l | 04/08/2005 | 88 | |
| 17/11/2005 | SAP = ALP | 32-91 u/l | 10/08/2005 | 84 | |
| 17/11/2005 | SAP = ALP | 32-91 u/l | 23/08/2005 | 90 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213565 **Seq:** 1
**Reported:** 17/11/2005
**Hospitalisation:**
**Onset Date:** 08/08/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 48Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **ARAVA (Suspected)** | | | **Reason:** | |
| Tablet | 20.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | 12/01/2005 | **Stopped:** | 09/08/2005 |
| **MOBIC (Suspected)** | | | **Reason:** | |
| | 7.5 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | **Stopped:** | 09/08/2005 |
| **ZYPREXA (Suspected)** | | | **Reason:** | |
| Tablet | 10.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | **Stopped:** | 09/08/2005 |
| **PLAQUENIL (Suspected)** | | | **Reason:** | |
| Tablet | 200.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | 12/12/2001 | **Stopped:** | 09/08/2005 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213565 **Seq:** 1
**Reported:** 17/11/2005
**Hospitalisation:**
**Onset Date:** 08/08/2005
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 48Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **ARTANE (Suspected)** | | | **Reason:** | | |
| Tablet | 1.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | 09/08/2005 |
| **EFEXOR (Suspected)** | | | **Reason:** | | |
| | 450.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | 09/08/2005 |
| **KLACID (Suspected)** | | | **Reason:** | | |
| | 500.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 31/07/2005 | | **Stopped:** | 08/08/2005 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213621 **Seq:** 1 **Gender:** M
**Reported:** 21/11/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 18Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | Patient attempted suicide. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Attempted auicide one week after starting Efexor XR.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213703 **Seq:** 1 **Gender:** F
**Reported:** 23/11/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 92
**Onset Date:** 02/11/2005 **DOB:** 01/01/1913
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Blood pressure increased<br><br>Therapy regimen changed | | The patient's Venlafaxine dose was increased from 75mg to 150mg daily and her blood pressure increased. | Venlafaxine ceased. |

### Medicine Details:

**ATENOLOL (Other drug)** **Reason:** Essential benign hypertension
**Batch:** **Started:** **Stopped:**

**ZYPREXA (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ZANTAC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**LORAZEPAM (Other drug)** **Reason:** Otr spec symp psychopathol nec
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 213703 **Seq:** 1
**Reported:** 23/11/2005
**Hospitalisation:**
**Onset Date:** 02/11/2005
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 92
**DOB:** 01/01/1913
**Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **COLOXYL WITH SENNA (Other drug)** | | | **Reason:** Constipation | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **EFEXOR (Suspected)** | | | **Reason:** Depression | |
| | 150.0 Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | **Stopped:** | 0 |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213740 **Seq:** 1 **Gender:** M
**Reported:** 24/11/2005 **Weight:** 100.00
**Hospitalisation:** **Age:** 100
**Onset Date:** 07/11/2005 **DOB:** 24/04/1905
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Overdose | Life | Serotonin syndrome, akathisia and suicide attempt induced by Efexor. | |
| Suicide attempt | Life | | |

### Medicine Details:

**ASASANTIN SR (Other drug)** **Reason:**
Capsule 2.0 Dose Unspecified Oral
**Batch:** **Started:** **Stopped:**

**LORAZEPAM (Other drug)** **Reason:** Otr spec symp psychopathol nec
Tablet 1.0 Milligram Oral
**Batch:** **Started:** 15/09/2005 **Stopped:**

**FOSAMAX (Other drug)** **Reason:**
70.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 300.0 Milligram Daily Oral
**Batch:** **Started:** 30/04/2005 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Previous CVA 3.5 years ago. Patient has had depression (mild) for years. He is a holocaust survivor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213743 **Seq:** 1 **Gender:** M
**Reported:** 24/11/2005 **Weight:** 70.00
**Hospitalisation:** **Age:** 72Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | Life | Suicide attempt. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
37.5 Milligram Daily Oral
**Batch:** **Started:** S TERM **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
225.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**OLANZAPINE (Suspected)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** S TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213763 **Seq:** 1 **Gender:** M
**Reported:** 24/11/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Death, maybe drug **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Completed suicide | Death | Patient committed suicide upon commencing treatment with Effexor. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Tablet Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213786 **Seq:** 1
**Reported:** 25/11/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/11/2005
**Outcome:** Unknown

**Gender:** M
**Weight:** 0.00
**Age:** 54
**DOB:** 14/07/1951
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state | Life | Patient presented with confusion, decreased level of conscious, shivering, tremor and fever, serotonin syndrome. | Stopped Efexor-XR, Selegiline and Tritace. Admitted HDU given supportive treatment and Cyproheptadine. |
| Chills | Life | | |
| Depressed level of consciousnes | Life | | |
| Pyrexia | Life | | |
| Serotonin syndrome | Life | | |
| Tremor | Life | | |

### Medicine Details:

**COMTAN (Other drug)** **Reason:**
Tablet 5.0 Dose Unspecified Oral
**Batch:** **Started:** **Stopped:**

**KINSON (Other drug)** **Reason:**
Tablet 5.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:** 0

**TRITACE (Other drug)** **Reason:**
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 213786 **Seq:** 1
**Reported:** 25/11/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/11/2005
**Outcome:** Unknown

**Gender:** M
**Weight:** 0.00
**Age:** 54
**DOB:** 14/07/1951
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**SELEGILINE HYDROCHLORIDE (Suspected)** **Reason:**

| | | | | |
|---|---|---|---|---|
| Tablet | 5.0 | Milligram | Daily | Oral |

**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213912 **Seq:** 1
**Reported:** 30/11/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 01/11/2005
**Outcome:** Recovered

**Gender:** M
**Weight:** 0.00
**Age:** 52
**DOB:** 19/08/1953
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Serotonin syndrome | Caused or prolonged inpatient hospitalisation | Patient experienced serotonin syndrome with sweating, tremor, dizziness, intemittent like flu illness, short of breath, disorientation, muscle spasm. | Ceased Parnate. |
| Disorientation | Caused or prolonged inpatient hospitalisation | | |
| Dizziness | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**PRAVACHOL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**DI-GESIC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**DUCENE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**AVAPRO HCT 150/12.5 (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

## Report Detail

**Case Number:** 213912 **Seq:** 1
**Reported:** 30/11/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 01/11/2005
**Outcome:** Recovered

**Gender:** M
**Weight:** 0.00
**Age:** 52
**DOB:** 19/08/1953
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyspnoea | Caused or prolonged inpatient hospitalisation | | |
| Hyperhidrosis | Caused or prolonged inpatient hospitalisation | | |
| Influenza like illness | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**STEMETIL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**PARNATE (Suspected)** **Reason:** Depression
Tablet 70.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213912 **Seq:** 1
**Reported:** 30/11/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 01/11/2005
**Outcome:** Recovered

**Gender:** M
**Weight:** 0.00
**Age:** 52
**DOB:** 19/08/1953
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle spasms | Caused or prolonged inpatient hospitalisation | | |
| Tremor | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

| | | | |
|---|---|---|---|
| **PRAVACHOL (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **DI-GESIC (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **DUCENE (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **AVAPRO HCT 150/12.5 (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213912 **Seq:** 1
**Reported:** 30/11/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 01/11/2005
**Outcome:** Recovered

**Gender:** M
**Weight:** 0.00
**Age:** 52
**DOB:** 19/08/1953
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **STEMETIL (Other drug)** | | | **Reason:** | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **EFEXOR (Suspected)** | | | **Reason:** | | |
| Tablet | 150.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **PARNATE (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 70.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213958 **Seq:** 1
**Reported:** 02/12/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 71Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypotension | Caused or prolonged inpatient hospitalisation | The patient experienced hypotension. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 225.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 213959 **Seq:** 1 **Gender:** M
**Reported:** 02/12/2005 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 15/08/2004 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Homicidal ideation | Life | The patient broke into his wife's unit, taped her up, threatened to kill her and threatened to kill himself. The prison "psych" report noted "Efexor-induced akathisia" and serotonergic syndrome caused this violent behaviour. | |
| Aggression | Life | | |
| Akathisia | Life | | |
| Serotonin syndrome | Life | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 300.0 Milligram Daily Oral

**Batch:** **Started:** 15/06/2004 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient has a long history of violent behavior prior to Efexor XR use.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 214017 **Seq:** 1
**Reported:** 05/12/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 14/08/2005
**Outcome:** Recovered

**Gender:** M
**Weight:** 0.00
**Age:** 60
**DOB:** 25/09/1944
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Circulatory collapse | Caused or prolonged inpatient hospitalisation | About 1 hour after taking Chlorpromazine 100mg, patient had a witnessed collapse (in chair), was grey in colour, had altered breathing, uneven pupils, shaking left leg and blood pressure of 67/-. Improved spontaneously over 10 minutes. Also had Diazapam 5mg and 100mg Chlorpromazine same morning. | Treated with IV fluids (Hartman's) and Potassium supplements. Ceased Chlorpromazine |
| Convulsion | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

| | | | |
|---|---|---|---|
| **OLANZAPINE (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **MIRTAZAPINE (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **DIAZEPAM (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **Zolpidem Sandoz (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 05/12/2005 | Calcium | | 17/08/2005 | 2.00 | |
| 05/12/2005 | Creatinine | | 17/08/2005 | 89 | |
| 05/12/2005 | Magnesium | | 17/08/2005 | 0.63 | |
| 05/12/2005 | Potassium | | 17/08/2005 | 2.9 | |
| 05/12/2005 | Sodium | | 17/08/2005 | 120 | |
| 05/12/2005 | bicarbonate | | 17/08/2005 | 17 | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214017 **Seq:** 1
**Reported:** 05/12/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:** 14/08/2005
**Outcome:** Recovered

**Gender:** M
**Weight:** 0.00
**Age:** 60
**DOB:** 25/09/1944
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypokalaemia | Caused or prolonged inpatient hospitalisation | | |
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | | |
| Hypotension | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**CHLORPROMAZINE HYDROCHLORIDE (Suspected)** **Reason:**
50.0 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
225.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214071 **Seq:** 1
**Reported:** 07/12/2005
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 99U
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pulmonary eosinophilia | Caused or prolonged inpatient hospitalisation | Patient experienced pulmonary [illegible] | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 300.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214514 **Seq:** 1 **Gender:** F
**Reported:** 03/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 51
**Onset Date:** 15/04/2003 **DOB:** 10/05/1951
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Homicidal ideation | Caused or prolonged inpatient hospitalisation | She tried killing her children and herself | |

### Medicine Details:

**OROXINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
300.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

I never did that before I had the Efexor.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 214514 **Seq:** 1 **Gender:** F
**Reported:** 03/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 51
**Onset Date:** 15/04/2003 **DOB:** 10/05/1951
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Automatism | Caused or prolonged inpatient hospitalisation | The patient experienced non-insane automatism, was extremely fidgety, agitated, was scratching herself, her body was contorting, she was unable to keep her legs still, unable to stay in one position, complained of aches and pains in her chest and shoulders, had abnormal liver function tests, suspected serotonin syndrome, was confused, was in acute withdrawal akathisia, had sudden mood changes, wet the bed, she becomes abusive and throws things at ther children and has violent thoughts all of the time | |

## Medicine Details:

**OROXINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
300.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

## Additional Information:

I never did that before I had the Efexor.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 214514 **Seq:** 1 **Gender:** F
**Reported:** 03/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 51
**Onset Date:** 15/04/2003 **DOB:** 10/05/1951
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression | Caused or prolonged inpatient hospitalisation | | |
| Akathisia | Caused or prolonged inpatient hospitalisation | | |
| Confusional state | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**OROXINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
300.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

## Additional Information:

I never did that before I had the Efexor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214514 **Seq:** 1 **Gender:** F
**Reported:** 03/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 51
**Onset Date:** 15/04/2003 **DOB:** 10/05/1951
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delirium | Caused or prolonged inpatient hospitalisation | | |
| Drug withdrawal syndrome | Caused or prolonged inpatient hospitalisation | | |
| Liver function test abnormal | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**OROXINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
300.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

### Additional Information:
I never did that before I had the Efexor.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 214514 **Seq:** 1 **Gender:** F
**Reported:** 03/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 51
**Onset Date:** 15/04/2003 **DOB:** 10/05/1951
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mood altered | Caused or prolonged inpatient hospitalisation | | |
| Psychomotor hyperactivity | Caused or prolonged inpatient hospitalisation | | |
| Serotonin syndrome | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**OROXINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
300.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

## Additional Information:

I never did that before I had the Efexor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214514 **Seq:** 1 **Gender:** F
**Reported:** 03/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 51
**Onset Date:** 15/04/2003 **DOB:** 10/05/1951
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | Caused or prolonged inpatient hospitalisation | | |
| Urinary incontinence | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**OROXINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
300.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

### Additional Information:
I never did that before I had the Efexor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214548 **Seq:** 1 **Gender:** M
**Reported:** 04/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 36
**Onset Date:** **DOB:** 18/08/1969
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | Caused or prolonged inpatient hospitalisation | He attempted to kill himself four times and had thoughts of killing his wife. | |
| Akathisia | Caused or prolonged inpatient hospitalisation | The patient developed suspected serotonin syndrome and akathisia. | |
| Automatism | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**OXYCONTIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ENDEP (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 214548 **Seq:** 1
**Reported:** 04/01/2006
**Hospitalisation:**
**Onset Date:**
**Outcome:** Unknown

**Gender:** M
**Weight:** 0.00
**Age:** 36
**DOB:** 18/08/1969
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depression | Caused or prolonged inpatient hospitalisation | | |
| Homicidal ideation | Caused or prolonged inpatient hospitalisation | | |
| Serotonin syndrome | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**OXYCONTIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ENDEP (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214554 **Seq:** 1 **Gender:** F
**Reported:** 04/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 48
**Onset Date:** 28/12/2005 **DOB:** 25/09/1957
**Outcome:** Recovered 04/01/2006 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash papular<br><br>Pruritus | | Red, papular, itchy rash over scalp and back of neck and in pubic area. Settled over about 5 days after ceasing effexor. | Nil required as settled by time |

### Medicine Details:

**METHADONE HYDROCHLORIDE (Other drug)** **Reason:**
Oral Liquid 40.0 Milligram 1 time Oral
**Batch:** **Started:** 23/09/2002 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 150.0 Milligram 1 time Oral
**Batch:** **Started:** 01/12/2005 **Stopped:** 30/12/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214565 **Seq:** 1 **Gender:** F
**Reported:** 04/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 42
**Onset Date:** **DOB:** 14/11/1963
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug ineffective<br>Aggression<br>Fatigue<br>Hypothyroidism<br>Influenza like illness<br>Insomnia<br>Weight increased | | In spite of Efexor treatment, the patient's depression had not remitted. She suffered a lot of flu-like illnesses and could not get out of bed on the high dose of Efexor. She was very tired and at night she could not sleep. She put on a lot of weight and developed hypothyroidism. | Oroxine 150 mcg daily. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214574 **Seq:** 1 **Gender:** M
**Reported:** 04/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mania<br>Akathisia<br>Muscle spasms<br>Serotonin syndrome | | The patient experienced mania and akathisia with delirium and suspected serotonin syndrome. He was imagining horrible things, that he'd lost things. He felt really strange. A psychiatrist told him that he'd been having 'classical blackouts'. He | Biquinate for cramps. |

### Medicine Details:

| | | | |
|---|---|---|---|
| **OXYNORM (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **ENDONE (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **VIOXX (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **CELEBREX (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

He eventually stopped taking Efexor and then took it for three days again whereupon he had classical blackouts, mania nd akathisia.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214574 **Seq:** 1 **Gender:** M
**Reported:** 04/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

He eventually stopped taking Efexor and then took it for three days again whereupon he had classical blackouts, mania nd akathisia.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214575 **Seq:** 1 **Gender:** F
**Reported:** 04/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 16Y
**Onset Date:** 28/11/2005 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delusion<br><br>Hallucination<br>Yawning | | Pateint experienced increased yawning "felt as if everyone was staring at her" and hallucination (unspecified). | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 28/11/2005 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214576 **Seq:** 1 **Gender:** M
**Reported:** 04/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 23
**Onset Date:** **DOB:** 07/09/1982
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression<br><br>Suicide attempt | | The patient became violent, slept badly and woke at night, lost twenty kg in three weeks, was agitated and suicidal. | |

### Medicine Details:

**LOVAN (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**SEREPAX (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**ALCOHOL (Suspected)** **Reason:**
Oral Liquid Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214768 **Seq:** 1 **Gender:** F
**Reported:** 10/01/2006 **Weight:** 129.00
**Hospitalisation:** **Age:** 59
**Onset Date:** 15/09/2005 **DOB:** 02/09/1946
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abnormal faeces | | Patient report "medication granules" in faeces when taking Efexor SR. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214770 **Seq:** 1 **Gender:** F
**Reported:** 10/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 51
**Onset Date:** 15/05/2005 **DOB:** 10/04/1954
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br><br><br>Drug withdrawal syndrome<br><br>Aggression<br>Agitation<br>Hyperhidrosis<br>Insomnia | | The patient experienced excessive sweating throughout the whole day, difficulty sleeping due to sweating, aggression, agitation and suicidal thoughts.<br><br>experienced sleepless nights and diarrhoea when tapering off efexor | |

### Medicine Details:

**VENTOLIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**FLIXOTIDE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 214834 **Seq:** 1
**Reported:** 11/01/2006
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 15/11/2005
**Outcome:** Recovered

**Gender:** F
**Weight:** 74.00
**Age:** 47
**DOB:** 25/02/1958
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Extrapyramidal disorder | Caused or prolonged inpatient hospitalisation | Patient experienced extrapyramidal movements and paeudo seizures. | |
| Conversion disorder | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** 21/10/2005 **Stopped:** 05/12/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215082 **Seq:** 1 **Gender:** M
**Reported:** 19/01/2006 **Weight:** 65.00
**Hospitalisation:** **Age:** 54Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br><br><br>Disorientation<br>Motor dysfunction<br>Paranoia | | severe withdrawal phenomena after Efexor discontinuation.<br>disorientation, paranoia, motor problems.<br>slowly resolving | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
150.0 Milligram
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215144 **Seq:** 1 **Gender:** M
**Reported:** 21/01/2006 **Weight:** 70.00
**Hospitalisation:** **Age:** 47
**Onset Date:** 16/12/2005 **DOB:** 01/01/1958
**Outcome:** Recovered 24/12/2005 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysarthria | Caused or prolonged inpatient hospitalisation | Intermittent dysarthria after increasing venlafaxine from 150mg to 225mg. Subsequent investigations including MRI brain, cardiological and neurological assessments were normal. Dysarthria ceased some days after ceasing the | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Daily Oral
**Batch:** **Started:** 03/11/2005 **Stopped:** 16/12/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

dose related

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215214 **Seq:** 1 **Gender:** M
**Reported:** 24/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 60Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Agitation<br>Akathisia<br>Dizziness<br>Hyperhidrosis<br>Nightmare<br>Palpitations<br>Weight increased | | Patient experienced feeling dizzy in the head, developed drug withdrawal syndrome, began sweating, heart palpitations, agitation, paronoria and weight gain. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215221 **Seq:** 1
**Reported:** 24/01/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 63Y
**DOB:**
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary retention | Caused or prolonged inpatient hospitalisation | After taking just one tablet of Efexor the patient experienced urinary retention. | Catheterised. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Tablet 75.0 Milligram Daily Oral

**Batch:** **Started:** S TERM **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215256 **Seq:** 1 **Gender:** F
**Reported:** 24/01/2006 **Weight:** 85.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Syncope<br>Agitation<br>Food craving<br>Headache<br>Hunger<br>Hypoglycaemia<br>Irritability<br>Tachycardia | | Patient experienced rapid heart rapid, faint feelings, hungry, carbohydrate cravings, agitated,irritable, headache, hypoglycaemia, patient says "thats how it feels". | Efexor XR ceased by patient. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 28/10/2005 **Stopped:** 05/12/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215276 **Seq:** 1 **Gender:** M
**Reported:** 25/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 60Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Abnormal dreams<br>Agitation<br>Dizziness<br>Hyperhidrosis | | Within hours of missing his morning dose in order to slowly wean himself off Efexor XR the patient began to feel dizzy in the head. When he stretched the gap between doses to 3 days he experienced sweating, heart palpitations, poor sleeping, kicking of his legs whilst watching TV, agitation and "vivid dreams" which are often accompanied by shouting and punching his | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/06/2004 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

