# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 91476 **Seq:** 1 **Gender:** M
**Reported:** 07/03/1994 **Weight:**
**Hospitalisation:** **Age:** 44Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Oral application 30.0 Milligram Daily Oral
**Batch:** **Started:** 08/02/1994 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 92447 **Seq:** 1 **Gender:** F
**Reported:** 28/04/1994 **Weight:**
**Hospitalisation:** **Age:** 23Y
**Onset Date:** 21/04/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

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

Oral application 60.0 Milligram Total Oral

**Batch:** **Started:** 21/04/1994 **Stopped:** 23/04/1994

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 92859 **Seq:** 1 **Gender:** M
**Reported:** 10/05/1994 **Weight:**
**Hospitalisation:** **Age:** 31Y
**Onset Date:** 21/04/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pulmonary embolism | | | Heparin, warfarin. |

## Medicine Details:

**FLUPENTHIXOL DECANOATE (Other drug)** **Reason:**

Injection 40.0 Milligram Fortnightly Intramuscular

**Batch:** **Started:** 17/03/1994 **Stopped:** 14/04/1994

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**

Oral application 20.0 Milligram Daily Oral

**Batch:** **Started:** 25/03/1994 **Stopped:** 01/05/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 92864 **Seq:** 1 **Gender:** M
**Reported:** 11/05/1994 **Weight:** 73.00
**Hospitalisation:** **Age:** 18Y
**Onset Date:** 16/03/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Erectile dysfunction | | Anorgasmia | |

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Anxiety neurosis
Tablet 0.0 Dose Unspecified Oral
**Batch:** **Started:** 16/03/1994 **Stopped:** 04/04/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 92960 **Seq:** 1 **Gender:** F
**Reported:** 12/05/1994 **Weight:** 52.00
**Hospitalisation:** **Age:** 59Y
**Onset Date:** 31/03/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia | | 4 hours sleep for 1 night. | |
| Hyperkinesia | | Excessive activity. | |
| Mania | Required Specialist Consultation | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Oral application 10.0 Milligram Daily Oral
**Batch:** **Started:** 29/03/1994 **Stopped:** 01/04/1994

## Laboratory Investigations:

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

## Additional Information:

Dose of aropax was increased to 20 mg with no further reactions

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 93032 **Seq:** 1 **Gender:** M
**Reported:** 19/05/1994 **Weight:**
**Hospitalisation:** **Age:** 67Y
**Onset Date:** 02/05/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

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

**AROPAX (Suspected)** **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
**Batch:** **Started:** 17/04/1994 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 93168 **Seq:** 1 **Gender:** F
**Reported:** 25/05/1994 **Weight:**
**Hospitalisation:** **Age:** 36Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia<br>Libido decreased<br>Pruritus<br>Rash maculo-papular | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/03/1994 **Stopped:** 01/05/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 93264 **Seq:** 1 **Gender:** F
**Reported:** 30/05/1994 **Weight:**
**Hospitalisation:** **Age:** 44Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depersonalisation<br>Malaise<br>Nausea | | Felt very spacey and weird | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 11D

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 93655 **Seq:** 1 **Gender:** F
**Reported:** 09/06/1994 **Weight:** 120.00
**Hospitalisation:** **Age:** 59Y
**Onset Date:** 31/03/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea<br>Nausea | | | Isoptin and lomotil. |

## Medicine Details:

**PROVERA (Other drug)** **Reason:**
30.0 Milligram Daily
**Batch:** **Started:** S TERM **Stopped:**

**STELAZINE (Other drug)** **Reason:** Anxiety neurosis
4.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**MELLERIL (Other drug)** **Reason:** Anxiety neurosis
50.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 25/03/1994 **Stopped:** 05/05/1994

## Laboratory Investigations:

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

## Additional Information:

See original report for other medication.

### Report Detail

**Case Number:** 93660 **Seq:** 1 **Gender:** F
**Reported:** 06/06/1994 **Weight:**
**Hospitalisation:** **Age:** 45
**Onset Date:** 22/05/1994 **DOB:** 06/03/1949
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delirium<br>Pallor<br>Tremor | | | |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
**Batch:** **Started:** 06/05/1994 **Stopped:** 20/05/1994

**MOCLOBEMIDE (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 22/05/1994 **Stopped:** 22/05/1994

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 93797 **Seq:** 1 **Gender:** F
**Reported:** 20/06/1994 **Weight:** 70.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** 12/05/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura<br>Bleeding time prolonged<br>Platelet disorder | | Ecchymoses on arms, legs and abdomen.<br>Prolonged bleeding time of 12mins | |

### Medicine Details:

**XANAX (Other drug)** **Reason:**
Tablet 125.0 Microgram Daily Oral
**Batch:** **Started:** 24/02/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
**Batch:** **Started:** 04/04/1994 **Stopped:** 12/05/1994

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Bleeding time | 3 - 9 | | | Bleeding time 12 minutes |

### Additional Information:

### Report Detail

**Case Number:** 93872 **Seq:** 1 **Gender:** F
**Reported:** 23/06/1994 **Weight:** 60.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 31/05/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/03/1994 **Stopped:** 28/05/1994