I waited for 24 hours and then took my dose. Almost immedicately the dizzy effect began to abate, and totally disappeared after about 2 hours.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215276 **Seq:** 1 **Gender:** M
**Reported:** 25/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 60Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia<br>Palpitations | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/06/2004 **Stopped:**

### Laboratory Investigations:

### Additional Information:

I waited for 24 hours and then took my dose. Almost immedicately the dizzy effect began to abate, and totally disappeared after about 2 hours.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215307 **Seq:** 1 **Gender:** F
**Reported:** 27/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 41
**Onset Date:** **DOB:** 03/10/1964
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br><br>Akathisia | | The patient developed impulses to kill herself and was restless. She could not sit down and was pacey. She had panic attacks, violent dreams and would sleep all day. | |

### Medicine Details:

**ZYPREXA (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**CANNABIS PREPARATION (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
175.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215313 **Seq:** 1 **Gender:** M
**Reported:** 27/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 46
**Onset Date:** **DOB:** 10/06/1959
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Homicidal ideation<br><br>Aggression<br>Suicidal ideation | | The patient experienced constant violent and homicidal and suicidal ideation. | |

### Medicine Details:

**CANNABIS PREPARATION (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215322 **Seq:** 1 **Gender:** F
**Reported:** 27/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Affective disorder<br>Aggression<br>Akathisia<br>Mania<br>Psychotic disorder<br>Restlessness<br>Suicidal ideation | | The patient experienced headaches whilst taking Efexor. She became suicidal, voilent with anyone, unable to sit down and relax, restless and pacing. When she stopped taking it she felt awful. | Codeine and Serepax. Efexor |

### Medicine Details:

**Amphetamine (Suspected)** **Reason:**
**Batch:** **Started:** 15/03/2004 **Stopped:**

**METHADONE HYDROCHLORIDE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215324 **Seq:** 1 **Gender:** M
**Reported:** 27/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 47
**Onset Date:** **DOB:** 11/11/1958
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination<br>Akathisia<br>Amnesia<br>Disorientation<br>Drug withdrawal syndrome | | The patient experienced "like a pressure build up in my head, like fainting, like dizzy, light headed, shaky. My heart pounds and I have to leave the office with a panic". He had surges of anger, racing thoughts and violent thoughts. He was restless, hallucinated that he saw shadows and could hear music. He had involuntary movements of his toes and hands, got agitated and could not sleep. | Efexor replaced with Avanza, then Lexapro. |

### Medicine Details:

**NAPROSYN (Other drug)** **Reason:** Unspecified arthritis
2.0 Gram
**Batch:** **Started:** **Stopped:**

**DOLOBID (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**VALIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**VALIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215324 **Seq:** 1 **Gender:** M
**Reported:** 27/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 47
**Onset Date:** **DOB:** 11/11/1958
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Panic disorder | | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215350 **Seq:** 1 **Gender:** M
**Reported:** 30/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 54
**Onset Date:** **DOB:** 15/09/1951
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Akathisia<br>Amnesia<br>Depression<br>Hypertension<br>Panic attack | | The patient experienced akathisia, was more depressed, restless, pacing at night, had restless legs, tingling in his hands and the soles of his feet, was quick to anger, had surges of energy, palpitations, high blood pressure, a panic attack and was very vague and forgetful. | |

### Medicine Details:

**FIORINAL (Other drug)** **Reason:** Pain
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215364 **Seq:** 1 **Gender:** M
**Reported:** 30/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 17Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression<br>Akathisia<br>Drug withdrawal syndrome<br>Homicidal ideation<br>Paranoia<br>Suicidal ideation<br>Vomiting | | The patient experienced violent thoughts, wanted to kill himself and others, was restless and couldn't sit, was irritable, was pacing, was paranoid, vomiting and had withdrawal syndrome. | Efexor ceased. Given Mogadon for sleep. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215419 **Seq:** 1 **Gender:** F
**Reported:** 31/01/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 14
**Onset Date:** 14/10/2004 **DOB:** 20/03/1990
**Outcome:** Death, maybe drug 14/10/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug ineffective | Death | Patient received Efexor XR therapy and committed suicide. Patient also experienced drug ineffective | Efexor XR discontinued. |
| Completed suicide | Death | hanging | |

### Medicine Details:

**ZYPREXA (Other drug)** **Reason:**
2.5 Milligram
**Batch:** **Started:** 20/09/2004 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 12/08/2004 **Stopped:** 08/10/2004

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

State Coroner's case. For more than a year prior to committing suicide the patient suffered from a depressive illness. During the course of this period there were episodes of self-harm, evidence of suicidal ideation and hospitalisations. The patient took the last dose of Efexor XR" on or about" 8 October 2004.
Also took Stilnox, Endep and Diane-35.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215746 **Seq:** 1 **Gender:** F
**Reported:** 10/02/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 30
**Onset Date:** 15/06/2005 **DOB:** 01/03/1975
**Outcome:** Recovered 15/10/2005 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Oculogyration | | Oculogyration | benztropine |

### Medicine Details:

**SOLIAN (Suspected)** **Reason:**
Tablet 400.0 Milligram Daily Oral
**Batch:** **Started:** 15/01/2005 **Stopped:** 15/01/2006

**EFEXOR (Suspected)** **Reason:**
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215925 **Seq:** 1
**Reported:** 16/02/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:** 21/02/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 51
**DOB:** 12/05/1953
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Caused or prolonged inpatient hospitalisation | Patient experienced a convulsion and withdrawal reaction. | Monitored and supportive. |
| Convulsion | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**TEMAZEPAM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**THYROXINE SODIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**OMEPRAZOLE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**SODIUM VALPROATE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Report 215928 is the second sequence to this report.
Ebixa interacts with anticonvulsants, Epilim was withdrawn over 1 week (AMS Prescrober suggests 16 weeks), Efexor should be used with caution in epilepsy, Possible fits due to Epilim withdrawal twoo quick whilst introducting epileptogenic drug.

## Report Detail

**Case Number:** 215925 **Seq:** 1
**Reported:** 16/02/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:** 21/02/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 51
**DOB:** 12/05/1953
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **Ebixa (Suspected)** | | | **Reason:** | Unspecified psychosis |
| Tablet | 20.0 Milligram | | Daily | Oral |
| **Batch:** | **Started:** | 14/02/2005 | | **Stopped:** |
| **EPILIM (Suspected)** | | | **Reason:** | |
| Tablet | 200.0 Milligram | | Daily | Oral |
| **Batch:** | **Started:** | 14/02/2005 | | **Stopped:** 20/02/2005 |

## Laboratory Investigations:

## Additional Information:

Report 215928 is the second sequence to this report.
Ebixa interacts with anticonvulsants, Epilim was withdrawn over 1 week (AMS Prescrober suggests 16 weeks), Efexor should be used with caution in epilepsy, Possible fits due to Epilim withdrawal twoo quick whilst introducting epileptogenic drug.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215926 **Seq:** 1
**Reported:** 16/02/2006
**Hospitalisation:**
**Onset Date:** 15/01/2006
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia<br>Agitation<br>Serotonin syndrome<br>Tension | | The patient experienced suspected serotonin syndrome, felt very agitated, was unable to sleep, felt all his muscles were tense and had to pace around. | Ceased Efexor. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** 23/11/2005 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 215937 **Seq:** 1 **Gender:** F
**Reported:** 16/02/2006 **Weight:** 91.00
**Hospitalisation:** **Age:** 29
**Onset Date:** 15/11/2005 **DOB:** 12/05/1976
**Outcome:** Recovered 20/12/2005 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyskinesia | | Pateint experienced facial dyskinesia. | Abilify was ceased, Efexor XR was reduced to 150mg. |

### Medicine Details:

**Abilify (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 27/06/2005 **Stopped:** 29/11/2005 0

**EFEXOR-XR (Suspected)** **Reason:** Unspecified schizophrenia
Capsule 300.0 Milligram Daily Oral
**Batch:** **Started:** 27/06/2005 **Stopped:** 25/07/2005 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 216028 **Seq:** 1 **Gender:** F
**Reported:** 21/02/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 25
**Onset Date:** 15/07/2005 **DOB:** 08/11/1979
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Amenorrhoea | | The patient experienced amenorrhea. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** 15/07/2005 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 21/02/2006 | Other data | | | | 24 Jan 2006: Blood follicle stimulating hormone - 9 (normal range: 2-12).<br>24 Jan 2006: Blood luteinising hormone - 2.2 (normal range 2-12) |
| 21/02/2006 | Prolactin | 40-570 | 24/01/2006 | 151 | Blood prolactin. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 216096 **Seq:** 1 **Gender:** M
**Reported:** 22/02/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Dizziness<br>Hyperhidrosis<br>Irritability<br>Nausea<br>Nightmare<br>Restless legs syndrome<br>Tinnitus | | Patient developed severe withdrawal symptoms, nausea, very severe dizziness, sweating, kicking of my legs whilst watching TV, whoosing sounds in my head (whop whop sound) and vivid dreams which became physical. | Withdrawal of Efexor-EX. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 216119 **Seq:** 1 **Gender:** F
**Reported:** 23/02/2006 **Weight:** 60.00
**Hospitalisation:** **Age:** 23Y
**Onset Date:** 15/12/2005 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea<br><br>Insomnia | | Patient experienced nausea and sleeplessness with Efexor. | |

### Medicine Details:

**DOLASED (Other drug)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 216211 **Seq:** 1 **Gender:** F
**Reported:** 01/03/2006 **Weight:** 95.00
**Hospitalisation:** Required a visit to the doctor **Age:** 16
**Onset Date:** 01/02/2006 **DOB:** 10/11/1989
**Outcome:** Recovered 26/02/2006 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mydriasis<br><br>Diplopia | | The patient experienced mydriasis and diplopia after ceasing Efexor. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 27/01/2006 **Stopped:** 01/02/2006

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 216233 **Seq:** 1 **Gender:** M
**Reported:** 01/03/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br><br>Balance disorder<br>Tremor | | The patient experienced dizziness getting up from bed, tremors and losing his balance | |

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression | |
| Capsule | 225.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | 15/01/2006 |
| **NORVASC (Suspected)** | | | **Reason:** | | |
| Tablet | 1.0 | Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **HYTRIN (Suspected)** | | | **Reason:** | | |
| Tablet | 5.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **COVERSYL (Suspected)** | | | **Reason:** | | |
| Tablet | 4.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 216271 **Seq:** 1 **Gender:** F
**Reported:** 06/03/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 25Y
**Onset Date:** 27/02/2006 **DOB:**
**Outcome:** Recovered 27/02/2006 **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus generalised<br><br>Urticaria | | Patient developed generalised moderate pruritis and 4 to 5 hives effecting UL's/LL's resolving after 15 minutes. | |

## Medicine Details:

**TROPISETRON HYDROCHLORIDE (Suspected)** **Reason:**
Injection 2.0 Milligram Daily Intravenous
**Batch:** **Started:** 27/02/2006 **Stopped:**

**PARACETAMOL (Suspected)** **Reason:**
4.0 Gram Daily Oral
**Batch:** **Started:** 27/02/2006 **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** 27/02/2006 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 216521 **Seq:** 1 **Gender:** F
**Reported:** 15/03/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 87Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Condition aggravated | | Patient had a low platelet count of 100 x 10^12/L when she commenced on Efexor-XR. The Efexor-XR dose was tiltrated upwards in the last month and the patient's platelet count in now 50 x 10^12/L. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Oral
**Batch:** **Started:** 22/12/2005 **Stopped:** 15/01/2006 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 15/03/2006 | Platelets | | | | 2005 - 100 x 10^12/L (parameters not provided)<br>2006 - 50 x 10^12/L (parameters not provided) |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 216605 **Seq:** 1 **Gender:** F
**Reported:** 22/03/2006 **Weight:** 63.00
**Hospitalisation:** **Age:** 52
**Onset Date:** 22/03/2006 **DOB:** 05/09/1953
**Outcome:** Recovered 22/03/2006 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Syncope | Incapacity/disability | took 37.5mg capsule of Efexor (first time) last night @ 2100. woke up at 0400 with faint, nausea, jaw tightness, diarrhoea, dry mouth, sweaty | supportive |
| Diarrhoea | Incapacity/disability | | |
| Dry mouth | Incapacity/disability | | |
| Hyperhidrosis | Incapacity/disability | | |
| Muscle tightness | Incapacity/disability | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Capsule 37.5 Milligram 1 time Oral
**Batch:** **Started:** 21/03/2006 **Stopped:** 22/03/2006

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 216605 **Seq:** 1 **Gender:** F
**Reported:** 22/03/2006 **Weight:** 63.00
**Hospitalisation:** **Age:** 52
**Onset Date:** 22/03/2006 **DOB:** 05/09/1953
**Outcome:** Recovered 22/03/2006 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea | Incapacity/disability | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Capsule 37.5 Milligram 1 time Oral
**Batch:** **Started:** 21/03/2006 **Stopped:** 22/03/2006

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 216683 **Seq:** 1 **Gender:** F
**Reported:** 27/03/2006 **Weight:** 70.00
**Hospitalisation:** **Age:** 75
**Onset Date:** **DOB:** 10/12/1930
**Outcome:** Recovered 08/03/2006 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | | |

### Medicine Details:

**VERAPAMIL HYDROCHLORIDE (Other drug)** **Reason:** Otr&nos disord of heart rhythm
**Batch:** **Started:** **Stopped:**

**DIGOXIN (Other drug)** **Reason:** Otr&nos disord of heart rhythm
**Batch:** **Started:** **Stopped:**

**ASASANTIN SR (Other drug)** **Reason:** Otr&nos disord of heart rhythm
**Batch:** **Started:** **Stopped:**

**EVISTA (Other drug)** **Reason:** Other diseases of bone
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 216683 **Seq:** 1 **Gender:** F
**Reported:** 27/03/2006 **Weight:** 70.00
**Hospitalisation:** **Age:** 75
**Onset Date:** **DOB:** 10/12/1930
**Outcome:** Recovered 08/03/2006 **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | |
|---|---|---|---|
| **VENTOLIN (Other drug)** | | **Reason:** | Asthma |
| **Batch:** | **Started:** | | **Stopped:** |
| **EFEXOR-XR (Suspected)** | | **Reason:** | Anxiety neurosis |
| | 75.0 Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** 01/03/2006 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 216894 **Seq:** 1 **Gender:** M
**Reported:** 03/04/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | After commencing Zyprexa pateint experienced a seizure. | |

### Medicine Details:

**SEROQUEL (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**LITHIUM CARBONATE (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

**ZYPREXA (Suspected)** **Reason:** Unspecifid affective psychosis
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient's medical history includes the patient experiencing extreme agitation whilst receiving Lithium. This report 216894 is a duplicate of 216945.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217100 **Seq:** 1 **Gender:** F
**Reported:** 07/04/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 56Y
**Onset Date:** 04/03/2006 **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia<br><br>Feeling hot<br>Influenza like illness | | Muscle pain - creepy, tense pain and deep, dull ache in shoulder and upper back. Also felt hot (but temp only 37.2 degrees C) and tender, like when coming down with the flu. | Efexor XR ceased. Given Paracetamol. |

### Medicine Details:

**OROXINE (Other drug)** **Reason:** Myxedema
50.0 Microgram
**Batch:** **Started:** 15/02/2006 **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Suspect drug certain rechallenge.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217288 **Seq:** 1 **Gender:** M
**Reported:** 11/04/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Anger<br>Asthenia<br>Back pain<br>Eye pain | | Patient has attempted to discontinued Venlafaxine for the "6th time", each time he has experienced feeling angry all the time, verbally abusive, somnolence, body pain in the back, bones, muscles and eyes, feeling different, feeling out of control, kept thiniing there were things wrong with him, lost interest in things, electric shocks in head, and feels like lying around all day. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 70.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Suspect drug certain rechallenge.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 217288 **Seq:** 1 **Gender:** M
**Reported:** 11/04/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Somnolence | | | |

## Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 70.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

Suspect drug certain rechallenge.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217311 **Seq:** 1
**Reported:** 11/04/2006
**Hospitalisation:**
**Onset Date:** 17/03/2006
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 48
**DOB:** 08/11/1957
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Homicidal ideation<br><br>Hallucination, auditory<br>Nausea | | Patient experienced nausea, appetite loss, weight loss of 3kg and hearing voices in the head (saying things such as "go and get a gun") | |

### Medicine Details:

**AVANZA (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**CELAPRAM (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 37.5 Milligram Daily Oral
**Batch:** **Started:** 17/03/2006 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient reported that hearing voices in her head was experienced with other antidepressants as well.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217333 **Seq:** 1 **Gender:** M
**Reported:** 12/04/2006 **Weight:** 75.00
**Hospitalisation:** **Age:** 44
**Onset Date:** 25/01/2006 **DOB:** 28/08/1961
**Outcome:** Death, maybe drug 25/01/2006 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Death | Death | Presumed sudden death. | |
| Sudden death | Death | Presumed sudden death. | |

### Medicine Details:

**ASMOL CFC-FREE (Other drug)** **Reason:**
Inhalation 100.0 Microgram Inhalation
**Batch:** **Started:** **Stopped:**

**PANADEINE FORTE (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Oral
**Batch:** **Started:** **Stopped:**

**SEROQUEL (Suspected)** **Reason:** Unspecifid affective psychosis
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 12/04/2006 | Coroners findings | | | | Cause of death: unascertained |

### Additional Information:

History: Brain damage (perinatal). Minimal brain syndrome, diagnosed bipolar in January 2006.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217333 **Seq:** 1 **Gender:** M
**Reported:** 12/04/2006 **Weight:** 75.00
**Hospitalisation:** **Age:** 44
**Onset Date:** 25/01/2006 **DOB:** 28/08/1961
**Outcome:** Death, maybe drug 25/01/2006 **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | |
|---|---|---|---|
| **ALCOHOL (Suspected)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **CANNABIS PREPARATION (Suspected)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **EPILIM (Suspected)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

### Additional Information:

History: Brain damage (perinatal). Minimal brain syndrome, diagnosed bipolar in January 2006.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217521 **Seq:** 1
**Reported:** 20/04/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/06/2005
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anaemia | Caused or prolonged inpatient hospitalisation | Patient experienced anemia post delivery, and remained in the hospital for 5 days. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 15/03/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217556 **Seq:** 1 **Gender:** F
**Reported:** 20/04/2006 **Weight:** 55.00
**Hospitalisation:** Required a visit to the doctor **Age:** 50
**Onset Date:** **DOB:** 17/10/1955
**Outcome:** Recovered 07/04/2006 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Anorexia<br>Lethargy<br>Myalgia<br>Nausea | | 4 hours after taking Efexor patient experienced dizziness, nausea, bunable to eat, muscle aches and pains, lethargy - slept for 2 nighs and 1 day | |

### Medicine Details:

**FOLIC ACID (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**METHOTREXATE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PARIET (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PREDNISONE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 217556 **Seq:** 1
**Reported:** 20/04/2006
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Recovered 07/04/2006
**Gender:** F
**Weight:** 55.00
**Age:** 50
**DOB:** 17/10/1955
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **SALAZOPYRIN (Other drug)** | | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **EFEXOR (Suspected)** | | | **Reason:** | |
| | 75.0 Milligram | Daily | Oral | |
| **Batch:** | **Started:** 03/04/2006 | | **Stopped:** 03/04/2006 | 0 |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217659 **Seq:** 1
**Reported:** 24/04/2006
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 15/12/2005
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 73.00
**Age:** 48
**DOB:** 09/06/1957
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary hesitation<br><br>Spermatorrhoea | | Patient experienced urinary hesitancy, discharge of semen in the urine. | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
300.0 Milligram Daily
**Batch:** **Started:** 25/08/2004 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217774 **Seq:** 1 **Gender:** F
**Reported:** 28/04/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Oropharyngeal swelling<br><br>Pruritus | | Patient experienced itchy hives and "swelling of airway". | |

### Medicine Details:

**NUROFEN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PANADOL (Suspected)** **Reason:** Headache
Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule, modified release 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/10/2005 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217775 **Seq:** 1 **Gender:** F
**Reported:** 28/04/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Epilepsy | | Patient experienced "epileptic fit". | Efexor XR discontinued. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule, modified release Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217802 **Seq:** 1 **Gender:** F
**Reported:** 01/05/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 40
**Onset Date:** 15/09/2005 **DOB:** 21/12/1964
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depression | Caused or prolonged inpatient hospitalisation | Patient developed depression due to "emotional problems" and "life stresses". | Efexor discontinued. |
| Drug ineffective | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**LIPITOR (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NOTEN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**FISH OIL NOS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**MAGNESIUM NOS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 217802 **Seq:** 1
**Reported:** 01/05/2006
**Hospitalisation:**
**Onset Date:** 15/09/2005
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 40
**DOB:** 21/12/1964
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Tablet 225.0 Milligram Daily Oral

**Batch:** **Started:** 01/01/1996 **Stopped:** 15/03/2006

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217803 **Seq:** 1
**Reported:** 01/05/2006
**Hospitalisation:**
**Onset Date:** 01/01/2001
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 62
**DOB:** 29/01/1938
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Deafness | Incapacity/disability | Patient experienced tinnitus and loss of hearing in the left ear. | |
| Tinnitus | Incapacity/disability | | |

### Medicine Details:

**MICARDIS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PARIET (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ZOCOR (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/2001 **Stopped:** Continuing.

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217826 **Seq:** 1 **Gender:** F
**Reported:** 01/05/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 05/04/2006 **DOB:**
**Outcome:** Recovered 12/04/2006 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br><br>Anxiety<br>Nausea<br>Vomiting | | Patient experienced vomiting, nausea, anxiety, throbbing headache. | Ceased Efexor XR |

### Medicine Details:

**OROXINE (Other drug)** **Reason:**
100.0 Microgram
**Batch:** **Started:** 15/06/2002 **Stopped:** 0

**LITHICARB (Other drug)** **Reason:**
Tablet 500.0 Milligram Oral
**Batch:** **Started:** 15/12/2000 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Unspecifid affective psychosis
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 15/02/2005 **Stopped:** 04/04/2006 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217892 **Seq:** 1
**Reported:** 02/05/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** U
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Patient was found unconscious and diagnosed with hyponatraemia. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217932 **Seq:** 1 **Gender:** F
**Reported:** 02/05/2006 **Weight:** 65.00
**Hospitalisation:** **Age:** 52Y
**Onset Date:** 15/03/2006 **DOB:**
**Outcome:** Recovered 29/03/2006 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abnormal dreams<br><br><br>Anxiety<br>Drug interaction<br>Myalgia | | Patient experienced vivid dreams, muscle aches, anxiety (acute). Effects started about 1 week after commencing Singulair with acute anxiety commencing about 1 and a half weeks after starting. | Xanax 250mcg 1 daily for 4 |

### Medicine Details:

**EFEXOR-XR (Interaction)** **Reason:** Depression
**Batch:** **Started:** **Stopped:** 0

**SINGULAIR (Interaction)** **Reason:**
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 08/03/2006 **Stopped:** 22/03/2006 0

**PREDNISOLONE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**VENTOLIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 217932 **Seq:** 1 **Gender:** F
**Reported:** 02/05/2006 **Weight:** 65.00
**Hospitalisation:** **Age:** 52Y
**Onset Date:** 15/03/2006 **DOB:**
**Outcome:** Recovered 29/03/2006 **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | |
|---|---|---|---|
| **ATROVENT (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **Seretide 250/50 Accuhaler (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217942 **Seq:** 1
**Reported:** 03/05/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:** 18/03/2006
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 57
**DOB:** 31/01/1949
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Hyponatraemia due to ? Venlafaxine. | Suspected drugs withheld. |

### Medicine Details:

**EPILIM (Other drug)** **Reason:** Other&unspecified epilepsy
Tablet 800.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**NORVASC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ASPIRIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**SENNA FRUIT (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 03/05/2006 | Sodium | | | | Na - 119. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217942 **Seq:** 1
**Reported:** 03/05/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:** 18/03/2006
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 57
**DOB:** 31/01/1949
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **PARACETAMOL (Other drug)** | | | **Reason:** | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **PANTOPRAZOLE (Other drug)** | | | **Reason:** | | |
| | 40.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | 0 |
| **PAXAM (Other drug)** | | | **Reason:** | Other&unspecified epilepsy | |
| Tablet | 1.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **FRUSEMIDE (Suspected)** | | | **Reason:** | | |
| | 40.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 217942 **Seq:** 1
**Reported:** 03/05/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:** 18/03/2006
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 57
**DOB:** 31/01/1949
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **LISINOPRIL (Suspected)** | | | **Reason:** | | |
| Tablet | 10.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | 19/03/2006 |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | Depression | |
| | 150.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | 19/03/2006 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 217973 **Seq:** 1 **Gender:** M
**Reported:** 04/05/2006 **Weight:** 130.00
**Hospitalisation:** **Age:** 30Y
**Onset Date:** 04/05/2006 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | Caused or prolonged inpatient hospitalisation | First presentaion of generalised seizure during hospital admission for knee arthroplasty. Occurred on day 1 post-op. Pt was on tramadol SR 150 BD pre-operatively and subsequently received a total of 1150mg pethidine via PCA in the post-operative. There is a past h/o N,V secondary to morphine. I reported since tramadol may have interacted and lowered seizure threshold. Pt is large adult male with normal renal function. Pt on tramadol chronically pre-op. Also on venlafaxine | |

## Medicine Details:

**PETHIDINE HYDROCHLORIDE (Interaction)** **Reason:**
Injection 1150.0 Milligram As necessary Intravenous
**Batch:** **Started:** 03/05/2006 **Stopped:** 04/05/2006

**TRAMADOL HYDROCHLORIDE (Interaction)** **Reason:**
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 04/05/2006

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:**
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 04/05/2006 | Computerised | | | | CT Brain normal |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218069 **Seq:** 1 **Gender:** F
**Reported:** 05/05/2006 **Weight:** 60.00
**Hospitalisation:** **Age:** 82
**Onset Date:** 10/04/2006 **DOB:** 07/05/1923
**Outcome:** Recovered 05/05/2006 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Liver function test abnormal | Caused or prolonged inpatient hospitalisation | Increased LFTs predominantly cholestatic picture. Abdominal ultrasound excluded mechanical cause | Ceased venlafaxine |

### Medicine Details:

**PARACETAMOL (Other drug)** **Reason:**
Tablet 4.0 Gram 4 times Oral
**Batch:** **Started:** **Stopped:**

**SULFASALAZINE (Other drug)** **Reason:**
Tablet 3.0 Gram 3 times Oral
**Batch:** **Started:** **Stopped:**

**RISEDRONATE SODIUM (Other drug)** **Reason:**
Tablet 35.0 Milligram Weekly Oral
**Batch:** **Started:** **Stopped:**

**TEMAZEPAM (Other drug)** **Reason:**
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 05/05/2006 | ALT = SGPT | | 04/04/2006 | 20 | 04/04/06 ALP 64; GGT 67; ALT 20; AST 22<br>10/04/06 ALP 321; GGT 682; ALT 216; AST 137<br>13/04/06 ALP 234; GGT 565; ALT 102; AST 45<br>05/05/06 ALP 60; GGT 161; ALT 13; AST 21 |
| 05/05/2006 | ALT = SGPT | | 10/04/2006 | 216 | 04/04/06 ALP 64; GGT 67; ALT 20; AST 22<br>10/04/06 ALP 321; GGT 682; ALT 216; AST 137<br>13/04/06 ALP 234; GGT 565; ALT 102; AST 45<br>05/05/06 ALP 60; GGT 161; ALT 13; AST 21 |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218069 **Seq:** 1 **Gender:** F
**Reported:** 05/05/2006 **Weight:** 60.00
**Hospitalisation:** **Age:** 82
**Onset Date:** 10/04/2006 **DOB:** 07/05/1923
**Outcome:** Recovered 05/05/2006 **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **FOLIC ACID (Other drug)** | | | **Reason:** | | |
| Tablet | 5.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **OSTELIN 1000 (Other drug)** | | | **Reason:** | | |
| | 1000.0 | Unit | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **ATORVASTATIN (Other drug)** | | | **Reason:** | | |
| Tablet | 20.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **FELODIPINE (Other drug)** | | | **Reason:** | | |
| Tablet | 10.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 05/05/2006 | ALT = SGPT | | 13/04/2006 | 102 | 04/04/06 ALP 64; GGT 67; ALT 20; AST 22<br>10/04/06 ALP 321; GGT 682; ALT 216; AST 137<br>13/04/06 ALP 234; GGT 565; ALT 102; AST 45<br>05/05/06 ALP 60; GGT 161; ALT 13; AST 21 |
| 05/05/2006 | ALT = SGPT | | 05/05/2006 | 13 | 04/04/06 ALP 64; GGT 67; ALT 20; AST 22<br>10/04/06 ALP 321; GGT 682; ALT 216; AST 137<br>13/04/06 ALP 234; GGT 565; ALT 102; AST 45<br>05/05/06 ALP 60; GGT 161; ALT 13; AST 21 |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218069 **Seq:** 1 **Gender:** F
**Reported:** 05/05/2006 **Weight:** 60.00
**Hospitalisation:** **Age:** 82
**Onset Date:** 10/04/2006 **DOB:** 07/05/1923
**Outcome:** Recovered 05/05/2006 **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)** | | | **Reason:** | | |
| | 40.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **FERROUS SULPHATE (Other drug)** | | | **Reason:** | | |
| Tablet | 325.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **PREDNISOLONE (Other drug)** | | | **Reason:** | | |
| | 15.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **CALTRATE (Other drug)** | | | **Reason:** | | |
| Tablet | 600.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | 0 |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 05/05/2006 | AST = SGOT | | 04/04/2006 | 22 | |
| 05/05/2006 | AST = SGOT | | 10/04/2006 | 137 | |
| 05/05/2006 | AST = SGOT | | 13/04/2006 | 45 | |
| 05/05/2006 | AST = SGOT | | 05/05/2006 | 21 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218069 **Seq:** 1 **Gender:** F
**Reported:** 05/05/2006 **Weight:** 60.00
**Hospitalisation:** **Age:** 82
**Onset Date:** 10/04/2006 **DOB:** 07/05/1923
**Outcome:** Recovered 05/05/2006 **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

**CLOPIDOGREL (Other drug)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Capsule 37.5 Milligram Daily Oral
**Batch:** **Started:** 07/04/2006 **Stopped:** 11/04/2006 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 05/05/2006 | GGT = SGGT = [illegible] | | 04/04/2006 | 67 | 04/04/06 ALP 64; GGT 67; ALT 20; AST 22<br>10/04/06 ALP 321; GGT 682; ALT 216; AST 137<br>13/04/06 ALP 234; GGT 565; ALT 102; AST 45<br>05/05/06 ALP 60; GGT 161; ALT 13; AST 21 |
| 05/05/2006 | GGT = SGGT = [illegible] | | 10/04/2006 | 682 | 04/04/06 ALP 64; GGT 67; ALT 20; AST 22<br>10/04/06 ALP 321; GGT 682; ALT 216; AST 137<br>13/04/06 ALP 234; GGT 565; ALT 102; AST 45<br>05/05/06 ALP 60; GGT 161; ALT 13; AST 21 |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218069 **Seq:** 1 **Gender:** F
**Reported:** 05/05/2006 **Weight:** 60.00
**Hospitalisation:** **Age:** 82
**Onset Date:** 10/04/2006 **DOB:** 07/05/1923
**Outcome:** Recovered 05/05/2006 **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **PARACETAMOL (Other drug)** | | | **Reason:** | |
| Tablet | 4.0 | Gram | 4 times | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **SULFASALAZINE (Other drug)** | | | **Reason:** | |
| Tablet | 3.0 | Gram | 3 times | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **RISEDRONATE SODIUM (Other drug)** | | | **Reason:** | |
| Tablet | 35.0 | Milligram | Weekly | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **TEMAZEPAM (Other drug)** | | | **Reason:** | |
| Tablet | 10.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 05/05/2006 | GGT = SGGT = | | 05/05/2006 | 161 | 04/04/06 ALP 64; GGT 67; ALT 20; AST 22<br>10/04/06 ALP 321; GGT 682; ALT 216; AST 137<br>13/04/06 ALP 234; GGT 565; ALT 102; AST 45<br>05/05/06 ALP 60; GGT 161; ALT 13; AST 21 |
| 05/05/2006 | GGT = SGGT = | | 13/04/2006 | 565 | 04/04/06 ALP 64; GGT 67; ALT 20; AST 22<br>10/04/06 ALP 321; GGT 682; ALT 216; AST 137<br>13/04/06 ALP 234; GGT 565; ALT 102; AST 45<br>05/05/06 ALP 60; GGT 161; ALT 13; AST 21 |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218069 **Seq:** 1 **Gender:** F
**Reported:** 05/05/2006 **Weight:** 60.00
**Hospitalisation:** **Age:** 82
**Onset Date:** 10/04/2006 **DOB:** 07/05/1923
**Outcome:** Recovered 05/05/2006 **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **FOLIC ACID (Other drug)** | | | **Reason:** | | |
| Tablet | 5.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **OSTELIN 1000 (Other drug)** | | | **Reason:** | | |
| | 1000.0 | Unit | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **ATORVASTATIN (Other drug)** | | | **Reason:** | | |
| Tablet | 20.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **FELODIPINE (Other drug)** | | | **Reason:** | | |
| Tablet | 10.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 05/05/2006 | SAP = ALP | | 04/04/2006 | 64 | |
| 05/05/2006 | SAP = ALP | | 10/04/2006 | 321 | |
| 05/05/2006 | SAP = ALP | | 13/04/2006 | 234 | |
| 05/05/2006 | SAP = ALP | | 05/05/2006 | 60 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218069 **Seq:** 1 **Gender:** F
**Reported:** 05/05/2006 **Weight:** 60.00
**Hospitalisation:** **Age:** 82
**Onset Date:** 10/04/2006 **DOB:** 07/05/1923
**Outcome:** Recovered 05/05/2006 **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)** | | | **Reason:** | | |
| | 40.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **FERROUS SULPHATE (Other drug)** | | | **Reason:** | | |
| Tablet | 325.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **PREDNISOLONE (Other drug)** | | | **Reason:** | | |
| | 15.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **CALTRATE (Other drug)** | | | **Reason:** | | |
| Tablet | 600.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | 0 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218069 **Seq:** 1 **Gender:** F
**Reported:** 05/05/2006 **Weight:** 60.00
**Hospitalisation:** **Age:** 82
**Onset Date:** 10/04/2006 **DOB:** 07/05/1923
**Outcome:** Recovered 05/05/2006 **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **CLOPIDOGREL (Other drug)** | | | **Reason:** | | |
| | 75.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **VENLAFAXINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | Depression | |
| Capsule | 37.5 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | 07/04/2006 | | **Stopped:** | 11/04/2006 0 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218291 **Seq:** 1
**Reported:** 12/05/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** M
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Intentional overdose | Caused or prolonged inpatient hospitalisation | The patient was suspected of taking an intentional overdose of Efexor XR with alcohol | |
| Suicide attempt | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

Capsule, modified release 160.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218303 **Seq:** 1
**Reported:** 12/05/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | Life | overdosed on efexor in response to difficulties with a friend | |
| Intentional overdose | Life | | Efexor XR ceased. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218560 **Seq:** 1 **Gender:** F
**Reported:** 22/05/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 56
**Onset Date:** **DOB:** 14/04/1950
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia<br>Dizziness | | Insomnia, dizziness usually midday - | |

### Medicine Details:

**TEGRETOL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**ASPIRIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**THYROXINE SODIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NEXIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218560 **Seq:** 1
**Reported:** 22/05/2006
**Hospitalisation:**
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 56
**DOB:** 14/04/1950
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | |
|---|---|---|---|
| **SIMVASTATIN (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | **Stopped:** | |
| **CLONAZEPAM (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | **Stopped:** | |
| **TRITACE (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | **Stopped:** | 0 |
| **DIAFORMIN (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218560 **Seq:** 1
**Reported:** 22/05/2006
**Hospitalisation:**
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 56
**DOB:** 14/04/1950
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | |
|---|---|---|---|
| **CALTRATE (Other drug)** | | **Reason:** | |
| | | | Oral |
| **Batch:** | **Started:** | | **Stopped:** |
| **EFEXOR-XR (Suspected)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218643 **Seq:** 1
**Reported:** 24/05/2006
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 22
**DOB:** 12/10/1983
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Galactorrhoea | | Patient experienced galactorrhoea. | |

### Medicine Details:

**BREVINOR (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Oral
**Batch:** **Started:** 05/10/1999 **Stopped:**

**BRICANYL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 160.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 09/11/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient previously experienced galactorrhoea while taking Zoloft (sertraline hydrochloride).

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218816 **Seq:** 1
**Reported:** 31/05/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/04/2006
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 68Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Gastroenteritis viral | Caused or prolonged inpatient hospitalisation | Patient experienced viral gastroenteritis, insomnia (waking early), nausea, and tiredness | |
| Fatigue | Caused or prolonged inpatient hospitalisation | | |
| Insomnia | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**ALPRAZOLAM (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/04/2006 **Stopped:** 15/04/2006

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

## Report Detail

**Case Number:** 218816 **Seq:** 1
**Reported:** 31/05/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/04/2006
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 68Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**ALPRAZOLAM (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/04/2006 **Stopped:** 15/04/2006

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218917 **Seq:** 1 **Gender:** M
**Reported:** 05/06/2006 **Weight:** 70.00
**Hospitalisation:** **Age:** 72
**Onset Date:** 18/05/2006 **DOB:** 13/05/1934
**Outcome:** Recovered 29/05/2006 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | Suspected hyponatraemia. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** 11/05/2006 **Stopped:** 24/05/2006

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 218922 **Seq:** 1 **Gender:** F
**Reported:** 05/06/2006 **Weight:** 53.00
**Hospitalisation:** Admitted to hospital **Age:** 38
**Onset Date:** 11/05/2006 **DOB:** 09/11/1967
**Outcome:** Recovered 19/05/2006 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyskinesia | Caused or prolonged inpatient hospitalisation | Patient took 1 tablet of Efexor-XR and 2 hours afterwards had a seizure and had abnormal jerking boby and head movement for 8/7 | |
| Convulsion | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Tablet 75.0 Milligram 1 time Oral
**Batch:** **Started:** 11/05/2006 **Stopped:** 11/05/2006

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient had Aropax in the past without any ill effect.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 219125 **Seq:** 1 **Gender:** M
**Reported:** 13/06/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 47
**Onset Date:** **DOB:** 14/04/1959
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Intentional overdose<br><br>Drug ineffective | | Patient experienced lack of effect and intentional overdose in an attempt to get the "peak" he felt while on the tablets. | |

### Medicine Details:

**RIVOTRIL (Other drug)** **Reason:**
1.0 Milligram
**Batch:** **Started:** **Stopped:**

**POLARAMINE REPETABS (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 37.5 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 219625 **Seq:** 1 **Gender:** F
**Reported:** 03/07/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 29/04/2006 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension | | The patient experienced worsening | Efexor XR ceased. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule, modified release 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 09/06/2006 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 03/07/2006 | Blood pressure | | | | Blood pressure was 200/120. |

### Additional Information:

The dose of Efexor XR was reduced to 75mg daily and the patient's blood pressure dropped to 17/100 on an unspecified date.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 219627 **Seq:** 1 **Gender:** M
**Reported:** 03/07/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 72
**Onset Date:** 14/06/2006 **DOB:** 18/01/1934
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Accidental overdose | Caused or prolonged inpatient hospitalisation | Patient was very nauseous, giddy and headache increased dramatically after he accidentally took 300mg instead of 150mg. | Dose reduced to 150mg daily. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 300.0 Milligram Daily Oral
**Batch:** **Started:** 14/06/2006 **Stopped:** 14/06/2006 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 219628 **Seq:** 1 **Gender:** U
**Reported:** 03/07/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Benign intracranial hypertension | | Patient experienced benign intra-cranium hypertension. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 219691 **Seq:** 1 **Gender:** M
**Reported:** 04/07/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 82Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Jaundice<br>Alanine aminotransferase increas<br>Blood alkaline phosphatase incre<br>Blood bilirubin increased<br>Cholecystitis<br>Gamma-glutamyltransferase incr<br>Liver function test abnormal | | Patient developed jaundice, abnormal liver function tests, elevated bilirubin, elevated alaine aminotransferase, elevated gamma glutamyl transferase and elevated alkaline phosphatase. | Ceased Avandia, Augmentin, Efexor and Rulide. |

### Medicine Details:

**AUGMENTIN (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**RULIDE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**AVANDIA (Suspected)** **Reason:**
Tablet 8.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 219806 **Seq:** 1 **Gender:** F
**Reported:** 10/07/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** 16/06/2006 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety<br>Serotonin syndrome<br>Feeling cold<br>Nausea<br>Thinking abnormal<br>Tremor | | Patient experienced anxiety, nausea, shakiness, "cotton wool in head" and feeling cold suspected. Venlafaxine ceased and lovan started on the same day without wash out period. | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:**