### Laboratory Investigations:

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

### Additional Information:

- 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 93874 **Seq:** 1 **Gender:** F
**Reported:** 23/06/1994 **Weight:** 50.00
**Hospitalisation:** **Age:** 24Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**EPILIM (Other drug)** **Reason:** Other&unspecified epilepsy
Tablet 800.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1993 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1994 **Stopped:** 28/06/1994

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

## Report Detail

**Case Number:** 93886 **Seq:** 1 **Gender:** F
**Reported:** 24/06/1994 **Weight:** 66.00
**Hospitalisation:** **Age:** 72Y
**Onset Date:** 21/06/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Salivary gland enlargement | | Enlargement of left gland | |

## Medicine Details:

**CORDILOX (Other drug)** **Reason:** Essential benign hypertension
Tablet, modified release 240.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**ISORDIL (Other drug)** **Reason:** Essential benign hypertension
30.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**OROXINE (Other drug)** **Reason:** Myxedema
100.0 Microgram Daily
**Batch:** **Started:** **Stopped:**

**NATRILIX (Other drug)** **Reason:** Essential benign hypertension
2.5 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 93886 **Seq:** 1
**Reported:** 24/06/1994
**Hospitalisation:**
**Onset Date:** 21/06/1994
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 66.00
**Age:** 72Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **ZOCOR (Other drug)** | | | **Reason:** | Othr&unspec metabolic diseases |
| | 10.0 Milligram | Daily | | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Essential benign hypertension |
| Tablet | 20.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 07/06/1994 | | **Stopped:** | 22/06/1994 |

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 94042 **Seq:** 1
**Reported:** 28/06/1994
**Hospitalisation:** Admitted to hospital
**Onset Date:** 31/05/1994
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 50.00
**Age:** 79Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br>Hypotension | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

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

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | | | Sodium: approx 128 mmol/l may 94-june 94 (133 mmol/l on |

## Additional Information:

Previous tendency to hypotension with antidepressant medication. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

## Report Detail

**Case Number:** 94191 **Seq:** 1 **Gender:** F
**Reported:** 04/07/1994 **Weight:**
**Hospitalisation:** **Age:** 76Y
**Onset Date:** 03/05/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | | Gtn solution prn, lactilase, chloral hydrate prn. |

## Medicine Details:

**OXAZEPAM (Other drug)** **Reason:**
Tablet 15.0 Milligram As necessary Oral
**Batch:** **Started:** 08/04/1994 **Stopped:**

**HALOPERIDOL (Other drug)** **Reason:**
0.0 As necessary
**Batch:** **Started:** **Stopped:**

**THYROXINE SODIUM (Other drug)** **Reason:** Myxedema
Tablet 150.0 Microgram Daily Oral
**Batch:** **Started:** 07/04/1994 **Stopped:** CONTIN

**TEMAZEPAM (Other drug)** **Reason:** Specific disorders of sleep
Capsule 20.0 Milligram Daily Oral
**Batch:** **Started:** 02/05/1994 **Stopped:** CONTIN

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | 134 - 146 | 08/04/1994 | 143 | |
| | Sodium | 134 - 146 | 05/05/1994 | 119 | |
| | Sodium | 134 - 146 | 07/05/1994 | 117 | |
| | Sodium | 134 - 146 | 09/05/1994 | 126 | |
| | Sodium | 134 - 146 | 23/05/1994 | 138 | |

## Additional Information:

## Report Detail

**Case Number:** 94191 **Seq:** 1 **Gender:** F
**Reported:** 04/07/1994 **Weight:**
**Hospitalisation:** **Age:** 76Y
**Onset Date:** 03/05/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **TIMOLOL MALEATE (Other drug)** | | | | **Reason:** | Unspecified glaucoma | |
| Eye Drops | 2.0 | Dose Unspecified | Daily | | Ophthalmic | |
| **Batch:** | **Started:** | | | **Stopped:** | | CONTIN |
| **PROPINE (Other drug)** | | | | **Reason:** | Unspecified glaucoma | |
| Eye Drops | 2.0 | Dose Unspecified | Daily | | Ophthalmic | |
| **Batch:** | **Started:** | | | **Stopped:** | | CONTIN |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | | | **Reason:** | Depression | |
| Oral application | 20.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | 03/05/1994 | | **Stopped:** | 05/05/1994 | |
| **MODURETIC (Suspected)** | | | | **Reason:** | | |
| Tablet | 1.0 | Dose Unspecified | Daily | | Oral | |
| **Batch:** | **Started:** | 08/04/1994 | | **Stopped:** | 04/05/1994 | |

## Laboratory Investigations:

## Additional Information:

## Report Detail

**Case Number:** 94191 **Seq:** 1 **Gender:** F
**Reported:** 04/07/1994 **Weight:**
**Hospitalisation:** **Age:** 76Y
**Onset Date:** 03/05/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**DOTHIEPIN HYDROCHLORIDE (Suspected)** **Reason:**

Oral application 25.0 Milligram Daily Oral

**Batch:** **Started:** 29/04/1994 **Stopped:** 03/05/1994

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 94193 **Seq:** 1 **Gender:** F
**Reported:** 04/07/1994 **Weight:** 60.00
**Hospitalisation:** **Age:** 37Y
**Onset Date:** 16/06/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety<br>Affect lability<br>Aggression<br>Agitation<br>Dry mouth<br>Insomnia<br>Rash erythematous | Severe | Tension | |

## Medicine Details:

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

Tablet 10.0 Milligram Daily Oral

**Batch:** **Started:** 15/06/1994 **Stopped:** 19/06/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 94205 **Seq:** 1 **Gender:** M
**Reported:** 04/07/1994 **Weight:** 88.00
**Hospitalisation:** **Age:** 55Y
**Onset Date:** 22/06/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain | | | |
| Cold sweat | | | |
| Depersonalisation | | | |
| Depression | | | |
| Headache | | | |
| Hyperhidrosis | | | |
| Hyperkinesia | | | |
| Malaise | | | |
| Suicide attempt | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
20.0 Milligram 3 times
**Batch:** **Started:** 22/06/1994 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Patient had reaction to paroxetine 4 hours after first dose.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 94213 **Seq:** 1 **Gender:** M
**Reported:** 05/07/1994 **Weight:** 83.00
**Hospitalisation:** **Age:** 30Y
**Onset Date:** 25/05/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthralgia<br>Pruritus<br>Rash maculo-papular | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 94267 **Seq:** 1 **Gender:** F
**Reported:** 07/07/1994 **Weight:** 59.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** 21/06/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Visual disturbance | | Marked change in colour perception. | |

## Medicine Details:

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

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 21/06/1994 **Stopped:** CONTIN

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 94397 **Seq:** 1 **Gender:** F
**Reported:** 11/07/1994 **Weight:** 80.00
**Hospitalisation:** **Age:** 47Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthralgia<br>Haematuria<br>Pollakiuria | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 60.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 03M

## Laboratory Investigations:

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

## Additional Information:

Previous exposure in 1984 caused same reaction. allergies to lithium, hypnotics and tegretol.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 94417 **Seq:** 1 **Gender:** M
**Reported:** 15/07/1994 **Weight:**
**Hospitalisation:** **Age:** 55Y
**Onset Date:** 31/07/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion<br>Muscle twitching | | | |

## Medicine Details:

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

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 2D

## Laboratory Investigations:

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

## Additional Information:

Similar reaction to other antidepressants including allegron (nortriptyline) in the past. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 94893 **Seq:** 1 **Gender:** M
**Reported:** 04/08/1994 **Weight:**
**Hospitalisation:** **Age:** 78Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cardiac arrest<br>Ventricular tachycardia | | | <br>Cardioversion |

## Medicine Details:

**ASCORBIC ACID (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

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

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

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

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 94893 **Seq:** 1 **Gender:** M
**Reported:** 04/08/1994 **Weight:**
**Hospitalisation:** **Age:** 78Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | |
|---|---|---|---|
| **CODEINE PHOSPHATE (Suspected)** | | **Reason:** | |
| | 0.0 | | |
| **Batch:** | **Started:** | | **Stopped:** |
| **FOLIC ACID (Suspected)** | | **Reason:** | |
| | 0.0 | | |
| **Batch:** | **Started:** | | **Stopped:** |
| **BETOPTIC (Suspected)** | | **Reason:** | |
| Eye Drops | 0.0 | | Ophthalmic |
| **Batch:** | **Started:** | | **Stopped:** |
| **PROPINE (Suspected)** | | **Reason:** | |
| Eye Drops | 0.0 | | Ophthalmic |
| **Batch:** | **Started:** | | **Stopped:** |

## Laboratory Investigations:

## Additional Information:

## Report Detail

**Case Number:** 94893 **Seq:** 1 **Gender:** M
**Reported:** 04/08/1994 **Weight:**
**Hospitalisation:** **Age:** 78Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **ISOPTO CARPINE (Suspected)** | | | **Reason:** | | |
| | 0.0 | | | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | | |
| Tablet | 1.0 | Dose Unspecified | 1 time | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 94955 **Seq:** 1 **Gender:** F
**Reported:** 11/08/1994 **Weight:** 65.00
**Hospitalisation:** **Age:** 17Y
**Onset Date:** 08/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination<br>Psychotic disorder | Severe | Visual and auditory hallucinations. | |

## Medicine Details:

**FASIGYN (Suspected)** **Reason:** Giardiasis
Tablet 2.0 Gram 1 time Oral
**Batch:** **Started:** 08/08/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/08/1994 **Stopped:** 09/08/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 95106 **Seq:** 1 **Gender:** F
**Reported:** 17/08/1994 **Weight:**
**Hospitalisation:** **Age:** 63Y
**Onset Date:** 02/08/1994 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | Severe | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 27/07/1994 **Stopped:** 03/08/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 95147 **Seq:** 1 **Gender:** F
**Reported:** 18/08/1994 **Weight:** 51.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 10/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia | | | |
| Diarrhoea | | | |
| Nausea | | | |
| Tremor | | | Symptomatic |

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **AROPAX (Suspected)** | | **Reason:** Depression | | |
| Tablet | 20.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 09/08/1994 | | **Stopped:** | 10/08/1994 |
| **INDERAL (Suspected)** | | **Reason:** Depression | | |
| Tablet | 30.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 02/08/1994 | | **Stopped:** | 10/08/1994 |
| **SEREPAX (Suspected)** | | **Reason:** Depression | | |
| Tablet | 7.5 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 02/08/1994 | | **Stopped:** | 10/08/1994 |