**LOVAN (Suspected)** **Reason:**

20.0 Milligram Daily

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 220099 **Seq:** 1
**Reported:** 17/07/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:** 30/06/2006
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 75.00
**Age:** 43
**DOB:** 02/04/1963
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Patient experienced hyponatraemia and longstanding mild neutropenia markedly worse with increased dose of Carbamazepine. | Venlafaxine XR decreased on 30/06/2006. |
| Neutropenia | Caused or prolonged inpatient hospitalisation | | |
| Therapy regimen changed | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

**CARBAMAZEPINE (Suspected)** **Reason:** Convulsions

1.2 Gram Daily Oral

**Batch:** **Started:** 02/06/2006 **Stopped:** 30/06/2006

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220105 **Seq:** 1
**Reported:** 17/07/2006
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus | | Itching under the skin and on the scalp. | Treated with Elocon lotion, Celeston-M cream and Phenergan 25mg up to twice a day |

### Medicine Details:

**ALEPAM (Other drug)** **Reason:** Depression
Tablet 15.0 Milligram As necessary Oral
**Batch:** **Started:** 29/03/2006 **Stopped:** 0

**AVAPRO HCT 300/12.5 (Other drug)** **Reason:** Essential benign hypertension
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 11/08/2005 **Stopped:**

**NEXIUM (Other drug)** **Reason:** Other diseases of esophagus
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 14/07/2005 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Tablet 112.5 Milligram Daily Oral
**Batch:** **Started:** 30/03/2006 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220105 **Seq:** 1
**Reported:** 17/07/2006
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**Seretide 500/50 Accuhaler (Suspected)** **Reason:** Asthma

Inhalation 2.0 Dose Unspecified Daily Inhalation

**Batch:** **Started:** 30/03/2006 **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220170 **Seq:** 1 **Gender:** F
**Reported:** 18/07/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 31Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence<br><br>Drug withdrawal syndrome | | On cessation of Efexor patient reported experiencing debilitating drowsiness for 5 to 6 days, could not function at work for 5 to 6 days | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 03/03/2005 **Stopped:** 28/05/2006

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220328 **Seq:** 1 **Gender:** F
**Reported:** 25/07/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 29
**Onset Date:** **DOB:** 18/09/1976
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br><br>Drug effect decreased<br>Insomnia<br>Memory impairment | | Efexor XR not working well, finds it hard to remember things. Takes dose in morning as evening dose makes her unable to sleep. One minute fine, next minute feels like committing suicide. | |

### Medicine Details:

**TOPAMAX (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**EFEXOR (Suspected)** **Reason:** Depression
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** 15/06/1992 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

PMHx, anorexia, post-traumatic stress disorder as being a victim of child abuse and sexual abuse

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220390 **Seq:** 1 **Gender:** F
**Reported:** 27/07/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 15Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Intentional overdose<br><br>Aggression<br>Fatigue<br>Nausea<br>Suicide attempt | | intentional overdose - "took 6 in a rage of agression". Felt quite nauseous and really tired | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 6.0 Dose Unspecified Total Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

PMHx marijuana use

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220487 **Seq:** 1 **Gender:** M
**Reported:** 01/08/2006 **Weight:** 75.00
**Hospitalisation:** **Age:** 66
**Onset Date:** 15/05/2006 **DOB:** 22/10/1939
**Outcome:** Recovered 21/07/2006 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Blood pressure increased | | Hypertensive reaction. | Atacand 16mg daily. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule, modified release 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/08/2005 **Stopped:** 11/07/2006

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220490 **Seq:** 1 **Gender:** F
**Reported:** 01/08/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 21
**Onset Date:** **DOB:** 16/06/1985
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug effect decreased | Incapacity/disability | Drug withdrawal syndrome, 'ineffective in controlling depression', bed bound and could not lift her head, vomiting and nausea | Efexor-XR was discontinued tempoprarily. |
| Drug withdrawal syndrome | Incapacity/disability | she tapered to an unspecified dose, and experienced nausea and vomiting on when she missed her dose for 4- 5 hours. efexor was discontinued temporarily and patient was bedbound and could not life her head and was vomiting for 3 weeks | recommenced venlafaxine treatment. increased dose to 150mg |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Otr ecz&der due otr&unsp cause
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220491 **Seq:** 1
**Reported:** 01/08/2006
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 70
**DOB:** 11/08/1935
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br>Chapped lips<br>Depressed mood<br>Dry mouth<br>Dyspnoea<br>Increased upper airway secretion<br>Muscular weakness | | Raised spotty red rash on body, breathing difficulty, suicidal thoughts, increased saliva, production of phlegm, sleepiness, swollen throat, cracked lips, red lips, feeling down, muscle weekness, blotchy rash, thirst, dry mouth, dilated pupils, panic attacks, puffy lips and weight loss | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** 01/05/2006 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

PMHx, hypertension, pain, scoliosis, sleep disorder. The patient previously expereinced suicidal ideation while taking Zoloft and Endep. Headache while taking Serepax and Stilnox. Dysgeusia while taking Karvea and Cordilox. Headache, skin tightness and pain in jaw while taking Neurontin and drug ineffective while taking Panamax

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220491 **Seq:** 1
**Reported:** 01/08/2006
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 70
**DOB:** 11/08/1935
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mydriasis | | | |
| Panic attack | | | |
| Pharyngeal oedema | | | |
| Rash | | | |
| Salivary hypersecretion | | | |
| Somnolence | | | |
| Thirst | | | |
| Weight decreased | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** 01/05/2006 **Stopped:**

### Laboratory Investigations:

### Additional Information:

PMHx, hypertension, pain, scoliosis, sleep disorder. The patient previously expereinced suicidal ideation while taking Zoloft and Endep. Headache while taking Serepax and Stilnox. Dysgeusia while taking Karvea and Cordilox. Headache, skin tightness and pain in jaw while taking Neurontin and drug ineffective while taking Panamax

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220553 **Seq:** 1 **Gender:** F
**Reported:** 03/08/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220554 **Seq:** 1 **Gender:** M
**Reported:** 03/08/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 54
**Onset Date:** **DOB:** 27/06/1952
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Disorientation<br>Tinnitus | | drug withdrawal syndrome (tinnitus, | |

### Medicine Details:

**LIPITOR (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NEXIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220730 **Seq:** 1 **Gender:** M
**Reported:** 11/08/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Caused or prolonged inpatient hospitalisation | experienced 12 days of vomiting and other nasty side effects | |
| Vomiting | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220764 **Seq:** 1 **Gender:** M
**Reported:** 14/08/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 26Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br>Depression<br>Dizziness<br>Drug ineffective<br>Headache<br>Paraesthesia | | Headache, dizziness, tingles in arms and neck, return of suicidal thoughts and depression. Switched to Efexor which he found ineffective | Efexor ceased. Returned to taking Zoloft at a dose of 50mg. |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
Tablet Oral
**Batch:** **Started:** **Stopped:**

**ZOLOFT (Suspected)** **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220921 **Seq:** 1 **Gender:** M
**Reported:** 22/08/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 12/05/2006 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination | Caused or prolonged inpatient hospitalisation | the patient "failed to sleep at all" on 12 May 2006. On 13 May 2006, in the afternoon about 3pm, the patient "seemed odd and continued to increase in strange behaviour." The patient was having "illegible conversations with people who were not present in the room". The patient then got into his car and "reversed the car at alarming speed, oblivious to the speed, ploughed into telegraph pole" On the way to the hospital, the patient was ripping wired out of the car and trying to fix the radar detector ( which wasn't broken). Several hours later the patient had regained himself and wasn't aware of any | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Oral
**Batch:** **Started:** 12/05/2006 **Stopped:** 12/05/2006 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

St John's Wort had been taken for the previous 18 months

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220921 **Seq:** 1 **Gender:** M
**Reported:** 22/08/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 12/05/2006 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abnormal behaviour | Caused or prolonged inpatient hospitalisation | | |
| Amnesia | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Oral
**Batch:** **Started:** 12/05/2006 **Stopped:** 12/05/2006 0

### Laboratory Investigations:

### Additional Information:
St John's Wort had been taken for the previous 18 months

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220928 **Seq:** 1 **Gender:** F
**Reported:** 22/08/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Serotonin syndrome | Caused or prolonged inpatient hospitalisation | Suspected Serotonin Syndrome | |

### Medicine Details:

**Norspan Nos (Other drug)** **Reason:**
20.0 Milligram
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 220935 **Seq:** 1 **Gender:** F
**Reported:** 22/08/2006 **Weight:** 0.00
**Hospitalisation:** Required a visit to the doctor **Age:** 39
**Onset Date:** 09/08/2006 **DOB:** 27/05/1967
**Outcome:** Recovered 11/08/2006 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mydriasis | | "Eyes went black" desending mydriasis after the first dose of Efexor-XR. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 37.5 Milligram Daily Oral
**Batch:** **Started:** 08/08/2006 **Stopped:** 09/08/2006 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 220962 **Seq:** 1 **Gender:** U
**Reported:** 23/08/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cleft palate | Congenital anomaly / birth defect | Infant born with small cleft palate. | |

## Medicine Details:

**LITHIUM CARBONATE (Suspected)** **Reason:** Depression
Tablet 900.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**OLANZAPINE (Suspected)** **Reason:** Depression
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**LAMOTRIGINE (Suspected)** **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Female baby born on 05/06/06.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221098 **Seq:** 1 **Gender:** M
**Reported:** 28/08/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 28/07/2006 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome neona | Caused or prolonged inpatient hospitalisation | Withdrawal syndrome from Efexor XR - jittery, low grade fever, high pitched cry, exaggerated reflexes and increased muscle tone | phenobarbitone. |
| Crying | Caused or prolonged inpatient hospitalisation | | |
| Feeling jittery | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule, modified release 300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Mother was taking medication.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221098 **Seq:** 1 **Gender:** M
**Reported:** 28/08/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 28/07/2006 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperreflexia | Caused or prolonged inpatient hospitalisation | | |
| Hypertonia | Caused or prolonged inpatient hospitalisation | | |
| Pyrexia | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule, modified release 300.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

Mother was taking medication.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221170 **Seq:** 1
**Reported:** 29/08/2006
**Hospitalisation:**
**Onset Date:** 15/08/2006
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 34
**DOB:** 19/06/1972
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br>Anger<br>Dizziness<br>Drug withdrawal syndrome<br>Emotional disorder<br>Fatigue | | The patient experienced suicidal tendency, extremely erratic and felt angry whilst taking efexor -XR, she then tapered the Efexor- XR dose down to 37.5mg daily and then stopped therapy in Aug 2006. Since stopping, patient has experienced tingling, emtional, tiredness, head"feels funny" when she moves it, nausea, and dizziness. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Capsule 37.5 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221170 **Seq:** 1
**Reported:** 29/08/2006
**Hospitalisation:**
**Onset Date:** 15/08/2006
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 34
**DOB:** 19/06/1972
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Feeling abnormal<br>Head discomfort<br>Nausea<br>Paraesthesia | | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Capsule 37.5 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221171 **Seq:** 1 **Gender:** M
**Reported:** 29/08/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 52
**Onset Date:** **DOB:** 04/04/1954
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Petit mal epilepsy | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 17/08/2006 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221421 **Seq:** 1 **Gender:** F
**Reported:** 06/09/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 61Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Serotonin syndrome | | Suspected serotonin syndrome which recurred when re-introduced | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

**DOTHEP (Suspected)** **Reason:**
25.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**TRAMAL SR (Suspected)** **Reason:**
200.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221424 **Seq:** 1 **Gender:** M
**Reported:** 06/09/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion<br><br>Dizziness<br>Headache | | Patient experienced seizure, feeling "gittey" and headache when he first started efexor | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221451 **Seq:** 1
**Reported:** 06/09/2006
**Hospitalisation:**
**Onset Date:** 15/08/2006
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 64
**DOB:** 22/07/1942
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cardiomyopathy<br><br>Atrial fibrillation<br>Cardiomegaly<br>Supraventricular tachycardia | | Cardiomyopathy, atrial arrhythmia, supraventricular tachycardia, enlarged heart | lasix 40mg, slow k, dilatrend |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 300.0 Milligram Oral

**Batch:** **Started:** 15/06/2004 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221522 **Seq:** 1 **Gender:** M
**Reported:** 08/09/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 20Y
**Onset Date:** 19/07/2006 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mania | Caused or prolonged inpatient hospitalisation | Mania | sodium valproate, olanzapine |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 26/06/2006 **Stopped:** 24/07/2006 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221565 **Seq:** 1 **Gender:** F
**Reported:** 12/09/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 06/05/2006 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Intentional overdose | Caused or prolonged inpatient hospitalisation | took 273 x75mg capsules of efexor-xr, and experienced vertigo, fever, vomiting, 5 grand mal seizures, tachycardia, discomfort nausea, asthenia, palpitations, rhabdomyolysis, acute renal insufficiency and rasied creatinine levels | |
| Suicide attempt | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**ALCOHOL (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**ZYPREXA (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:** 0

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 20.0 Gram Total Oral
**Batch:** **Started:** 06/05/2006 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221589 **Seq:** 1
**Reported:** 13/09/2006
**Hospitalisation:**
**Onset Date:** 15/07/2006
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 34
**DOB:** 11/02/1972
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Unintended pregnancy<br><br>Drug exposure during pregnancy<br>Drug ineffective | | Drug ineffective, unintended pregnancy, drug exposure during pregnancy. | |

### Medicine Details:

**OROXINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**MICROVAL (Suspected)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:** 0

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221631 **Seq:** 1 **Gender:** M
**Reported:** 14/09/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myocardial infarction | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221836 **Seq:** 1 **Gender:** F
**Reported:** 25/09/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 55Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Angioedema | | | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**OLANZAPINE (Suspected)** **Reason:** Depression
2.5 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221855 **Seq:** 1 **Gender:** M
**Reported:** 25/09/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 71
**Onset Date:** 15/08/2006 **DOB:** 25/09/1934
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Subdural haemorrhage | Caused or prolonged inpatient hospitalisation | Presented with headaches. Subdural haemorrhage diagnosed. | The subdural haematoma was evacuated |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 221869 **Seq:** 1 **Gender:** F
**Reported:** 25/09/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Hospitalisation Prolonged | Efexor XR was discontinued after 2.5 years. patient experienced discontinuation | Efexor XR treatment was recommenced |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 450.0 Milligram Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 222504 **Seq:** 1
**Reported:** 17/10/2006
**Hospitalisation:**
**Onset Date:** 15/08/2006
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 75
**DOB:** 06/12/1930
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorexia | Incapacity/disability | Experienced loss of appetite in August when she first started on efexor XR. Also experienced worsened irritable bowel syndrome (more episoded of sore stomach). Tripped and broke a knee bone and nausea | Stemetil for nausea |
| Irritable bowel syndrome | Incapacity/disability | | |
| Nausea | Incapacity/disability | | |

### Medicine Details:

**LANOXIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**XANAX (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**BETALOC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ASPRO (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 222504 **Seq:** 1
**Reported:** 17/10/2006
**Hospitalisation:**
**Onset Date:** 15/08/2006
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 75
**DOB:** 06/12/1930
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Tablet 75.0 Milligram Daily Oral

**Batch:** **Started:** 15/08/2006 **Stopped:** 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 222582 **Seq:** 1 **Gender:** M
**Reported:** 19/10/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 58Y
**Onset Date:** 14/07/2006 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Blood triglycerides increased<br>Liver function test abnormal | | | |

### Medicine Details:

**LIPITOR (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**COVERSYL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NEXIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PARACETAMOL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 19/10/2006 | ALT = SGPT | 0-45 IU/L | 14/07/2006 | 50 | |
| 19/10/2006 | GGT = SGGT = | | 14/07/2006 | 292 | 0-17 IU/L |
| 19/10/2006 | Triglyceride | | 14/07/2006 | 6.2 | 0.2-2.2 mmol/L |

### Additional Information:

3 drinks daily.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 222582 **Seq:** 1 **Gender:** M
**Reported:** 19/10/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 58Y
**Onset Date:** 14/07/2006 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **EFEXOR-XR (Suspected)** | | | **Reason:** | | |
| Tablet | 150.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | 0 |

### Laboratory Investigations:

### Additional Information:
3 drinks daily.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 222614 **Seq:** 1 **Gender:** F
**Reported:** 19/10/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 50
**Onset Date:** 15/09/2006 **DOB:** 16/07/1956
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug interaction<br>Fatigue<br>Muscular weakness | | Drug interaction, tiredness, felt that Efexor-XR did not work as well and jelly legs, muscular weakness.<br>Tiredness, felt that Efexor-XR did not work as well and jelly legs, muscular weakness. | |

## Medicine Details:

**SPIRULINA (Interaction)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**EFEXOR-XR (Interaction)** **Reason:** Unspecifid affective psychosis
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 222631 **Seq:** 1
**Reported:** 23/10/2006
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 70.00
**Age:** 28
**DOB:** 29/03/1978
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Blood prolactin increased | Incapacity/disability | Increased blood prolactin level | |

### Medicine Details:

**RAMIPRIL (Other drug)** **Reason:** Essential benign hypertension
1.3 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**RISPERDAL (Suspected)** **Reason:** Unspecified schizophrenia
**Batch:** **Started:** **Stopped:** 0

**EFEXOR-XR (Suspected)** **Reason:** Depression
375.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 23/10/2006 | Prolactin | | | | 3395 |

### Additional Information:

Not yet recovered but recovering

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 222847 **Seq:** 1 **Gender:** F
**Reported:** 01/11/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Incapacity/disability | Experience drug withdrawal symptoms within 2 days. Symptoms included vision problems, a speckled black and white effect, described as a visual migraine, feeling so sick, feeling of stabbing in the ears like knitting needles being pushed into them, a loss of balance, a zappin in the head, as if the head was waiting for the body to catch up, grumpy and cranky, burst into tears for no reason, extremely angry, bad digestion, short-term memory loss, personality change, cold not function, could not sleep, decision making was difficult, lost confidence with driving, bizarre dreams and was nearly comatose. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Oral
**Batch:** **Started:** 01/06/2006 **Stopped:** 22/07/2006 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 222847 **Seq:** 1 **Gender:** F
**Reported:** 01/11/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abnormal dreams | Incapacity/disability | | |
| Activities of daily living impaired | Incapacity/disability | | |
| Amnesia | Incapacity/disability | | |
| Anger | Incapacity/disability | | |
| Balance disorder | Incapacity/disability | | |
| Depressed level of consciousnes | Incapacity/disability | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Oral
**Batch:** **Started:** 01/06/2006 **Stopped:** 22/07/2006 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 222847 **Seq:** 1 **Gender:** F
**Reported:** 01/11/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyspepsia | Incapacity/disability | | |
| Ear pain | Incapacity/disability | | |
| Insomnia | Incapacity/disability | | |
| Malaise | Incapacity/disability | | |
| Mental impairment | Incapacity/disability | | |
| Mood altered | Incapacity/disability | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Oral
**Batch:** **Started:** 01/06/2006 **Stopped:** 22/07/2006 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 222847 **Seq:** 1 **Gender:** F
**Reported:** 01/11/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia | Incapacity/disability | | |
| Personality change | Incapacity/disability | | |
| Psychiatric symptom | Incapacity/disability | | |
| Tearfulness | Incapacity/disability | | |
| Visual disturbance | Incapacity/disability | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Oral
**Batch:** **Started:** 01/06/2006 **Stopped:** 22/07/2006 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223005 **Seq:** 1 **Gender:** F
**Reported:** 09/11/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 15/09/2006 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | Fit/seizure | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 150.0 Milligram Oral
**Batch:** **Started:** 01/03/2006 **Stopped:** 0

**CAFERGOT (Suspected)** **Reason:** Migraine
**Batch:** **Started:** **Stopped:**

**MERSYNDOL (Suspected)** **Reason:** Migraine
**Batch:** **Started:** **Stopped:**

**NIZORAL (Suspected)** **Reason:** Moniliasis
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

(DUPLICATE REPORT IS 225919)

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223005 **Seq:** 1 **Gender:** F
**Reported:** 09/11/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 15/09/2006 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**PANADEINE FORTE (Suspected)** **Reason:** Migraine