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 95236 **Seq:** 1 **Gender:** M
**Reported:** 22/08/1994 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 95412 **Seq:** 1 **Gender:** F
**Reported:** 29/08/1994 **Weight:** 50.00
**Hospitalisation:** **Age:** 34Y
**Onset Date:** 18/08/1994 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 18/08/1994 **Stopped:** 24/08/1994

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 95423 **Seq:** 1 **Gender:** F
**Reported:** 26/08/1994 **Weight:** 44.00
**Hospitalisation:** **Age:** 37Y
**Onset Date:** 23/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Gait disturbance<br>Coordination abnormal<br>Dysarthria<br>Dystonia<br>Opisthotonus<br>Tremor | | Shuffling gait | Cogentin |

### Medicine Details:

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

**SEREPAX (Suspected)** **Reason:** Specific disorders of sleep
30.0 Milligram As necessary
**Batch:** **Started:** 26/05/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 18/07/1994 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 95642 **Seq:** 1 **Gender:** F
**Reported:** 02/09/1994 **Weight:**
**Hospitalisation:** **Age:** 47Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vulval disorder | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 17/06/1994 **Stopped:** CONTIN

**PROZAC (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 28/02/1994 **Stopped:** 15/05/1994

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Other data | | | | Reduction in size of clitoris. |

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 95807 **Seq:** 1 **Gender:** F
**Reported:** 09/09/1994 **Weight:** 65.00
**Hospitalisation:** **Age:** 47Y
**Onset Date:** 31/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea | | Nausea and stomach rumbling | |
| Muscle twitching | | Twitching of muscles of face, trunk and limbs | |
| Anorexia | | | |
| Bowel sounds abnormal | | | |
| Dizziness | | | |
| Insomnia | | | |
| Tremor | | | |
| Vomiting | Required Specialist Consultation | | |

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Phobic neurosis
20.0 Milligram Daily Oral
**Batch:** **Started:** 29/08/1994 **Stopped:** 02/09/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 95828 **Seq:** 1 **Gender:** F
**Reported:** 12/09/1994 **Weight:**
**Hospitalisation:** **Age:** 17Y
**Onset Date:** 02/09/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/09/1994 **Stopped:** 08/09/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 95852 **Seq:** 1 **Gender:** M
**Reported:** 12/09/1994 **Weight:** 80.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 23/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

**Batch:** **Started:** 22/08/1994 **Stopped:** 24/08/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 95954 **Seq:** 1 **Gender:** M
**Reported:** 19/09/1994 **Weight:** 92.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 07/09/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure<br>Paraesthesia<br>Nausea | | Delayed ejaculation<br>Forehead paraesthesia | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 19/08/1994 **Stopped:** 07/09/1994

## Laboratory Investigations:

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

## Additional Information:

Patient has had no known previous allergies

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96002 **Seq:** 1 **Gender:** F
**Reported:** 23/09/1994 **Weight:** 60.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Herpes simplex<br>Mouth ulceration | | Cold sore | |

## Medicine Details:

**OVESTIN (Other drug)** **Reason:**
Ointment 0.0 Vaginal
**Batch:** **Started:** **Stopped:**

**EUHYPNOS (Other drug)** **Reason:**
10.0 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**PROVERA (Other drug)** **Reason:**
2.5 Milligram Daily
**Batch:** **Started:** **Stopped:**

**OGEN (Other drug)** **Reason:**
312.5 Microgram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96002 **Seq:** 1
**Reported:** 23/09/1994
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 60.00
**Age:** 40Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 25/08/1994 **Stopped:**

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96049 **Seq:** 1 **Gender:** F
**Reported:** 23/09/1994 **Weight:**
**Hospitalisation:** **Age:** 35Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia<br>Libido decreased | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96079 **Seq:** 1 **Gender:** F
**Reported:** 28/09/1994 **Weight:** 70.00
**Hospitalisation:** **Age:** 61Y
**Onset Date:** 03/09/1994 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depression<br>Drug ineffective<br>Insomnia<br>Nausea<br>Suicide attempt<br>Tremor | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/09/1994 **Stopped:** 2D

## 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96189 **Seq:** 1 **Gender:** M
**Reported:** 30/09/1994 **Weight:** 79.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** 22/09/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**ZANTAC (Other drug)** **Reason:** Other diseases of esophagus
300.0 Milligram Daily
**Batch:** **Started:** 01/07/1994 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 22/09/1994 **Stopped:** 27/09/1994

## 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96281 **Seq:** 1 **Gender:** F
**Reported:** 04/09/1994 **Weight:**
**Hospitalisation:** **Age:** 14Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 96336 **Seq:** 1 **Gender:** F
**Reported:** 07/10/1994 **Weight:** 65.00
**Hospitalisation:** **Age:** 78Y
**Onset Date:** 20/06/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Exophthalmos | | Stare and lid retraction | Therapy changed to tolvon. |

## Medicine Details:

**PROPRANOLOL HYDROCHLORIDE (Other drug)** **Reason:** Essential benign hypertension
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

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

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 17/06/1994 **Stopped:** 24/06/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96510 **Seq:** 1 **Gender:** F
**Reported:** 14/10/1994 **Weight:**
**Hospitalisation:** **Age:** 46Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Euphoric mood<br>Hyperkinesia<br>Sleep disorder<br>Speech disorder | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 08/08/1994 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96511 **Seq:** 1 **Gender:** M
**Reported:** 14/10/1994 **Weight:**
**Hospitalisation:** **Age:** 70Y
**Onset Date:** 23/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash vesicular<br>Delusion<br>Drug ineffective<br>Hallucination<br>Nightmare | | Rash on chest, arms and left calf. | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 16/08/1994 **Stopped:** 05/09/1994

## Laboratory Investigations:

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

## Additional Information:

Aropax dose increased as paranoid delusions and auditory hallucinations thought to be symptom of severe depression. aropax ceased with development of rash 19 days after starting on aropax.

### Report Detail

**Case Number:** 96512 **Seq:** 1 **Gender:** F
**Reported:** 14/10/1994 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 01/08/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Psychotic disorder | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 14/07/1994 **Stopped:** 13/08/1994

### Laboratory Investigations:

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

### Additional Information:

### Report Detail

**Case Number:** 96513 **Seq:** 1 **Gender:** M
**Reported:** 14/10/1994 **Weight:** 118.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 20.0 Milligram Daily Oral

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

### Laboratory Investigations:

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

### Additional Information:

## Report Detail

**Case Number:** 96563 **Seq:** 1 **Gender:** F
**Reported:** 19/10/1994 **Weight:** 55.00
**Hospitalisation:** **Age:** 85Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 20.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 28/08/1994 | | **Stopped:** | 14/09/1994 |
| **PANADEINE (Suspected)** | | | **Reason:** | Pain | |
| Oral application | 2.0 | Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** | 28/08/1994 | | **Stopped:** | 27/09/1994 |
| **COLOXYL WITH SENNA (Suspected)** | | | **Reason:** | Constipation | |
| Tablet | 2.0 | Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** | 28/08/1994 | | **Stopped:** | 27/09/1994 |

## Laboratory Investigations:

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

## Additional Information:

Symptoms resolved within 2 days of ceasing paroxetine.

## Report Detail

**Case Number:** 96635 **Seq:** 1 **Gender:** F
**Reported:** 24/10/1994 **Weight:** 60.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** 29/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety<br>Delirium<br>Depersonalisation<br>Hyperventilation<br>Malaise | | | |

## Medicine Details:

**ALPRAZOLAM (Other drug)** **Reason:** Anxiety neurosis
Tablet 100.0 Milligram Daily Oral
**Batch:** **Started:** 08/08/1994 **Stopped:** 29/08/1994

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 29/08/1994 **Stopped:** 29/08/1994

**NORTRIPTYLINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Oral application 100.0 Milligram Daily Oral
**Batch:** **Started:** 08/08/1994 **Stopped:** 29/08/1994

## Laboratory Investigations:

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

## Additional Information:

Aropax ceased and recommenced later with no effect - without nortriptyline.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96636 **Seq:** 1 **Gender:** F
**Reported:** 24/10/1994 **Weight:** 80.00
**Hospitalisation:** **Age:** 59Y
**Onset Date:** 20/09/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**ASPIRIN (Other drug)** **Reason:** Chron isch heart dis no hyper
Oral application 150.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1993 **Stopped:**

**LITHICARB (Other drug)** **Reason:** Unspecified psychosis
Tablet 750.0 Milligram Daily Oral
**Batch:** **Started:** 04/09/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 20/09/1994 **Stopped:** 03/10/1994

## 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:** 96639 **Seq:** 1 **Gender:** M
**Reported:** 24/10/1994 **Weight:** 105.00
**Hospitalisation:** **Age:** 54Y
**Onset Date:** 05/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Chest pain<br>Dizziness<br>Insomnia<br>Libido decreased | | | |

## Medicine Details:

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

**PANADEINE FORTE (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

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

**MINIPRESS (Other drug)** **Reason:**
1.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electrocardiograph | | | | Ecg 16.8.94 "incomplete right bundle branch block of doubtful |

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96639 **Seq:** 1 **Gender:** M
**Reported:** 24/10/1994 **Weight:** 105.00
**Hospitalisation:** **Age:** 54Y
**Onset Date:** 05/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **CARAFATE (Other drug)** | | | **Reason:** | |
| | 2.0 | Gram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **VALIUM (Other drug)** | | | **Reason:** | |
| | 5.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **LOSEC (Other drug)** | | | **Reason:** | |
| | 30.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **ACCUPRIL (Other drug)** | | | **Reason:** | |
| | 40.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |

## Laboratory Investigations:

## Additional Information:

### Report Detail

**Case Number:** 96639 **Seq:** 1 **Gender:** M
**Reported:** 24/10/1994 **Weight:** 105.00
**Hospitalisation:** **Age:** 54Y
**Onset Date:** 05/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **LOPID (Other drug)** | | | **Reason:** | | |
| | 1.2 | Gram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 20.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 05/08/1994 | | **Stopped:** | 16/08/1994 |

### Laboratory Investigations:

### Additional Information:

### Report Detail

**Case Number:** 96691 **Seq:** 1 **Gender:** F
**Reported:** 27/10/1994 **Weight:** 60.00
**Hospitalisation:** **Age:** 86Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