**Batch:** **Started:** **Stopped:**

**TRAMAL (Suspected)** **Reason:** Headache

200.0 Milligram Daily

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

### Additional Information:
(DUPLICATE REPORT IS 225919)

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223026 **Seq:** 1 **Gender:** F
**Reported:** 10/11/2006 **Weight:** 53.00
**Hospitalisation:** Required a visit to the doctor **Age:** 55
**Onset Date:** 12/10/2006 **DOB:** 08/05/1951
**Outcome:** Recovered 15/10/2006 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vision blurred<br>Disorientation<br>Dry mouth<br>Insomnia<br>Nausea<br>Oedema<br>Restlessness | | Within 6 hrs had the following reactions: blurred vision, disoriented, swollen neck, cheeks, eyes and tops of hands. Felt nauseous, dry throat, fidgety. Was completely awake at night, extremely thirsty. Symptoms lasted 3 days. Felt like a massive hangover without the alcohol. | |

### Medicine Details:

**OROXINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**MULTIVITAMINS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**TEMAZEPAM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram 1 time Oral
**Batch:** **Started:** 12/10/2006 **Stopped:** 12/10/2006 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient took one dose only of Efexor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223026 **Seq:** 1 **Gender:** F
**Reported:** 10/11/2006 **Weight:** 53.00
**Hospitalisation:** Required a visit to the doctor **Age:** 55
**Onset Date:** 12/10/2006 **DOB:** 08/05/1951
**Outcome:** Recovered 15/10/2006 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Thirst | | | |

### Medicine Details:

**OROXINE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**MULTIVITAMINS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**TEMAZEPAM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
75.0 Milligram 1 time Oral
**Batch:** **Started:** 12/10/2006 **Stopped:** 12/10/2006 0

### Laboratory Investigations:

### Additional Information:
Patient took one dose only of Efexor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223034 **Seq:** 1
**Reported:** 10/11/2006
**Hospitalisation:** Required a specialist consultation
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 72
**DOB:** 22/06/1934
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Electrocardiogram QT prolonged<br>Blood pressure decreased | | QT prolonged. | |

### Medicine Details:

**BETALOC (Other drug)** **Reason:**
150.0 Milligram
**Batch:** **Started:** **Stopped:**

**NEXIUM (Other drug)** **Reason:**
20.0 Milligram
**Batch:** **Started:** **Stopped:**

**VALIUM (Other drug)** **Reason:**
5.0 Milligram
**Batch:** **Started:** **Stopped:**

**NASONEX AQUEOUS NASAL SPRAY (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 10/11/2006 | Electrocardiograph | | | | Electrocardiogram QT prolonged. |

### Additional Information:

Advised by psychiatrist to stay on Efexor XR as he was in remission with depression.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223034 **Seq:** 1
**Reported:** 10/11/2006
**Hospitalisation:** Required a specialist consultation
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 72
**DOB:** 22/06/1934
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **MOGADON (Other drug)** | | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression |
| Capsule | 150.0 | Milligram | | Oral |
| **Batch:** | **Started:** | | **Stopped:** | 0 |

### Laboratory Investigations:

### Additional Information:
Advised by psychiatrist to stay on Efexor XR as he was in remission with depression.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223044 **Seq:** 1
**Reported:** 13/11/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:** 19/08/2006
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anaphylactic shock | Caused or prolonged inpatient hospitalisation | | Efexor withdrawn, Endep |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

75.0 Milligram Daily Oral

**Batch:** **Started:** 13/05/2005 **Stopped:** 19/08/2006 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223132 **Seq:** 1
**Reported:** 14/11/2006
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 24/09/2006
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 135.00
**Age:** 65
**DOB:** 29/12/1940
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus<br>Rash maculo-papular | | Generalised pruritis and macular papular | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Other puritis conditions

300.0 Milligram Daily

**Batch:** **Started:** 20/09/2006 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

CERT: RECHALL. Had similar problem in past when trial Efexor XR (not with Efexor tablets) but efexor tablets have been discontinued.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223143 **Seq:** 1 **Gender:** F
**Reported:** 14/11/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 31
**Onset Date:** 30/10/2006 **DOB:** 27/05/1975
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vomiting | | Developed nausea and vomiting soon after starting Efexor treatment | Ceased treatment with Efexor |

### Medicine Details:

**XANAX (Other drug)** **Reason:**
Tablet 1.0 Milligram 4 times Oral
**Batch:** **Started:** **Stopped:**

**PANADEINE (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified 4 times Oral
**Batch:** **Started:** **Stopped:** 0

**EFEXOR (Suspected)** **Reason:**
Capsule 1.0 Dose Unspecified 1 time Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223201 **Seq:** 1 **Gender:** M
**Reported:** 15/11/2006 **Weight:** 86.00
**Hospitalisation:** **Age:** 35
**Onset Date:** 10/10/2006 **DOB:** 21/09/1971
**Outcome:** Recovered 11/10/2006 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Malaise<br>Dry mouth<br>Feeling abnormal<br>Hallucination<br>Hot flush<br>Nasopharyngitis<br>Nausea<br>Panic attack | | Within 2 hours of 1st dose felt unwell with hot flushes, went to bed, woke 4am in a panic, cold, nausea, dry mouth, felt strange, hallucinated | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 10/10/2006 **Stopped:** 11/10/2006

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223304 **Seq:** 1 **Gender:** F
**Reported:** 17/11/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 30Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Electrocardiogram QT prolonged<br><br>Electrocardiogram QT prolonged | | Electrocardiogram QT prolonged, Increased QT interval. | |

### Medicine Details:

**SOLIAN (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:** 0

**EPILIM (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**LAMICTAL (Suspected)** **Reason:** Unspecified psychosis
50.0 Milligram Daily Oral
**Batch:** **Started:** 01/06/2006 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 17/11/2006 | QT interval | | | | Increased QT interval. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223528 **Seq:** 1 **Gender:** F
**Reported:** 27/11/2006 **Weight:** 67.00
**Hospitalisation:** Required a visit to the doctor **Age:** 45
**Onset Date:** **DOB:** 11/03/1961
**Outcome:** Recovered 26/09/2006 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Amnesia<br>Anger<br>Crying<br>Disorientation<br>Dyspepsia<br>Ear pain<br>Mood swings | | When withdrawing Efexor, short term memory loss, stabbing pain in ears, disorentation, sporadic crying, extreme anger, loss of confidence with decisions, indigestion, change in bowel pattern, mood swings. | |

### Medicine Details:

**NORIMIN (Other drug)** **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 22/07/2006

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223666 **Seq:** 1
**Reported:** 01/12/2006
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** M
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Serotonin syndrome | Caused or prolonged inpatient hospitalisation | Patient experienced blood pressure jumped to systolic 220, dizziness, numbness, tingling in the arms and seeing black spots, which was diagnosed as serotonin syndrome | |
| Dizziness | Admitted to Hospital | | |
| Hypoaesthesia | Admitted to Hospital | | |
| Paraesthesia | Admitted to Hospital | | |
| Visual disturbance | Admitted to Hospital | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223935 **Seq:** 1 **Gender:** M
**Reported:** 08/12/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 50
**Onset Date:** 27/10/2006 **DOB:** 23/05/1956
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia<br>Hot flush<br>Hypertension<br>Hyponatraemia | | Asthenia | |

### Medicine Details:

**EFEXOR-XR (Other drug)** **Reason:** Depression
Capsule, modified release 150.0 Milligram Daily Oral
**Batch:** **Started:** 10/02/2006 **Stopped:** 20/10/2006

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule, modified release 225.0 Milligram Daily Oral
**Batch:** **Started:** 20/10/2006 **Stopped:** 27/10/2006 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 08/12/2006 | Blood pressure | | | | 220/110 |
| 08/12/2006 | Sodium | 135-145 | | | 130 |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 223970 **Seq:** 1 **Gender:** M
**Reported:** 11/12/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 25
**Onset Date:** **DOB:** 07/12/1981
**Outcome:** Recovered 05/10/2004 **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Neuroleptic malignant syndrome<br>Alanine aminotransferase increas<br>Aspartate aminotransferase incre<br>Blood alkaline phosphatase incre<br>Blood lactate dehydrogenase inc<br>Gamma-glutamyltransferase incr | | Neuroleptic malignant syndrome, tachycardia, liver function test abnormal, white blood cell count increased, gamma-glutamyltransferase increased, blood alkaline phosphate increased, alanine aminotransferase increased, aspartate aminotransferase increased, blood lactate dehydrogenase increased. | Treatment was discontnued on 25/8/04 and rechallenged on 30/8/04. Rechallenge result was persistent tachycardia (non-serious. Treatment with Clozaril was ceased on |

## Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:** 25/08/2004

**CLOZARIL (Suspected)** **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

**Batch:** **Started:** 20/07/2004 **Stopped:** 25/08/2004

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 11/12/2006 | ALT = SGPT | | 24/08/2006 | 90 U/L | |
| 11/12/2006 | AST = SGOT | | 24/08/2006 | 58 U/L | |
| 11/12/2006 | GGT = SGGT = | | 24/08/2006 | 113U/L | |
| 11/12/2006 | LDH | | 24/08/2006 | 262 U/L | |
| 11/12/2006 | SAP = ALP | | 24/08/2004 | 123 U/L | |

## Additional Information:

+ve recahllenge

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 223970 **Seq:** 1 **Gender:** M
**Reported:** 11/12/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 25
**Onset Date:** **DOB:** 07/12/1981
**Outcome:** Recovered 05/10/2004 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Liver function test abnormal<br>Tachycardia<br>White blood cell count increased | | | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:** 25/08/2004

**CLOZARIL (Suspected)** **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

**Batch:** **Started:** 20/07/2004 **Stopped:** 25/08/2004

### Laboratory Investigations:

### Additional Information:

+ve recahllenge

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224185 **Seq:** 1 **Gender:** F
**Reported:** 19/12/2006 **Weight:** 95.00
**Hospitalisation:** Admitted to hospital **Age:** 71
**Onset Date:** 20/11/2006 **DOB:** 21/10/1935
**Outcome:** Recovered 21/11/2006 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Torsade de pointes | Caused or prolonged inpatient hospitalisation | Small episode of Torsades de pointes. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 450.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**ASPIRIN (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**ALPRAZOLAM (Suspected)** **Reason:**
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224246 **Seq:** 1
**Reported:** 20/12/2006
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 01/04/2006
**Outcome:** Recovered

**Gender:** F
**Weight:** 105.00
**Age:** 52
**DOB:** 05/02/1954
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug interaction<br><br>Major depression<br>Psychomotor hyperactivity<br>Serotonin syndrome<br>Tremor | | Marked tremor, hyperactive, agitation for major depression. Serotonin syndrome. | Efexor weaned off and ceased. |

### Medicine Details:

**EFEXOR (Interaction)** **Reason:** Depression
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 15/06/2005 **Stopped:** 15/10/2006

**TRAMAL (Interaction)** **Reason:** Headache
50.0 Milligram Daily
**Batch:** **Started:** 15/01/2006 **Stopped:** 15/10/2006

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

PH of major depressive disorders

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224327 **Seq:** 1 **Gender:** M
**Reported:** 28/12/2006 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Death, maybe drug **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug toxicity | Death | "toxic dose of venlafaxine in the blood" | |
| Completed suicide | Death | Completed suicide by being deliberatelt run | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Unspecifid affective psychosis
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224592 **Seq:** 1
**Reported:** 11/01/2007
**Hospitalisation:**
**Onset Date:** 15/12/2006
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 59
**DOB:** 16/11/1947
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br><br>Paraesthesia | | Experienced tingling in the body in the mornings and worsened suicidal feelings. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

75.0 Milligram Daily Oral

**Batch:** **Started:** 01/12/2006 **Stopped:** 12/01/2007 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224595 **Seq:** 1 **Gender:** F
**Reported:** 11/01/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sedation | Incapacity/disability | Information was received from the husband of a female patient who experienced feeling "dopey" and "has not been able to function" on a day to day basis. | |
| Decreased activity | Incapacity/disability | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
112.0 Milligram
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224611 **Seq:** 1 **Gender:** F
**Reported:** 12/01/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Epilepsy | | "Epileptic fit". | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule, modified release 300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224638 **Seq:** 1
**Reported:** 15/01/2007
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 20/10/2006
**Outcome:** Unknown

**Gender:** F
**Weight:** 65.00
**Age:** 40Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Skin burning sensation<br><br><br><br>Agitation<br>Hyperaesthesia<br>Hyperhidrosis<br>Nightmare | | Taking Tramal for 3yrs for fibromyalgia. Dr wanted to reduce Tramal dose added Efexor-XR 5 weeks ago. Side effects straight away- sweats, burning and skin sensitivity. After a few weeks nightmares, agitation. | Stopped Efexor- XR 37.5mg straight away |

### Medicine Details:

**TRAMAL (Other drug)** **Reason:** Otr mus rheum,fibrosit&myalgia
100.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**THYROXINE SODIUM (Other drug)** **Reason:**
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 37.5 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224669 **Seq:** 1 **Gender:** F
**Reported:** 15/01/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 21
**Onset Date:** 01/04/2006 **DOB:** 31/05/1984
**Outcome:** Recovered 02/04/2006 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Gastritis viral | Caused or prolonged inpatient hospitalisation | Gastroenteritis viral. | Maxolon, Stemetil |
| Enteritis | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**JULIET-35 ED (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:** 0

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule, modified release 75.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/2005 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224695 **Seq:** 1
**Reported:** 16/01/2007
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 59
**DOB:** 29/04/1947
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Neutropenia | | Neutropenia | |

### Medicine Details:

**SIMVASTATIN (Other drug)** **Reason:**
10.0 Milligram
**Batch:** **Started:** 15/09/2004 **Stopped:**

**EFEXOR (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224793 **Seq:** 1 **Gender:** F
**Reported:** 17/01/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Epilepsy<br><br>Bradycardia<br>Hypertension<br>Posturing<br>Tardive dyskinesia | | Epileptiform activity, extensor limb posturing, lip smacking, bradycardia, hypertension | Phenobarbitone for the baby. |

### Medicine Details:

**LABETALOL HYDROCHLORIDE (Other drug)** **Reason:** Essential benign hypertension

**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

150.0 Milligram Daily

**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 17/01/2007 | Computerised | | | | CT scan of head- normal. |
| 17/01/2007 | Other data | | | | FBC, Blood culture, electolytes, glucose, EEG at 12 hours : Normal. Meconium urine toxicology screen negative |

### Additional Information:

Apgar at birth satisfactory in utero exposure to venlaxafine.
Seizures ceased at 4 hours of age.
Growth and neurodevelopment normal at 1 year.
Serum venlaxafine levels not obtained.
Venlaxafine withdrawal on toxicity.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224795 **Seq:** 1 **Gender:** F
**Reported:** 18/01/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vomiting<br><br>Convulsion | | Vomiting, seizures (at 24 hrs of age), multifocal myclonic seizures. | Phenobarbitone for baby |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
225.0 Milligram
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 18/01/2007 | Electroencephalog | | | | |
| 18/01/2007 | Electrolytes | | | | |
| 18/01/2007 | Serum glucose | | | | |
| 18/01/2007 | Ultrasound | | | | |

### Additional Information:

LIT REPORT: PAKALPATI. Apgar at birth satisfactory. In utero exposure to venlaxafine. Serum venlaxafine levels not obtained ? venlaxafine withdrawal or toxicity.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224797 **Seq:** 1 **Gender:** F
**Reported:** 18/01/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 38
**Onset Date:** **DOB:** 11/11/1968
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pre-eclampsia<br>Feeling abnormal<br>Anxiety | | Pre-eclampsia<br>spaced out | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
37.0 Milligram Daily Oral
**Batch:** **Started:** 15/04/2006 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224805 **Seq:** 1 **Gender:** F
**Reported:** 18/01/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 29
**Onset Date:** **DOB:** 30/11/1977
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pregnancy induced hypertension<br><br>Gestational diabetes<br>Vomiting in pregnancy | | Pregnancy induced hypertension, gestational diabetes, vomiting, drug exposure during pregnancy. | Betaloc |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224808 **Seq:** 1
**Reported:** 18/01/2007
**Hospitalisation:** Hospitalisation prolonged
**Onset Date:** 17/10/2006
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 0
**DOB:** 17/10/2006
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Premature baby | Caused or prolonged inpatient hospitalisation | Premature baby 34 weeks | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
150.0 Milligram Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224822 **Seq:** 1 **Gender:** F
**Reported:** 18/01/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99U
**Onset Date:** 25/07/2006 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cardiac murmur<br>Premature baby | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule, modified release 225.0 Milligram Daily Oral

**Batch:** **Started:** 15/07/2004 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224825 **Seq:** 1
**Reported:** 18/01/2007
**Hospitalisation:**
**Onset Date:** 25/07/2006
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 31
**DOB:** 02/03/1975
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pre-eclampsia<br>Placental disorder<br>Premature separation of placenta | | Pre-eclampsia<br>placental abruption | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule, modified release 225.0 Milligram Daily Oral

**Batch:** **Started:** 15/07/2004 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 224930 **Seq:** 1
**Reported:** 22/01/2007
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Unknown

**Gender:** M
**Weight:** 0.00
**Age:** 55
**DOB:** 15/04/1951
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Yawning<br>Dizziness<br>Sexual dysfunction | | Yawing, followed by dizziness. Sexual | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225057 **Seq:** 1 **Gender:** F
**Reported:** 24/01/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 29
**Onset Date:** 05/12/2006 **DOB:** 07/01/1977
**Outcome:** Recovered 12/12/2006 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | | After missing a dose of Efexor XR on 5 December 2006, patient experienced crying, photophobia, blurred vision, collapsed and felt weak all over, dizziness, nausea, and headache. She was diagnosed with panic attack | Efexor XR was recommenced |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 09/09/2005 **Stopped:** 30/11/2006 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 24/01/2007 | Computerised | | 05/12/2006 | no abnormality | Brain Scan |
| 24/01/2007 | Electrocardiograph | | 05/12/2006 | no abnormality | |
| 24/01/2007 | Other data | | 05/12/2006 | no abnormality | Lumbar puncture |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225130 **Seq:** 1 **Gender:** F
**Reported:** 29/01/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Blood sodium decreased. Sodium 118 | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 150.0 Milligram Total Oral
**Batch:** **Started:** **Stopped:** discontinued

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 29/01/2007 | Sodium | | | | blood sodium: 118 mmol/L unspecified date |

### Additional Information:

Patient was elderly

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225306 **Seq:** 1 **Gender:** F
**Reported:** 02/02/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 30
**Onset Date:** **DOB:** 20/01/1977
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hirsutism | | excessive facial and body hair | |
| Polycystic ovaries | | polycystic ovary syndrome | |
| Amenorrhoea | | | |
| Blood testosterone increased | | | |
| Breast enlargement | | | |
| Dizziness | | | |
| Galactorrhoea | | | |
| Menstruation irregular | | | |
| Psychotic disorder | | | |
| Rash pruritic | | | |
| Skin odour abnormal | | | |

### Medicine Details:

**RISPERDAL (Suspected)** **Reason:** Unspecified schizophrenia

**Batch:** **Started:** L TERM **Stopped:** 0

**EFEXOR (Suspected)** **Reason:**

**Batch:** **Started:** L TERM **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225306 **Seq:** 1
**Reported:** 02/02/2007
**Hospitalisation:**
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 30
**DOB:** 20/01/1977
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | | | |

### Medicine Details:

**RISPERDAL (Suspected)** **Reason:** Unspecified schizophrenia

**Batch:** **Started:** L TERM **Stopped:** 0

**EFEXOR (Suspected)** **Reason:**

**Batch:** **Started:** L TERM **Stopped:** 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225408 **Seq:** 1 **Gender:** M
**Reported:** 05/02/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | | Experienced slight nausea, slight dizziness/vertigo, excessive sweating, restless sleep, poor concentration, weight gain of 10 to 15 kg in 2.5 years, apathy, loss of libido, rare suicidal swings, occasional homicidal or violent thoughts, and circulation problems in the arms at night. Also experienced drug withdrawal syndrome with missing a maximum fo 2 doses. Whilst coming off Efexor XR he experienced brain shivers, loss of sleep, extreme itchiness while trying to sleep, mild nausea, extreme dizziness/vertigo, sweating, high irritability, muscle spasms, irritable bowel, tiredness, lethargy, occasional homicidal or violent thoughts, and circulation problems in the arms at | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 225408 **Seq:** 1 **Gender:** M
**Reported:** 05/02/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Apathy | | | |
| Disturbance in attention | | | |
| Dizziness | | | |
| Drug withdrawal syndrome | | | |
| Homicidal ideation | | | |
| Hyperhidrosis | | | |
| Irritability | | | |
| Loss of libido | | | |
| Nausea | | | |
| Poor quality sleep | | | |
| Weight increased | | | |

## Medicine Details:

**EFEXOR (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:** 0

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225589 **Seq:** 1
**Reported:** 08/02/2007
**Hospitalisation:**
**Onset Date:** 29/01/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 84
**DOB:** 23/01/1923
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agranulocytosis | | Agranulocytosis | |

### Medicine Details:

**CLOPIDOGREL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**CALTRATE + VITAMIN D (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ATENOLOL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**COVERSYL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Not yet recovered but recovering

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225589 **Seq:** 1
**Reported:** 08/02/2007
**Hospitalisation:**
**Onset Date:** 29/01/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 84
**DOB:** 23/01/1923
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | |
|---|---|---|---|
| **MADOPAR (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **SPIRONOLACTONE (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **EFEXOR-XR (Suspected)** | | **Reason:** | Depression |
| Capsule, modified release | 75.0 Milligram | Daily | Oral |
| **Batch:** | **Started:** 21/12/2006 | | **Stopped:** 30/01/2007 0 |

### Laboratory Investigations:

### Additional Information:
Not yet recovered but recovering

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225629 **Seq:** 1 **Gender:** M
**Reported:** 09/02/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 57
**Onset Date:** **DOB:** 11/08/1949
**Outcome:** Unknown **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug interaction<br><br>Antipsychotic drug level increase<br>Convulsion | | Seizures after several years without any seizures, increase in clozapine levels. | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:**
225.0 Milligram
**Batch:** **Started:** **Stopped:**

**CLOZARIL (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 25.0 Milligram Daily Oral
**Batch:** **Started:** 22/02/1995 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 09/02/2007 | Serum drug level | | | | Clozapine level:600 (dose and reference range not provided). (unknown date) clozapine level:400. |

### Additional Information:

Therapeutic threshold for clozapine plasma, through levels are 350-400ng/L.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225716 **Seq:** 1
**Reported:** 12/02/2007
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 93Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Bone marrow failure | Caused or prolonged inpatient hospitalisation | The patient was admitted to hospital (ICU) on an unknown date and diagnosed with bone marrow suppression (bone marrow failure). See attachment | Efexor XR stopped |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

**Batch:** **Started:** 01/10/2006 **Stopped:** 01/02/2007 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 225869 **Seq:** 1
**Reported:** 15/02/2007
**Hospitalisation:**
**Onset Date:** 22/01/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 55
**DOB:** 09/07/1951
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Extrapyramidal disorder | Caused or prolonged inpatient hospitalisation | Extraagramidal symptom, sweating, parkinsonism, rigidity and poor mobility. | Given bentropine. |
| Hyperhidrosis | Caused or prolonged inpatient hospitalisation | | |
| Mobility decreased | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**SODIUM VALPROATE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NEXIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ACTOS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**GLICLAZIDE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

History of weight gain, drooling, slurred speech, movement problems with risperidone.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225869 **Seq:** 1
**Reported:** 15/02/2007
**Hospitalisation:**
**Onset Date:** 22/01/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 55
**DOB:** 09/07/1951
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle rigidity | Caused or prolonged inpatient hospitalisation | | |
| Parkinsonism | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 25/01/2007

**RISPERIDONE (Suspected)** **Reason:**

Tablet 4.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 23/01/2007

### Laboratory Investigations:

### Additional Information:

History of weight gain, drooling, slurred speech, movement problems with risperidone.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225905 **Seq:** 1 **Gender:** F
**Reported:** 16/02/2007 **Weight:** 71.00
**Hospitalisation:** **Age:** 84
**Onset Date:** 25/01/2007 **DOB:** 23/01/1923
**Outcome:** Recovered 03/02/2007 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agranulocytosis | | agranulocytosis | |

### Medicine Details:

**ISCOVER (Other drug)** **Reason:**
75.0 Milligram
**Batch:** **Started:** **Stopped:** 0

**ATENOLOL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PERINDOPRIL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**CALTRATE + VITAMIN D (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 16/02/2007 | Bone marrow | | | | drug induced agranulocytosis |

### Additional Information:

History of Parkinson's disease, depression and urinary retention.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225905 **Seq:** 1 **Gender:** F
**Reported:** 16/02/2007 **Weight:** 71.00
**Hospitalisation:** **Age:** 84
**Onset Date:** 25/01/2007 **DOB:** 23/01/1923
**Outcome:** Recovered 03/02/2007 **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **ARGININE HYDROCHLORIDE (Other drug)** | | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **DITROPAN (Other drug)** | | | **Reason:** | |
| | 10.0 Milligram | | Oral | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **SINEMET CR (Other drug)** | | | **Reason:** | Paralysis agitans |
| | 1.0 Dose Unspecified | Daily | | |
| **Batch:** | **Started:** | | **Stopped:** | 0 |
| **MADOPAR (Other drug)** | | | **Reason:** | Paralysis agitans |
| Tablet | 3.0 Dose Unspecified | Daily | Oral | |
| **Batch:** | **Started:** | | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:
History of Parkinson's disease, depression and urinary retention.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225905 **Seq:** 1 **Gender:** F
**Reported:** 16/02/2007 **Weight:** 71.00
**Hospitalisation:** **Age:** 84
**Onset Date:** 25/01/2007 **DOB:** 23/01/1923
**Outcome:** Recovered 03/02/2007 **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **ALDACTONE (Suspected)** | | | **Reason:** | Edema and dropsy | |
| Tablet | 25.0 Milligram | | Daily | Oral | |
| **Batch:** | **Started:** | 16/01/2007 | | **Stopped:** | 28/01/2007 discontinued |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | Depression | |
| | 75.0 Milligram | | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | 28/01/2007 |

### Laboratory Investigations:

### Additional Information:
History of Parkinson's disease, depression and urinary retention.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225919 **Seq:** 1 **Gender:** F
**Reported:** 19/02/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 15/09/2006 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | convulsion | |

### Medicine Details:

**KETOCONAZOLE (Suspected)** **Reason:** Moniliasis
**Batch:** **Started:** **Stopped:** 0

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

**CAFERGOT (Suspected)** **Reason:** Headache
**Batch:** **Started:** **Stopped:**

**MERSYNDOL (Suspected)** **Reason:** Headache
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225919 **Seq:** 1 **Gender:** F
**Reported:** 19/02/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 15/09/2006 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | |
|---|---|---|---|
| **PANADEINE (Suspected)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **TRAMAL (Suspected)** | | **Reason:** | Headache |
| | 200.0 Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225921 **Seq:** 1 **Gender:** M
**Reported:** 19/02/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 25Y
**Onset Date:** 15/06/2004 **DOB:**
**Outcome:** Recovered 15/04/2005 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | Patient described seizures as "involuntary muscle movements and jerks of legs and arms, like intense muscle spasm and cramp". GP witnessed one episode and described it as a seizure, no loss of conciousness | Epilim. All drugs ceased by |

### Medicine Details:

**DI-GESIC (Other drug)** **Reason:**
8.0 Dose Unspecified
**Batch:** **Started:** **Stopped:**

**VIOXX (Other drug)** **Reason:**
25.0 Milligram
**Batch:** **Started:** **Stopped:** 15/10/2004

**VALIUM (Other drug)** **Reason:** Pain
8.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 15/02/2005

**TRAMADOL HYDROCHLORIDE (Suspected)** **Reason:** Pain
200.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 15/02/2005

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 225921 **Seq:** 1 **Gender:** M
**Reported:** 19/02/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 25Y
**Onset Date:** 15/06/2004 **DOB:**
**Outcome:** Recovered 15/04/2005 **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **EFEXOR (Suspected)** | | | **Reason:** | Pain |
| | 150.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** | 15/03/2005 |
| **ENDEP (Suspected)** | | | **Reason:** | Pain |
| | 25.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** | 15/02/2005 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 226032 **Seq:** 1 **Gender:** F
**Reported:** 22/02/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 13/02/2007 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysstasia | Incapacity/disability | " cannot remain standing" | |
| Fatigue | Incapacity/disability | "feeling exhausted , can't get on with daily tasks, can't go to work " | |
| Insomnia | Incapacity/disability | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 13/02/2007 **Stopped:** 15/02/2007

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient has a history of drug hypersensitivity

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 226036 **Seq:** 1
**Reported:** 22/02/2007
**Hospitalisation:**
**Onset Date:** 15/02/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 59
**DOB:** 23/03/1947
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Incapacity/disability | " current type" jerks , parasthesia, feeling very emotional, nausea, vomiting, head felt like it was going to explode, lack of energy, disorientation, anxiety, fear | |
| Anxiety | Incapacity/disability | | |
| Asthenia | Incapacity/disability | | |
| Disorientation | Incapacity/disability | | |
| Dyskinesia | Incapacity/disability | | |

### Medicine Details:

**SOMAC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NORMISON (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/02/2006 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Venlafaxine re-introduced with some relief of symptoms

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 226036 **Seq:** 1
**Reported:** 22/02/2007
**Hospitalisation:**
**Onset Date:** 15/02/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 59
**DOB:** 23/03/1947
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fear | Incapacity/disability | | |
| Headache | Incapacity/disability | | |
| Nausea | Incapacity/disability | | |
| Paraesthesia | Incapacity/disability | | |
| Vomiting | Incapacity/disability | | |

### Medicine Details:

**SOMAC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**NORMISON (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/02/2006 **Stopped:** 0

### Laboratory Investigations:

### Additional Information:
Venlafaxine re-introduced with some relief of symptoms

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 226045 **Seq:** 1 **Gender:** U
**Reported:** 22/02/2007 **Weight:** 116.00
**Hospitalisation:** Admitted to hospital **Age:** 22
**Onset Date:** 29/01/2007 **DOB:** 06/02/1984
**Outcome:** Death, maybe drug 08/02/2007 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Heat stroke | Life | Heat stroke:Severe Heat stroke,leading to multi-organ failure with rhabdomyolysis, coagulopathy and hepatic dysfunction. | |
| Blood creatine phosphokinase in | Life | | |
| Circulatory collapse | Life | | |
| Coagulopathy | Life | | |
| Hepatic function abnormal | Life | | |
| Hypotension | Life | | |
| Loss of consciousness | Life | | |
| Multi-organ failure | Life | | |
| Rhabdomyolysis | Life | | |

### Medicine Details:

**CLOZAPINE (Other drug)** **Reason:** No reason given
**Batch:** **Started:** 11/12/2001 **Stopped:** 10/01/2007 0

**CLOPINE (Suspected)** **Reason:** No reason given
Tablet 500.0 Milligram Daily Oral
**Batch:** **Started:** 10/01/2007 **Stopped:** 30/01/2007 0

**EFEXOR-XR (Suspected)** **Reason:** No reason given
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

**SOLIAN (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/2006 **Stopped:** 08/02/2007 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 22/02/2007 | Creatine kinase | | | | CK "very high" |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 226045 **Seq:** 1 **Gender:** U
**Reported:** 22/02/2007 **Weight:** 116.00
**Hospitalisation:** Admitted to hospital **Age:** 22
**Onset Date:** 29/01/2007 **DOB:** 06/02/1984
**Outcome:** Death, maybe drug 08/02/2007 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sepsis | Life | | |

### Medicine Details:

**CLOZAPINE (Other drug)** **Reason:** No reason given
**Batch:** **Started:** 11/12/2001 **Stopped:** 10/01/2007 0

**CLOPINE (Suspected)** **Reason:** No reason given
Tablet 500.0 Milligram Daily Oral
**Batch:** **Started:** 10/01/2007 **Stopped:** 30/01/2007 0

**EFEXOR-XR (Suspected)** **Reason:** No reason given
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

**SOLIAN (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/2006 **Stopped:** 08/02/2007 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 226065 **Seq:** 1
**Reported:** 23/02/2007
**Hospitalisation:** Admitted to hospital
**Onset Date:** 22/12/2006
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 43
**DOB:** 23/02/1963
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Patient became acutely psychotic, severe hyponatraemia, drug induced psychosis. | Antipsychotic medication. |
| Psychotic disorder | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 20/12/2006 **Stopped:** 22/12/2006

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 226137 **Seq:** 1 **Gender:** M
**Reported:** 27/02/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 14/02/2007 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fatigue | Incapacity/disability | | |
| Feeling abnormal | Incapacity/disability | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 14/02/2007 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 226138 **Seq:** 1
**Reported:** 27/02/2007
**Hospitalisation:**
**Onset Date:**
**Outcome:** Unknown

**Gender:** M
**Weight:** 0.00
**Age:** 44
**DOB:** 18/10/1962
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Chest pain | | Onset of chest pain in February and pain could last up to a full day | |
| Suicidal ideation | | The patient experienced this when first starting this medication in November, episodes generally lasting up to 2 minutes, the latest episode was in February and lasted 8 hours | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/11/2006 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient has HIV infection and is also taking unspecified antiretroviral therapy

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 226508 **Seq:** 1
**Reported:** 09/03/2007
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 99u
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Diarrhoea<br>Vomiting | | Drug Withdrawal Syndrome, Diarrhoea, | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 226532 **Seq:** 1 **Gender:** F
**Reported:** 12/03/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 74
**Onset Date:** 24/02/2007 **DOB:** 26/12/1932
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vaginal haemorrhage | Caused or prolonged inpatient hospitalisation | vaginal haemorrhage and clotting | |
| Blood pressure increased | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**SEREPAX (Other drug)** **Reason:**
Tablet 30.0 Milligram Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 26/01/2007 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Has a history of diverticulitis

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227044 **Seq:** 1 **Gender:** U
**Reported:** 27/03/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Death **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Heart disease congenital | Congenital anomaly / birth defect | Heart disease congenital, drug exposure during pregnancy. See attachment. | |
| Death neonatal | Congenital anomaly / birth defect | cardiac arrest and respiratory arrest 2 days after birth | |
| Drug exposure during pregnancy | Congenital anomaly / birth defect | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
75.0 Milligram
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227052 **Seq:** 1 **Gender:** F
**Reported:** 28/03/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 85
**Onset Date:** 27/02/2007 **DOB:** 12/01/1922
**Outcome:** Recovered 02/03/2007 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Patient had hyponatraemia, experienced nausea and vomiting. | Ceased venlafaxine, IV fluids. |
| Nausea | Caused or prolonged inpatient hospitalisation | | |
| Vomiting | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**NEXIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**CARTIA (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**OXAZEPAM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**BRICANYL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 28/03/2007 | Sodium | | | | Sodium Level:121 mmol/L. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227052 **Seq:** 1 **Gender:** F
**Reported:** 28/03/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 85
**Onset Date:** 27/02/2007 **DOB:** 12/01/1922
**Outcome:** Recovered 02/03/2007 **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | |
|---|---|---|---|
| **VITAMINORUM B.P.C. (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **MOTILIUM (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **EFEXOR-XR (Suspected)** | | **Reason:** | Depression |
| Capsule | 75.0 Milligram | Daily | Oral |
| **Batch:** | **Started:** 20/02/2007 | | **Stopped:** 27/02/2007 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227158 **Seq:** 1 **Gender:** F
**Reported:** 30/03/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 01/02/2007 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Incapacity/disability | Reduced dosage of Efexor from ? to 37.5mg and developed Cerebrovascular accident; stopped Efexor SR "cold turkey" . Developed DRUG WITHDRAWAL SYNDROME; | |
| Cerebrovascular accident | Incapacity/disability | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
37.0 Milligram Oral
**Batch:** **Started:** **Stopped:** 01/02/2007 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 227363 **Seq:** 1
**Reported:** 04/04/2007
**Hospitalisation:**
**Onset Date:** 29/03/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 41
**DOB:** 03/03/1966
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Erythema multiforme | Life | erythema multiforme rash, fever, oedema.? Steven Johnson Syndrome | |
| Oedema | Life | | |
| Pyrexia | Life | | |
| Stevens-Johnson syndrome | Life | | |

## Medicine Details:

**AMOXYCILLIN SODIUM (Suspected)** **Reason:**
Tablet 500.0 Milligram 3 times Oral
**Batch:** **Started:** 26/03/2007 **Stopped:** 29/03/2007

**QUILONUM SR (Suspected)** **Reason:**
Tablet 450.0 Milligram 2 times Oral
**Batch:** **Started:** 01/02/2007 **Stopped:** 02/04/2007

**LAMICTAL (Suspected)** **Reason:**
Tablet 25.0 Milligram 1 time Oral
**Batch:** **Started:** 01/02/2007 **Stopped:** 02/04/2007

**SEROQUEL (Suspected)** **Reason:**
Tablet 25.0 Milligram 1 time Oral
**Batch:** **Started:** 01/03/2007 **Stopped:** 02/04/2007

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 04/04/2007 | White blood cells | | | | elevated |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227363 **Seq:** 1
**Reported:** 04/04/2007
**Hospitalisation:**
**Onset Date:** 29/03/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 41
**DOB:** 03/03/1966
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **EFEXOR-XR (Suspected)** | | | **Reason:** | |
| Tablet | 75.0 Milligram | 1 time | | Oral |
| **Batch:** | **Started:** 01/11/2006 | | **Stopped:** | 02/04/2007 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227394 **Seq:** 1
**Reported:** 05/04/2007
**Hospitalisation:**
**Onset Date:** 06/03/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 74.00
**Age:** 18
**DOB:** 01/07/1988
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sedation<br><br>Disturbance in attention | | Patient is vague, dazed, has poor concentration. If people move quickly "feels that she sees trails of people", feels drugged | |

### Medicine Details:

**NORIMIN-1 (Other drug)** **Reason:** Contraception
**Batch:** **Started:** **Stopped:**

**ROXITHROMYCIN (Suspected)** **Reason:** Pulmonary collapse
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 02/03/2007 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 26/01/2007 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227466 **Seq:** 1 **Gender:** M
**Reported:** 11/04/2007 **Weight:** 92.00
**Hospitalisation:** **Age:** 59
**Onset Date:** 26/03/2007 **DOB:** 28/05/1947
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Syncope | Caused or prolonged inpatient hospitalisation | Syncope ; found to have VENTRICULAR TACHYCARDIA;Ventricular fibrillation; Atrial flutter; Atrial tachycardia; | hospitalisation; withdrawal of efexor XR |
| Atrial fibrillation | Caused or prolonged inpatient hospitalisation | | |
| Atrial flutter | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**ZYPREXA (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Daily
**Batch:** **Started:** 07/03/2007 **Stopped:** 29/03/2007

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 11/04/2007 | Other data | | 01/03/2007 | normal | angiogram |
| 11/04/2007 | Other data | | 01/03/2007 | normal | cardiac electrophysiologic study |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227466 **Seq:** 1 **Gender:** M
**Reported:** 11/04/2007 **Weight:** 92.00
**Hospitalisation:** **Age:** 59
**Onset Date:** 26/03/2007 **DOB:** 28/05/1947
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Atrial tachycardia | Caused or prolonged inpatient hospitalisation | | |
| Ventricular fibrillation | Caused or prolonged inpatient hospitalisation | | |
| Ventricular tachycardia | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**ZYPREXA (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Daily
**Batch:** **Started:** 07/03/2007 **Stopped:** 29/03/2007

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227610 **Seq:** 1 **Gender:** F
**Reported:** 16/04/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | Caused or prolonged inpatient hospitalisation | After Efexor-XR was decreased to 75mg, patient experienced drug withdrawal syndrome, piloerection, feeling abnormal, tremor, paraesthesia, insomnia and nausea. Had taken Efexor-XR for 4 days and experienced 'sand in head' sensation and dizziness. | Efexor-XR ceased. |
| Dizziness | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 30/03/2007

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227610 **Seq:** 1 **Gender:** F
**Reported:** 16/04/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Feeling abnormal | Caused or prolonged inpatient hospitalisation | | |
| Insomnia | Caused or prolonged inpatient hospitalisation | | |
| Nausea | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 30/03/2007

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227610 **Seq:** 1 **Gender:** F
**Reported:** 16/04/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia | Caused or prolonged inpatient hospitalisation | | |
| Piloerection | Caused or prolonged inpatient hospitalisation | | |
| Tremor | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 30/03/2007

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227626 **Seq:** 1 **Gender:** F
**Reported:** 16/04/2007 **Weight:** 74.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abnormal sleep-related event<br><br>Eating disorder<br>Weight increased | | Patient has been taking Stilnox for 5-6 years, she was about 60kg when she started taking it and she has gained 15kg. Patient has driven to Coles in the middle of the night in her pajamas with no bra on, buying blocks of chocolate and eating it in the car. She only knows that she has done it when she finds receipts and chocolate wrappers in her car the next morning. | Lithium |