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

**SEREPAX (Other drug)** **Reason:**
22.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 20/05/1994 **Stopped:** 22/10/1994

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96710 **Seq:** 1 **Gender:** M
**Reported:** 28/10/1994 **Weight:** 90.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** 16/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 03/10/1994 **Stopped:** 17/10/1994

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 96730 **Seq:** 1 **Gender:** F
**Reported:** 28/10/1994 **Weight:**
**Hospitalisation:** **Age:** 30Y
**Onset Date:** 09/09/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 12/08/1994 **Stopped:** 23/09/1994

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96800 **Seq:** 1
**Reported:** 31/10/1994
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:**
**Age:**
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Speech disorder<br>Coma<br>Coordination abnormal<br>Somnolence | | Slurred speech | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

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

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 96801 **Seq:** 1 **Gender:** M
**Reported:** 31/10/1994 **Weight:**
**Hospitalisation:** **Age:** 30Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dental caries<br>Dry mouth | Severe | | |

### Medicine Details:

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96803 **Seq:** 1 **Gender:** M
**Reported:** 31/10/1994 **Weight:** 63.00
**Hospitalisation:** **Age:** 33Y
**Onset Date:** 07/10/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression | | | |
| Disturbance in attention | | | |
| Headache | | | |
| Insomnia | | | |
| Nausea | | | |
| Vomiting | | | |
| Weight decreased | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 07/10/1994 **Stopped:** 12/10/1994

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 96804 **Seq:** 1 **Gender:** F
**Reported:** 31/10/1994 **Weight:**
**Hospitalisation:** **Age:** 37Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Insomnia<br>Nausea | Severe | | Changed to another |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 18/07/1994 **Stopped:** 29/08/1994

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96805 **Seq:** 1 **Gender:** M
**Reported:** 31/10/1994 **Weight:**
**Hospitalisation:** **Age:** 48Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 03/06/1994 **Stopped:** 07/06/1994

## Laboratory Investigations:

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

## Additional Information:

Patient experienced reaction 2 days after commencing aropax.

## Report Detail

**Case Number:** 96820 **Seq:** 1 **Gender:** F
**Reported:** 31/10/1994 **Weight:**
**Hospitalisation:** **Age:** 62Y
**Onset Date:** 16/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state | | | |
| Coordination abnormal | | | |
| Delirium | | | |
| Hypertonia | | | |
| Hyponatraemia | | | Keflex, fluid retriction |
| Somnolence | | | |
| Thirst | | | |
| Urinary incontinence | | | |

## Medicine Details:

**STELAZINE (Other drug)** **Reason:**
15.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**LITHIUM CARBONATE (Other drug)** **Reason:**
Tablet 500.0 Milligram Daily Oral
**Batch:** **Started:** 10/10/1994 **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 10/10/1994 **Stopped:** 18/10/1994

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 96871 **Seq:** 1 **Gender:** F
**Reported:** 01/11/1994 **Weight:** 55.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** 13/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**PREPULSID (Other drug)** **Reason:** Gastritis&duodenitis
0.0
**Batch:** **Started:** **Stopped:**

**LOSEC (Other drug)** **Reason:** Gastritis&duodenitis
0.0
**Batch:** **Started:** **Stopped:**

**CARAFATE (Other drug)** **Reason:** Gastritis&duodenitis
0.0
**Batch:** **Started:** **Stopped:**

**PROTHIADEN (Other drug)** **Reason:** Depression
Oral application 200.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

### Laboratory Investigations:

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

### Additional Information:

### Report Detail

**Case Number:** 96871 **Seq:** 1 **Gender:** F
**Reported:** 01/11/1994 **Weight:** 55.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** 13/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **LEXOTAN (Other drug)** | | | **Reason:** | Anxiety neurosis | |
| Tablet | 24.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | CONTIN |
| **NEULACTIL (Other drug)** | | | **Reason:** | Anxiety neurosis | |
| Tablet | 20.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | CONTIN |
| **AROPAX (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 20.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | 06/10/1994 | | **Stopped:** | 20/10/1994 |

### Laboratory Investigations:

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96897 **Seq:** 1 **Gender:** F
**Reported:** 04/11/1994 **Weight:** 60.00
**Hospitalisation:** **Age:** 31Y
**Onset Date:** 14/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**HALOPERIDOL (Other drug)** **Reason:**
Oral application 2.5 Milligram Daily Oral
**Batch:** **Started:** 01/01/1993 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:**
20.0 Milligram 1 time
**Batch:** **Started:** 14/10/1994 **Stopped:**

**ALPRAZOLAM (Suspected)** **Reason:**
1.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

## 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.

## Report Detail

**Case Number:** 96914 **Seq:** 1 **Gender:** M
**Reported:** 03/11/1994 **Weight:** 63.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 28/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state<br>Hyponatraemia<br>Somnolence | | | Fluid restriction. |

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 27/10/1994 **Stopped:** 28/10/1994

**THIORIDAZINE HYDROCHLORIDE (Suspected)** **Reason:**
Tablet 100.0 Milligram Daily Oral
**Batch:** **Started:** 27/10/1994 **Stopped:** 28/10/1994