### Medicine Details:

**STILNOX (Suspected)** **Reason:** Specific disorders of sleep
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:** 0

**EFEXOR (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227661 **Seq:** 1
**Reported:** 17/04/2007
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 50Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abnormal sleep-related event<br>Amnesia<br>Fall<br>Head injury<br>Sleep walking | | Binge eating at night at least twice a week, smoking in bed, wakes up and finds sheets burning, cooking, puts saucepan on high, once went back to bed and burnt sacepan, has had 4 serious fall while sleepwalking, hospitalised each time recently she was found in a pool of blood from a head wound, she has tried to drive while | Stilnox ceased. |

### Medicine Details:

| | | | |
|---|---|---|---|
| **NEXIUM (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **NORFLEX (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **KAPANOL (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |
| **DUROLAX (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

No alcohol consumed.
All this strange behaviour has never been linked with Stilnox. Just considered psychiatric and sees psychiatrist. Has become reclusive over the years and ashamed of her erratic nocturnal behaviour. Dose not leave the house anymore. dose not trust herself.
No memory of any of the behaviour-all just assumed was reported by husband.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227661 **Seq:** 1
**Reported:** 17/04/2007
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 50Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **COLOXYL WITH SENNA (Other drug)** | | | **Reason:** | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **STILNOX (Suspected)** | | | **Reason:** | | |
| Tablet | 20.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | 22/03/2007 |
| **VALIUM (Suspected)** | | | **Reason:** | Anxiety neurosis | |
| Tablet | 20.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | L TERM | | **Stopped:** | |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | | |
| | 150.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | L TERM | | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:

No alcohol consumed.
All this strange behaviour has never been linked with Stilnox. Just considered psychiatric and sees psychiatrist. Has become reclusive over the years and ashamed of her erratic nocturnal behaviour. Dose not leave the house anymore. dose not trust herself.
No memory of any of the behaviour-all just assumed was reported by husband.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227779 **Seq:** 1
**Reported:** 20/04/2007
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 15/02/2007
**Outcome:** Recovered

**Gender:** M
**Weight:** 0.00
**Age:** 51Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br><br><br><br>Anxiety<br>Panic attack | | Patient had terrible nightmares - thinking dying in sleep, fighting people jumping around the bed, thrashing and screaming. Also developed anxiety the following day and having a panic attack - never had before. | Stilnox CR and Efexor-XR |

### Medicine Details:

**Stilnox CR (Suspected)** **Reason:** Specific disorders of sleep
Tablet 17.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 01/02/2007 **Stopped:** 01/03/2007

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 01/02/2007 **Stopped:** 01/03/2007

**ALCOHOL (Suspected)** **Reason:**
3.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient drinks 3 to 4 stubbies every night.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227868 **Seq:** 1 **Gender:** F
**Reported:** 24/04/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Jaundice | | Patient taking Efexor XR experienced | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227870 **Seq:** 1
**Reported:** 24/04/2007
**Hospitalisation:**
**Onset Date:** 01/01/2003
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 52
**DOB:** 24/10/1950
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mania<br>Hostility<br>Abnormal behaviour<br>Thinking abnormal | | taking on big projects and spending<br>towards close family members | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily

**Batch:** **Started:** 30/09/2002 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Twin brothers are diagnosed and treated bipolar one with paranoid tendencies. Has had several major depressions and many smaller ones.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227900 **Seq:** 1 **Gender:** F
**Reported:** 24/04/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 61Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br><br><br><br>Dizziness<br>Dry mouth<br>Paraesthesia | | After experiencing serotonin syndrome the patient caesed Efexor and experienced drug withdrawal symptoms, electric shock sensations, dizziness and dry mouth. | Re-introduction of Efexor |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Sequence to 221421

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227908 **Seq:** 1 **Gender:** M
**Reported:** 26/04/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Loss of consciousness<br><br>Electrocardiogram QT prolonged<br>Syncope | | Loss of consciousness and fainting episodes with a long QT interval | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227995 **Seq:** 1
**Reported:** 27/04/2007
**Hospitalisation:**
**Onset Date:** 19/01/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 64.00
**Age:** 59
**DOB:** 07/03/1947
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sleep walking | Caused or prolonged inpatient hospitalisation | Patient had fallen down a flight of stairs while sleep-walking and injured his head, experienced post trauma amnesia and developed very severe diarrhoea. | Stilnox ceased. |
| Amnesia | Caused or prolonged inpatient hospitalisation | | |
| Diarrhoea | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**INDERAL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**COLOFAC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**DESERIL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**SOMAC (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 227995 **Seq:** 1
**Reported:** 27/04/2007
**Hospitalisation:**
**Onset Date:** 19/01/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 64.00
**Age:** 59
**DOB:** 07/03/1947
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fall | Caused or prolonged inpatient hospitalisation | | |
| Head injury | Caused or prolonged inpatient hospitalisation | | |
| Memory impairment | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**CELEBREX (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**COVERSYL PLUS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**STILNOX (Suspected)** **Reason:** Specific disorders of sleep
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 15/01/2005 **Stopped:** 15/01/2007

**EFEXOR (Suspected)** **Reason:** Depression
150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228068 **Seq:** 1 **Gender:** F
**Reported:** 30/04/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 15/01/2007 **DOB:**
**Outcome:** Recovered 15/02/2007 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Amnesia<br><br>Abnormal sleep-related event | | Patient would start a conversation with her husband in the middle of the night, cleaned the house and did some painting, cooked in her sleep and set off smoke alarms in the kitchen and demanded sex in the middle of the night, with no memory of it the next day. | Ceased Stilnox |

### Medicine Details:

**STILNOX (Interaction)** **Reason:**
Tablet 5.0 Milligram As necessary Oral
**Batch:** **Started:** 15/01/2007 **Stopped:** 15/02/2007

**OXYCONTIN (Interaction)** **Reason:**
Tablet 120.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**EFEXOR-XR (Interaction)** **Reason:**
Capsule 300.0 Milligram Daily Oral
**Batch:** **Started:** 15/09/2005 **Stopped:**

**EFEXOR-XR (Interaction)** **Reason:** Pain
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/09/2005 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

No alcohol.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228068 **Seq:** 1 **Gender:** F
**Reported:** 30/04/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 15/01/2007 **DOB:**
**Outcome:** Recovered 15/02/2007 **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **NEURONTIN (Interaction)** | | | **Reason:** | Pain | |
| | 600.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | | |
| **NEURONTIN (Interaction)** | | | **Reason:** | Pain | |
| Capsule | 1.8 | Gram | Daily | Oral | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | | Contin |
| **IMIGRAN (Other drug)** | | | **Reason:** | | |
| Spray | 2.0 | Dose Unspecified | | Nasal | |
| **Batch:** | **Started:** 15/07/2005 | | **Stopped:** | | |
| **DERALIN (Other drug)** | | | **Reason:** | | |
| Tablet | 80.0 | Milligram | | Oral | |
| **Batch:** | **Started:** 15/09/2005 | | **Stopped:** | | |

### Laboratory Investigations:

### Additional Information:
No alcohol.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228184 **Seq:** 1
**Reported:** 03/05/2007
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 52
**DOB:** 24/04/1955
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br><br>Drug dependence | | dose taken in the morning, several hours later the patient " craves" Efexor and experiences tinnitus | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule Reducing Oral
**Batch:** **Started:** 15/07/2006 **Stopped:** 15/03/2007

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Medical history includes chronic fatigue and glandular fever. Patient began reducing Efexor dose from 75mg once daily, then alternating 75mg and 37.5mg, then 37.5mg daily, then on alternate days. Therapy is continuing at time of reporting.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228206 **Seq:** 1 **Gender:** F
**Reported:** 04/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Galactorrhoea | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient was NOT taking concomitant medicines.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228218 **Seq:** 1 **Gender:** M
**Reported:** 04/05/2007 **Weight:** 92.00
**Hospitalisation:** **Age:** 59
**Onset Date:** 26/03/2007 **DOB:** 28/05/1947
**Outcome:** Recovered 02/04/2007 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Syncope | Caused or prolonged inpatient hospitalisation | Patient suffered syncope and collapse; regained consiousness spontaneously;when brought to hospital patient was in atrial fibrillation | Wean of Efexor, referred to psychiatrist for further treatment. Amiodarone. |
| Atrial fibrillation | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**ZYPREXA (Other drug)** **Reason:** Otr spec symp psychopathol nec
5.0 Milligram Daily Oral
**Batch:** **Started:** 15/10/2006 **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** 07/03/2006 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228229 **Seq:** 1
**Reported:** 07/05/2007
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 22Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pancreatitis<br>Haematuria<br>Malaise | | Hospitalization, Malaise, Pancreatitis, | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

225.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228243 **Seq:** 1
**Reported:** 07/05/2007
**Hospitalisation:**
**Onset Date:** 05/05/2007
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 75.00
**Age:** 28
**DOB:** 03/03/1979
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tinnitus | Incapacity/disability | brain buzzing | |
| Dizziness | Incapacity/disability | | |
| Headache | Incapacity/disability | | |
| Influenza like illness | Incapacity/disability | | |
| Vomiting | Incapacity/disability | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram 1 time Oral

**Batch:** **Started:** 01/03/2007 **Stopped:** 05/05/2007 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

consumer report included reference to the following website:
http://www.medicalnewstoday.com/youropinions.php?opinionid=11018

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228265 **Seq:** 1
**Reported:** 07/05/2007
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Recovered

**Gender:** M
**Weight:** 0.00
**Age:** 48Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abnormal sleep-related event | Caused or prolonged inpatient hospitalisation | Patient had apparent hallucinations, during the day would "drive like an idiot" had swerved across 3 lanes of traffic. After a friend hung himself there were several occasions when he would wander near his place "talking to the trees" at night. He had no memory of these events. | |
| Amnesia | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**MS CONTIN (Other drug)** **Reason:**
60.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**OXAZEPAM (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** L TERM **Stopped:** Continued.

**ENDONE (Other drug)** **Reason:**
3.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:** Continued.

**ZYPREXA (Suspected)** **Reason:**
5.0 Milligram Daily
**Batch:** **Started:** 31/05/2005 L TERM **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

No suicidal ideation.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228265 **Seq:** 1
**Reported:** 07/05/2007
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Recovered

**Gender:** M
**Weight:** 0.00
**Age:** 48Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination | Caused or prolonged inpatient hospitalisation | | |
| Stereotypy | Caused or prolonged inpatient hospitalisation | | |
| Suicidal behaviour | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**STILNOX (Suspected)** **Reason:** Specific disorders of sleep

Tablet 10.0 Milligram Daily Oral

**Batch:** **Started:** L TERM **Stopped:** 15/02/2005

**EFEXOR-XR (Suspected)** **Reason:**

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** 05/07/2005 L TERM **Stopped:**

### Laboratory Investigations:

### Additional Information:

No suicidal ideation.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228283 **Seq:** 1 **Gender:** F
**Reported:** 08/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 23/04/2007 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Parkinsonism<br><br>Serotonin syndrome | | Patient taking venlafaxine experienced suspected serotonin syndrome and parkinsonism | dose reduction |

### Medicine Details:

**ORAL CONTRACEPTIVE NOS (Other drug)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** S TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228387 **Seq:** 1 **Gender:** M
**Reported:** 10/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary incontinence<br>Testicular pain<br>Dizziness | | dribbling when urinating<br>when urinating | |

### Medicine Details:

**SAW PALMETTO (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**PRAZOSIN HYDROCHLORIDE (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** 15/04/2007 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient had a background of prostate problems

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228396 **Seq:** 1 **Gender:** F
**Reported:** 10/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Therapy regimen changed | | Efexor increased from 75mg daily to 150mg and onset of reaction | |
| Drug interaction | | possible interaction between venlafaxine and zopiclone | |
| Suicidal ideation | | was waking in the middle of the night wanting to kill herself | |
| Anxiety | | | |
| Depression | | | |

### Medicine Details:

**COLESE (Other drug)** **Reason:**
Tablet 135.0 Milligram 3 times Oral
**Batch:** **Started:** L TERM **Stopped:**

**XANAX (Other drug)** **Reason:**
Tablet 1.0 Milligram As necessary Oral
**Batch:** **Started:** L TERM **Stopped:**

**NEXIUM (Other drug)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 26/03/2007 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient had no history of suicidal ideation. Patient had no problems taking Efexor at lower dose

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228396 **Seq:** 1 **Gender:** F
**Reported:** 10/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**IMOVANE (Suspected)** **Reason:** Specific disorders of sleep
Tablet 7.5 Milligram Daily Oral
**Batch:** **Started:** 03/04/2007 **Stopped:**

### Laboratory Investigations:

### Additional Information:
Patient had no history of suicidal ideation. Patient had no problems taking Efexor at lower dose

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228403 **Seq:** 1 **Gender:** F
**Reported:** 10/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Migraine with aura<br>Headache | | left sided | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228524 **Seq:** 1 **Gender:** M
**Reported:** 15/05/2007 **Weight:** 70.00
**Hospitalisation:** **Age:** 25
**Onset Date:** 27/03/2007 **DOB:** 10/04/1981
**Outcome:** Recovered 30/03/2007 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension | | Patient diagnosed with hypertension 140/105 on Efexor-XR 150mg. | Efexor-XR ceased. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 26/02/2007 **Stopped:** 29/03/2007 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228623 **Seq:** 1 **Gender:** F
**Reported:** 17/05/2007 **Weight:** 65.00
**Hospitalisation:** Required a visit to the doctor **Age:** 56
**Onset Date:** 07/03/2007 **DOB:** 03/12/1950
**Outcome:** Recovered 20/03/2007 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence<br><br>Confusional state<br>Dizziness<br>Hyperhidrosis | | Patient experienced sweating, drowsiness, dizziness and confusion after taking Efexor 75mg increased form 37.5mg. | Efexor ceased. |

### Medicine Details:

**KAPANOL (Other drug)** **Reason:**
60.0 Milligram
**Batch:** **Started:** **Stopped:**

**PANADEINE FORTE (Other drug)** **Reason:**
2.0 Dose Unspecified
**Batch:** **Started:** **Stopped:**

**GABAPENTIN (Other drug)** **Reason:** Pain
600.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR (Suspected)** **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 1 week

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228637 **Seq:** 1 **Gender:** F
**Reported:** 17/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia<br><br>Piloerection | | Patient experienced insomnia and goose bumps on head, arms and inside mouth while on Efexor-XR therapy. | Efexor-XR reduced to 75mg. |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 15/02/2007 **Stopped:** 30/03/2007

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228669 **Seq:** 1 **Gender:** M
**Reported:** 18/05/2007 **Weight:** 92.00
**Hospitalisation:** **Age:** 76
**Onset Date:** 08/02/2007 **DOB:** 10/04/1930
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Constipation | | Constipation. | Weaned off Efexor. Commenced on Sertraline 50mg/daily. Treated with Movicol sachets. Changed to fluvoxamine |

### Medicine Details:

**ASPIRIN (Other drug)** **Reason:**
100.0 Milligram
**Batch:** **Started:** **Stopped:**

**ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)** **Reason:**
20.0 Milligram
**Batch:** **Started:** **Stopped:**

**METOPROLOL TARTRATE (Other drug)** **Reason:**
50.0 Milligram
**Batch:** **Started:** **Stopped:**

**SIMVASTATIN (Other drug)** **Reason:**
20.0 Milligram
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Further investigation - ulcerative colitis. Chronic renal impairment.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228669 **Seq:** 1
**Reported:** 18/05/2007
**Hospitalisation:**
**Onset Date:** 08/02/2007
**Outcome:** Unknown

**Gender:** M
**Weight:** 92.00
**Age:** 76
**DOB:** 10/04/1930
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **SERTRALINE HYDROCHLORIDE (Other drug)** | | | **Reason:** | Depression | |
| | 50.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **EFEXOR (Suspected)** | | | **Reason:** | Depression | |
| | 37.5 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | 08/02/2007 |

### Laboratory Investigations:

### Additional Information:
Further investigation - ulcerative colitis. Chronic renal impairment.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228694 **Seq:** 1
**Reported:** 21/05/2007
**Hospitalisation:** Admitted to hospital
**Onset Date:** 06/04/2007
**Outcome:** Recovered

**Gender:** U
**Weight:** 0.00
**Age:** 46
**DOB:** 03/05/1960
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pancreatitis | Caused or prolonged inpatient hospitalisation | Pancreatitis | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule, modified release 375.0 Milligram Daily Oral

**Batch:** **Started:** 25/12/2006 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228720 **Seq:** 1 **Gender:** F
**Reported:** 22/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 72
**Onset Date:** 25/12/2006 **DOB:** 09/03/1934
**Outcome:** Recovered 03/01/2007 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorexia | Caused or prolonged inpatient hospitalisation | Severe hyponatraemia leading to predominant volume loss (vomiting). Hyponatraemia multifactorial - only had soda water in the past 3 days. Inadequate solute intake (poor eating prior to admission) - nausea and seizure on | |
| Convulsion | Caused or prolonged inpatient hospitalisation | seizure on 29/12/06 | |

### Medicine Details:

**ZOCOR (Other drug)** **Reason:**
20.0 Milligram
**Batch:** **Started:** **Stopped:**

**FOSAMAX (Other drug)** **Reason:**
70.0 Milligram
**Batch:** **Started:** **Stopped:**

**AMIZIDE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ASTRIX 100 (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228720 **Seq:** 1 **Gender:** F
**Reported:** 22/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 72
**Onset Date:** 25/12/2006 **DOB:** 09/03/1934
**Outcome:** Recovered 03/01/2007 **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | | |
| Nausea | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR (Suspected)** **Reason:** Depression
4.0 Dose Unspecified Total Oral
**Batch:** **Started:** 21/12/2006 **Stopped:** 24/12/2006

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228784 **Seq:** 1 **Gender:** M
**Reported:** 23/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain | | | |
| Agitation | | | |
| Confusional state | | | |
| Dizziness | | | |
| Dyspepsia | | | |
| Gastric disorder | | | |
| Myalgia | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228785 **Seq:** 1 **Gender:** F
**Reported:** 23/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 45
**Onset Date:** **DOB:** 15/01/1962
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Alopecia | | | |
| Asthma | | | |
| Cough | | | |
| Diarrhoea | | | |
| Dizziness | | | |
| Dysgeusia | | | |
| Eating disorder | | | |
| Hallucination | | | |
| Headache | | | |
| Hyperhidrosis | | | |
| Loss of libido | | | |

### Medicine Details:

**MORPHINE NOS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**OXYCONTIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 15/04/2007 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

concurrent conditions include: muscle stiffness, intestinal functional disorder, anorexia, ADHD, chronic pain, hyperthyroidism, fibromyalgia. The patient had been taking Efexor since 2000 and had changed to Efexor XR at unspecified date. The patient has recovered from asthma, cough and suicidal ideation. The patient had a hisotry of child abuse by father.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228785 **Seq:** 1 **Gender:** F
**Reported:** 23/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 45
**Onset Date:** **DOB:** 15/01/1962
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle twitching<br>Suicidal ideation<br>Weight decreased | | | |

### Medicine Details:

**MORPHINE NOS (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**OXYCONTIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 15/04/2007 0

### Laboratory Investigations:

### Additional Information:

concurrent conditions include: muscle stiffness, intestinal functional disorder, anorexia, ADHD, chronic pain, hyperthyroidism, fibromyalgia. The patient had been taking Efexor since 2000 and had changed to Efexor XR at unspecified date. The patient has recovered from asthma, cough and suicidal ideation. The patient had a hisotry of child abuse by father.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228901 **Seq:** 1 **Gender:** F
**Reported:** 28/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 11/05/2007 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | Caused or prolonged inpatient hospitalisation | | |
| Malaise | Caused or prolonged inpatient hospitalisation | | |
| Nausea | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**DESMOPRESSIN (Other drug)** **Reason:**
Injection, intravenous infusion
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228940 **Seq:** 1
**Reported:** 28/05/2007
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 01/04/2007
**Outcome:** Unknown

**Gender:** F
**Weight:** 60.00
**Age:** 60Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abnormal dreams<br><br>Suicidal ideation | | Waking with thought of suicide-patient describes it as suicide, suicide going around her head | |

### Medicine Details:

**KALMA (Other drug)** **Reason:**
0.5 Milligram
**Batch:** **Started:** **Stopped:**

**Adefin XL (Other drug)** **Reason:**
60.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 0

**SOMAC (Other drug)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** 0

**ATACAND (Other drug)** **Reason:**
16.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

suffers anxiety and depression. Takes Efexor in the morning.