**PROPRANOLOL HYDROCHLORIDE (Suspected)** **Reason:**
Tablet 60.0 Milligram Daily Oral
**Batch:** **Started:** 27/10/1994 **Stopped:** 28/10/1994

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | 26/10/1994 | 137 | |
| | Sodium | | 28/10/1994 | 107 | |

## Additional Information:

Took overdose of thioridazine and propranolol on the 25/10/94.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 96919 **Seq:** 1 **Gender:** F
**Reported:** 03/11/1994 **Weight:** 54.00
**Hospitalisation:** **Age:** 17Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysphagia | Severe | Choking feeling in throat | |
| Dry mouth | | Dry tongue | |
| Asthenia | | | |
| Face oedema | | | |
| Headache | | | |
| Hepatic function abnormal | | | |
| Pyrexia | | | |
| Thyroid function test abnormal | | | |
| Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily Oral
**Batch:** **Started:** 09/08/1994 **Stopped:** 09/09/1994

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 17/12/2002 | ALT = SGPT | (UP TO 45) | 23/03/2007 | 12 | |
| 17/12/2002 | ALT = SGPT | (UP TO 45) | 23/03/2007 | 120 | |
| 17/12/2002 | AST = SGOT | (UP TO 45) | 23/03/2007 | 15 | |
| 17/12/2002 | AST = SGOT | (UP TO 45) | 23/03/2007 | 122 | |
| 17/12/2002 | Bilirubin | ( 2-20 ) | 23/03/2007 | 6 | |
| 17/12/2002 | Bilirubin | ( 2-20 ) | 23/03/2007 | 12 | |
| 17/12/2002 | GGT = SGGT = | (UP TO 45) | 23/03/2007 | 12 | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96919 **Seq:** 1 **Gender:** F
**Reported:** 03/11/1994 **Weight:** 54.00
**Hospitalisation:** **Age:** 17Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily Oral
**Batch:** **Started:** 09/08/1994 **Stopped:** 09/09/1994

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 17/12/2002 | GGT = SGGT = | (UP TO 45) | 23/03/2007 | 115 | |
| 17/12/2002 | Immunology | | | | Thyroid tissue antibodies 7/9/1994 anti-thyroglogulin ab 300 u/ml (up to 100) anti-microsomal (peroxidase) ab 150 u/m (up to 100) this pattern suggests an underlying autoimmune inflammatory process, such as graves' or hashimoto's. |
| 17/12/2002 | SAP = ALP | ( 30-300 ) | 23/03/2007 | 84 | |
| 17/12/2002 | SAP = ALP | ( 30-300 ) | 23/03/2007 | 288 | |

## Additional Information:

### Report Detail

**Case Number:** 96921 **Seq:** 1 **Gender:** F
**Reported:** 04/11/1994 **Weight:** 80.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

### Laboratory Investigations:

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

### Additional Information:

### Report Detail

**Case Number:** 96923 **Seq:** 1 **Gender:** F
**Reported:** 04/11/1994 **Weight:** 55.00
**Hospitalisation:** **Age:** 22Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mania<br>Confusional state<br>Dizziness<br>Paranoia | | Manic-depressive reaction | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 09/09/1994 **Stopped:** 14/10/1994

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96928 **Seq:** 1
**Reported:** 07/11/1994
**Hospitalisation:** Hospitalisation prolonged
**Onset Date:** 17/10/1994
**Outcome:** Recovered

**Gender:** F
**Weight:** 50.00
**Age:** 62Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delirium<br>Hyponatraemia | | | Fluid restriction |

## Medicine Details:

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

20.0 Milligram Daily

**Batch:** **Started:** 11/10/1994 **Stopped:** 17/10/1994

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electrolytes<br>Sodium | | | | Electrolytes normal by 20/10/94.<br>Sodium level of 113 (had been 140 on 11/10/94). |

## Additional Information:

## Report Detail

**Case Number:** 96961 **Seq:** 1 **Gender:** F
**Reported:** 07/11/1994 **Weight:** 58.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 29/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anticholinergic syndrome | | | |
| Confusional state | | | |
| Dystonia | | | |
| Extrapyramidal disorder | | | |
| Hyperhidrosis | | | |
| Hyperthermia malignant | | | |
| Hypertonia | | | |
| Pyrexia | | | |
| Tachycardia | | | |
| Tremor | | | |

## Medicine Details:

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

**VALIUM (Other drug)** **Reason:** Anxiety neurosis
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:** CONTIN

**MAXOLON (Suspected)** **Reason:** Nausea and vomiting
20.0 Milligram Total
**Batch:** **Started:** 29/10/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 20/10/1994 **Stopped:** 31/10/1994

## Laboratory Investigations:

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

## Additional Information:

The patient had been on sinequan 100mg daily long term before being switched to paroxetine without washout period. "serotonergic syndrome" the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96961 **Seq:** 1 **Gender:** F
**Reported:** 07/11/1994 **Weight:** 58.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 29/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**DEPTRAN (Suspected)** **Reason:** Depression