## Report Detail

**Case Number:** 228940 **Seq:** 1
**Reported:** 28/05/2007
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 01/04/2007
**Outcome:** Unknown

**Gender:** F
**Weight:** 60.00
**Age:** 60Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **IMOVANE (Other drug)** | | | **Reason:** | |
| | 7.5 Milligram | | Alternate days | |
| **Batch:** | **Started:** 27/01/2007 | | **Stopped:** | 0 |
| **EFEXOR-XR (Suspected)** | | | **Reason:** Depression | |
| Capsule | 150.0 Milligram | | Daily | Oral |
| **Batch:** | **Started:** 27/03/2007 | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

suffers anxiety and depression. Takes Efexor in the morning.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 228956 **Seq:** 1 **Gender:** F
**Reported:** 28/05/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br><br>Malaise<br>Nausea<br>Vertigo | | Received a trial infusion of desmopressin (DDAVP) in preparation for gynaecological surgery. The pre-treatment sodium was normal at 135 mmol/L. The following day she developed severe malaise, nausea and intense vertigo. When admitted to hospital later that day the serum sodium was 120 mmol/L. Her symptoms resolved when her serum sodium was returned to normal. | |

### Medicine Details:

**DESMOPRESSIN (Interaction)** **Reason:**
Injection Intravenous
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 28/05/2007 | Sodium | | | | Pre-treatment: 135 mmol/L, day after: 120 mmol/L |

### Additional Information:

White female with mild von Willebrands disease had been taking venlafaxine for depression for six months.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 229223 **Seq:** 1
**Reported:** 01/06/2007
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/05/2007
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 57
**DOB:** 14/04/1950
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Euphoric mood | Caused or prolonged inpatient hospitalisation | Dose reduced to 225mg and patient experienced euphoria- " too happy" | |
| Therapy regimen changed | Caused or prolonged inpatient hospitalisation | From 225mg to 375mg | |
| Depressed mood | Caused or prolonged inpatient hospitalisation | extremely depressed | |

## Medicine Details:

**ZOTON (Other drug)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:**

**SWISSE WOMENS ULTIVITE MULTI-VITAMIN, MINERAL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**MOVICOL (Other drug)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**SEROQUEL (Other drug)** **Reason:**
Tablet Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 01/06/2007 | Pharmacokinetics | | | | venlafaxine levels were higher than therapeutic range |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229223 **Seq:** 1
**Reported:** 01/06/2007
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/05/2007
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 57
**DOB:** 14/04/1950
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Antidepressant drug level above | Caused or prolonged inpatient hospitalisation | | |
| Anxiety | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**PRAVACHOL (Other drug)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**PANADOL (Other drug)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**VALIUM (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 225.0 Milligram Daily Oral
**Batch:** **Started:** 15/09/2006 **Stopped:** 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229244 **Seq:** 1 **Gender:** M
**Reported:** 04/06/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Death **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Completed suicide | | Completed suicide. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 325.0 Milligram Oral
**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229246 **Seq:** 1 **Gender:** F
**Reported:** 04/06/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 31
**Onset Date:** 20/05/2007 **DOB:** 22/10/1975
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Akathisia | | Akathisia secondary to commencement of SNRI (venlafaxine) | Efexor gradually reduced & ceased. Celapram to |

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **Valpam (Other drug)** | | | **Reason:** | |
| Tablet | 5.0 Milligram | | 2 times | Oral |
| **Batch:** | **Started:** 18/05/2007 | | **Stopped:** | 0 |
| **TEMAZE (Other drug)** | | | **Reason:** | |
| Tablet | 10.0 Milligram | | As necessary | Oral |
| **Batch:** | **Started:** 18/05/2007 | | **Stopped:** | 0 |
| **SEROQUEL (Other drug)** | | | **Reason:** | |
| Tablet | 50.0 Milligram | | As necessary | Oral |
| **Batch:** | **Started:** 18/05/2007 | | **Stopped:** | |
| **LARGACTIL (Other drug)** | | | **Reason:** | |
| Tablet | 100.0 Milligram | | As necessary | Oral |
| **Batch:** | **Started:** 18/05/2007 | | **Stopped:** | |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229246 **Seq:** 1
**Reported:** 04/06/2007
**Hospitalisation:**
**Onset Date:** 20/05/2007
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 31
**DOB:** 22/10/1975
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** 18/05/2007 **Stopped:** 03/06/2007 0

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229373 **Seq:** 1 **Gender:** F
**Reported:** 05/06/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 33Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety | Life | Patient started venlafaxine hydrochloride for anxiety and depression, anxiety and agitation increased during dose increase. The patient made plans to take her own and her children's lives. | |
| Agitation | Life | | |
| Suicidal ideation | Life | | |
| Therapy regimen changed | Life | | |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Healy D et al. antidepressants and violence: problems at the interface of medicine and law. PLoS Medicine 2006; 3 (9) : 1478-1487.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229500 **Seq:** 1 **Gender:** F
**Reported:** 07/06/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | | Suicidal ideation - feeling like taking all the capsules and be done with ti. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 150.0 Milligram Daily Oral
**Batch:** **Started:** 15/02/2007 **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229516 **Seq:** 1
**Reported:** 07/06/2007
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 62
**DOB:** 17/01/1945
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nephrolithiasis | Caused or prolonged inpatient hospitalisation | Patient was hospitalised with kidney stones while still on Efexor XR. | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229620 **Seq:** 1 **Gender:** M
**Reported:** 12/06/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression<br>Abnormal behaviour<br>Amnesia | | A patient received Efexor XR and experienced amnesia, abnormal behaviour, abusive behaviour and self harm | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

patient was admitted to hospital for cutting his arm and was then given cipramil.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229636 **Seq:** 1 **Gender:** F
**Reported:** 12/06/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pain | | pain in hip aggravated after commencing | |

### Medicine Details:

**MORPHINE NOS (Other drug)** **Reason:**
120.0 Milligram
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229655 **Seq:** 1 **Gender:** F
**Reported:** 13/06/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 31/05/2007 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Malaise<br>Intentional overdose<br>Mydriasis | | experienced feeling sick " like she was on<br>patient took 5 Efexor XR capsules | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 75.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229773 **Seq:** 1
**Reported:** 15/06/2007
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Unknown

**Gender:** U
**Weight:** 0.00
**Age:** 70
**DOB:** 03/07/1936
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | Patient experienced hyponatraemia. | |

### Medicine Details:

**ASASANTIN SR (Other drug)** **Reason:**
2.0
**Batch:** **Started:** **Stopped:**

**ASPIRIN (Other drug)** **Reason:**
150.0 Milligram
**Batch:** **Started:** **Stopped:**

**CABASER (Other drug)** **Reason:**
1.0 Milligram
**Batch:** **Started:** **Stopped:**

**CALTRATE (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 15/06/2007 | Sodium | | | | 126 |

### Additional Information:

Patient was on atacand and this ceased first but didnt help the Na levels..

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229773 **Seq:** 1
**Reported:** 15/06/2007
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Unknown

**Gender:** U
**Weight:** 0.00
**Age:** 70
**DOB:** 03/07/1936
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | |
|---|---|---|---|
| **DITROPAN (Other drug)** | | **Reason:** | |
| | 15.0 Milligram | | |
| **Batch:** | **Started:** | | **Stopped:** |
| **NASONEX AQUEOUS NASAL SPRAY (Other drug)** | | **Reason:** | |
| | 50.0 Microgram | | |
| **Batch:** | **Started:** | | **Stopped:** |
| **NEXIUM (Other drug)** | | **Reason:** | |
| | 40.0 Milligram | | |
| **Batch:** | **Started:** | | **Stopped:** |
| **PANADOL (Other drug)** | | **Reason:** | |
| **Batch:** | **Started:** | | **Stopped:** |

### Laboratory Investigations:

### Additional Information:

Patient was on atacand and this ceased first but didnt help the Na levels..

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229773 **Seq:** 1
**Reported:** 15/06/2007
**Hospitalisation:** Required a visit to the doctor
**Onset Date:**
**Outcome:** Unknown

**Gender:** U
**Weight:** 0.00
**Age:** 70
**DOB:** 03/07/1936
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **SINEMET (Other drug)** | | | **Reason:** | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **SINEMET CR (Other drug)** | | | **Reason:** | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **FLUVAX (Other drug)** | | | **Reason:** | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **EFEXOR-XR (Suspected)** | | | **Reason:** | |
| Capsule | 150.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |

### Laboratory Investigations:

### Additional Information:

Patient was on atacand and this ceased first but didnt help the Na levels..

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229795 **Seq:** 1
**Reported:** 18/06/2007
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 07/03/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 65.00
**Age:** 39
**DOB:** 27/09/1967
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary retention<br>Abdominal pain<br>Pollakiuria<br>Urinary incontinence | | Chronic urinary retention with overflow (residual volume after emptying=800ml), freq + urinary incontinence + associated abdominal pains | Reduced, then stopped |

### Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 18/05/2007

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was on 150-225mg daily of venlafaxine, initially started Efexor 75mg 25/05/2006.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229860 **Seq:** 1 **Gender:** F
**Reported:** 18/06/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 67Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br><br>Abnormal behaviour<br>Anxiety<br>Blood cholesterol increased<br>Bruxism<br>Confusional state<br>Constipation<br>Lethargy<br>Malaise | | malaise, anxiety confusion, inability to make decisions, a little paranoid, inability to cope and lethargy. | |

### Medicine Details:

**COVERSYL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**ZANIDIP (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:** 0

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

concurrent conditions : hypertension, overweight, arthritis.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 229860 **Seq:** 1 **Gender:** F
**Reported:** 18/06/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 67Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mental status changes<br>Paranoia<br>Stress<br>Tinnitus<br>Weight loss poor | | | |

### Medicine Details:

**COVERSYL (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**ZANIDIP (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:** 0

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:** 0

### Laboratory Investigations:

### Additional Information:
concurrent conditions : hypertension, overweight, arthritis.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 229887 **Seq:** 1
**Reported:** 19/06/2007
**Hospitalisation:**
**Onset Date:** 11/05/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 84
**DOB:** 09/07/1922
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delirium | Caused or prolonged inpatient hospitalisation | Delirium, confusion, tired, nervous, itching, unsteady on feet. | Ceased Tramal. |
| Balance disorder | Caused or prolonged inpatient hospitalisation | | |
| Confusional state | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**TRAMAL (Interaction)** **Reason:**
Tablet 2.0 Dose Unspecified Total Oral
**Batch:** **Started:** 11/05/2007 **Stopped:** 12/05/2007 0

**EFEXOR (Interaction)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** S TERM **Stopped:**

**WARFARIN SODIUM (Other drug)** **Reason:**
**Batch:** **Started:** L TERM **Stopped:**

**AMIODARONE HYDROCHLORIDE (Other drug)** **Reason:**
**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Previously takenTramal 18 months ago-> similar symptoms but resolved more quickly. At that time patient was on Zoloft instead of Efexor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 229887 **Seq:** 1
**Reported:** 19/06/2007
**Hospitalisation:**
**Onset Date:** 11/05/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 0.00
**Age:** 84
**DOB:** 09/07/1922
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fatigue | Caused or prolonged inpatient hospitalisation | | |
| Pruritus | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**TRAMAL (Interaction)** **Reason:**
Tablet 2.0 Dose Unspecified Total Oral
**Batch:** **Started:** 11/05/2007 **Stopped:** 12/05/2007 0

**EFEXOR (Interaction)** **Reason:**
75.0 Milligram Daily
**Batch:** **Started:** S TERM **Stopped:**

**WARFARIN SODIUM (Other drug)** **Reason:**
**Batch:** **Started:** L TERM **Stopped:**

**AMIODARONE HYDROCHLORIDE (Other drug)** **Reason:**
**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

## Additional Information:

Previously takenTramal 18 months ago-> similar symptoms but resolved more quickly. At that time patient was on Zoloft instead of Efexor.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 230161 **Seq:** 1 **Gender:** M
**Reported:** 25/06/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Epilepsy | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 230273 **Seq:** 1 **Gender:** F
**Reported:** 27/06/2007 **Weight:** 80.00
**Hospitalisation:** Required a visit to the doctor **Age:** 23
**Onset Date:** 31/05/2007 **DOB:** 14/07/1983
**Outcome:** Recovered 31/05/2007 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea<br><br>Headache<br>Palpitations<br>Tachycardia | | Patient experienced nausea, headaches, palpitations and tachycardia. | Ceased efexor |

### Medicine Details:

**MICROGYNON (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:**
Capsule 75.0 Milligram Daily Oral
**Batch:** **Started:** 31/05/2007 **Stopped:** 31/05/2007

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 230339 **Seq:** 1
**Reported:** 28/06/2007
**Hospitalisation:** Required a visit to the doctor
**Onset Date:** 17/04/2007
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 75.00
**Age:** 24
**DOB:** 01/07/1982
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Abnormal dreams<br>Depersonalisation<br>Drug withdrawal syndrome<br>Paraesthesia<br>Poisoning<br>Self-injurious ideation | | Nausea, dizziness, feels intoxicated, paraesthasia in limbs, depersonalisation, vivid dreams, self harm ideation. | |

### Medicine Details:

**IMPLANON IMPLANT (Other drug)** **Reason:**
Daily
**Batch:** **Started:** **Stopped:**

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule 300.0 Milligram Daily Oral
**Batch:** **Started:** 11/08/2006 **Stopped:** 16/04/2007

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 230400 **Seq:** 1 **Gender:** F
**Reported:** 29/06/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | Caused or prolonged inpatient hospitalisation | Convulsion, convulsive threshold lowered | |
| Convulsive threshold lowered | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:**
Capsule, modified release 75.0 Milligram Daily Oral
**Batch:** **Started:** 15/03/2007 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 230588 **Seq:** 1
**Reported:** 04/07/2007
**Hospitalisation:**
**Onset Date:** 30/12/2006
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 65.00
**Age:** 31
**DOB:** 31/07/1975
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Overdose<br><br>Suicide attempt | | Venlafaxine overdose. | Intubated and ventilated, charcoal , chlorpromazine. |

### Medicine Details:

**SALBUTAMOL (Other drug)** **Reason:** As necessary
**Batch:** **Started:** **Stopped:**

**VENLAFAXINE HYDROCHLORIDE (Suspected)** **Reason:**
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 230763 **Seq:** 1 **Gender:** M
**Reported:** 09/07/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyspepsia | | "slowed digestive system" | |
| Weight increased | | 7-8 kg over the years | |
| Suicidal ideation | | feeling suicidal at times | |
| Drug withdrawal syndrome | | pulsing in the ears, dizziness, feeling drunk, lack of concentration, shivers, weird dreams and feeling emotional | |
| Aggression | | | |
| Anorgasmia | | | |
| Insomnia | | | |
| Sexual dysfunction | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression
Capsule Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 06/06/2007

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient has a 30 year history of alcohol problems and depressive illness. He had been taking Efexor XR for 7-8 years. After ceasing, his suicidal ideation, sexual dysfunctions, insomnia and digestive problems resolved. Drug withdrawal symptoms continue.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 231012 **Seq:** 1 **Gender:** M
**Reported:** 18/07/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 99u
**Onset Date:** 05/07/2007 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tachycardia<br>Tremor | | | |

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Anxiety neurosis
Capsule 1 time Oral
**Batch:** **Started:** 01/07/2007 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 231061 **Seq:** 1
**Reported:** 19/07/2007
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 70
**DOB:** 05/02/1937
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation<br>Blood testosterone decreased<br>Somnolence | | feeling suicidal at night | |

### Medicine Details:

**PANADEINE FORTE (Other drug)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**OXYCONTIN (Other drug)** **Reason:**
**Batch:** **Started:** **Stopped:**

**LIPITOR (Other drug)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

**ZOTON (Suspected)** **Reason:**
Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Medical history: lung neoplasm, disc protrusion, pelvic fracture.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 231061 **Seq:** 1
**Reported:** 19/07/2007
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 0.00
**Age:** 70
**DOB:** 05/02/1937
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**EFEXOR-XR (Suspected)** **Reason:** Depression

Capsule 150.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

Medical history: lung neoplasm, disc protrusion, pelvic fracture.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 231192 **Seq:** 1
**Reported:** 25/07/2007
**Hospitalisation:**
**Onset Date:** 14/06/2007
**Outcome:** Unknown

**Gender:** F
**Weight:** 0.00
**Age:** 84
**DOB:** 23/01/1923
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vomiting | Caused or prolonged inpatient hospitalisation | Vomiting, hypokalaemia, tremor, suspected serotonin syndrome. | |
| Hypokalaemia | Caused or prolonged inpatient hospitalisation | | |
| Serotonin syndrome | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**TRAMADOL HYDROCHLORIDE (Interaction)** **Reason:** Unspecified arthritis
**Batch:** **Started:** 14/06/2007 **Stopped:** 14/06/2007

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:**
**Batch:** **Started:** **Stopped:**

**ATACAND PLUS 16/12.5 (Other drug)** **Reason:** Essential benign hypertension
**Batch:** **Started:** **Stopped:** 0

**SIMVASTATIN (Other drug)** **Reason:** Othr&unspec metabolic diseases
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 25/07/2007 | Potassium | | | | 2.7 |
| 25/07/2007 | Sodium | | | | 110 |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 231192 **Seq:** 1 **Gender:** F
**Reported:** 25/07/2007 **Weight:** 0.00
**Hospitalisation:** **Age:** 84
**Onset Date:** 14/06/2007 **DOB:** 23/01/1923
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | Caused or prolonged inpatient hospitalisation | | |

### Medicine Details:

**SOMAC (Other drug)** **Reason:** Other diseases of esophagus

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 231279 **Seq:** 1
**Reported:** 27/07/2007
**Hospitalisation:** Admitted to hospital
**Onset Date:** 26/12/2006
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 58
**DOB:** 13/04/1948
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Malaise | Caused or prolonged inpatient hospitalisation | Patient extremely unwell, unable to eat, walk or talk, needs constant care. Possible serotonin syndrome | Venlafaxine and mirtazapine withheld. Alternative regime for management of depression to be implemented. Mirtazapine ceased eventually. |
| Eating disorder | Caused or prolonged inpatient hospitalisation | | |
| Mobility decreased | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

**VENLAFAXINE HYDROCHLORIDE (Interaction)** **Reason:** Depression
Capsule 1.1 Gram Daily Oral
**Batch:** **Started:** **Stopped:**

**MIRTAZAPINE (Interaction)** **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 26/12/2006

**AMPHOTERICIN (Other drug)** **Reason:** Unspecified systemic mycosis
**Batch:** **Started:** **Stopped:**

**NYSTATIN (Other drug)** **Reason:** Unspecified systemic mycosis
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient dose of alprazolam was recently decreased. Also takes Promensil (natural HRT). Has allergy to sulphur.

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

## Report Detail

**Case Number:** 231279 **Seq:** 1
**Reported:** 27/07/2007
**Hospitalisation:** Admitted to hospital
**Onset Date:** 26/12/2006
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 58
**DOB:** 13/04/1948
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Serotonin syndrome | Caused or prolonged inpatient hospitalisation | | |
| Speech disorder | Caused or prolonged inpatient hospitalisation | | |

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **ZOPICLONE (Other drug)** | | **Reason:** | Menopausal symptoms | |
| **Batch:** | **Started:** | | **Stopped:** | 0 |
| **PROPRANOLOL HYDROCHLORIDE (Other drug)** | | **Reason:** | Migraine | |
| **Batch:** | **Started:** | | **Stopped:** | Ongoing. |
| **THYROXINE SODIUM (Other drug)** | | **Reason:** | Myxedema | |
| **Batch:** | **Started:** | | **Stopped:** | 0 |
| **ALPRAZOLAM (Other drug)** | | **Reason:** | Anxiety neurosis | |
| **Batch:** | **Started:** | | **Stopped:** | Ongoing. |

## Laboratory Investigations:

## Additional Information:

Patient dose of alprazolam was recently decreased. Also takes Promensil (natural HRT). Has allergy to sulphur.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: EFEXOR,EFEXOR-XR,VENLAFAXINE HYDROCHLORIDE

### Report Detail

**Case Number:** 231279 **Seq:** 1
**Reported:** 27/07/2007
**Hospitalisation:** Admitted to hospital
**Onset Date:** 26/12/2006
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 58
**DOB:** 13/04/1948
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**PROMENSIL (Other drug)** **Reason:** Menopausal symptoms

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

### Additional Information:

Patient dose of alprazolam was recently decreased. Also takes Promensil (natural HRT). Has allergy to sulphur.