Oral application 100.0 Milligram Daily Oral

**Batch:** **Started:** 01/08/1994 **Stopped:** 29/10/1994

## Laboratory Investigations:

## Additional Information:

The patient had been on sinequan 100mg daily long term before being switched to paroxetine without washout period. "serotonergic syndrome" the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96991 **Seq:** 1 **Gender:** F
**Reported:** 07/11/1994 **Weight:** 80.00
**Hospitalisation:** **Age:** 37Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 22/09/1994 **Stopped:** 24/10/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 96992 **Seq:** 1 **Gender:** F
**Reported:** 07/11/1994 **Weight:** 94.00
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

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

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 96993 **Seq:** 1 **Gender:** F
**Reported:** 07/11/1994 **Weight:** 65.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**MELLERIL (Other drug)** **Reason:** Anxiety neurosis

Oral application 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/07/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression

Tablet 60.0 Milligram Daily Oral

**Batch:** **Started:** 01/07/1994 **Stopped:**

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

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97005 **Seq:** 1 **Gender:** F
**Reported:** 09/11/1994 **Weight:** 110.00
**Hospitalisation:** **Age:** 47Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia<br>Libido decreased | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/09/1994 **Stopped:** 6W

## 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97006 **Seq:** 1 **Gender:** F
**Reported:** 09/11/1994 **Weight:** 130.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** **DOB:**
**Outcome:** Death **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cardiomyopathy<br>Pulmonary embolism<br>Sudden death | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 22D

## Laboratory Investigations:

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

## Additional Information:

Patient died 22 days after commencing aropax 20.

## Report Detail

**Case Number:** 97023 **Seq:** 1 **Gender:** M
**Reported:** 10/11/1994 **Weight:** 65.00
**Hospitalisation:** **Age:** 27Y
**Onset Date:** 10/10/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Erectile dysfunction | | Anorgasmia | |

## Medicine Details:

**VIBRAMYCIN (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** 07D

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 07/10/1994 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 97024 **Seq:** 1 **Gender:** M
**Reported:** 10/11/1994 **Weight:** 81.00
**Hospitalisation:** **Age:** 65Y
**Onset Date:** 04/09/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

### Medicine Details:

**DILTIAZEM HYDROCHLORIDE (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

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

**AROPAX (Suspected)** **Reason:** Manic-depression psycho,manic
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 20/08/1994 **Stopped:** 22/09/1994

### Laboratory Investigations:

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

### Additional Information:

### Report Detail

**Case Number:** 97026 **Seq:** 1 **Gender:** F
**Reported:** 10/11/1994 **Weight:** 93.00
**Hospitalisation:** **Age:** 37Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Acne<br>Dizziness<br>Nausea | Required Specialist Consultation | Acne on face and buttocks | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 17/08/1994 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

## Report Detail

**Case Number:** 97124 **Seq:** 1 **Gender:** F
**Reported:** 17/11/1994 **Weight:**
**Hospitalisation:** **Age:** 74Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

See sequence 1 (97123) for other drugs

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97139 **Seq:** 1 **Gender:** M
**Reported:** 17/11/1994 **Weight:**
**Hospitalisation:** **Age:** AD
**Onset Date:** 20/07/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Constipation | Severe | | Docusate and senna. |

## Medicine Details:

**PANADOL (Other drug)** **Reason:** Pain
0.0 As necessary
**Batch:** **Started:** L TERM **Stopped:**

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

**CLOZAPINE (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
**Batch:** **Started:** 08/07/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 08/07/1994 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Moderate to severe constipation two weeks after therapy with clozaril when dose was increased from 25mg bd to 200mg bd.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97187 **Seq:** 1 **Gender:** M
**Reported:** 21/11/1994 **Weight:**
**Hospitalisation:** **Age:** 58Y
**Onset Date:** 09/11/1994 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression | | Patient stabbed his wife. | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 03/11/1994 **Stopped:** 09/11/1994

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 97203 **Seq:** 1 **Gender:** F
**Reported:** 21/11/1994 **Weight:**
**Hospitalisation:** **Age:** 70Y
**Onset Date:** 02/11/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia<br>Nightmare | | | |

## Medicine Details:

**LIPEX (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**MIDAMOR (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

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

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 02/11/1994 **Stopped:** 05/11/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97230 **Seq:** 1 **Gender:** F
**Reported:** 21/11/1994 **Weight:**
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 01/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | Severe | | |
| Confusional state | Severe | | |
| Hyperhidrosis | | | |
| Hypertension | | | |
| Hyperventilation | | | |
| Palpitations | | | |

## Medicine Details:

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

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/10/1994 **Stopped:** 01/10/1994

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 97273 **Seq:** 1 **Gender:** F
**Reported:** 23/11/1994 **Weight:** 69.00
**Hospitalisation:** **Age:**
**Onset Date:** 09/11/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**PREMARIN (Other drug)** **Reason:** Menopausal symptoms
Tablet 625.0 Microgram Daily Oral
**Batch:** **Started:** 12/03/1991 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 08/11/1994 **Stopped:** 11/11/1994

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97301 **Seq:** 1 **Gender:** M
**Reported:** 24/11/1994 **Weight:** 55.00
**Hospitalisation:** **Age:** 81Y
**Onset Date:** 08/11/1994 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypokalaemia<br>Orthostatic hypotension | | | |

## Medicine Details:

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

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

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

**AROPAX (Suspected)** **Reason:**
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 97307 **Seq:** 1 **Gender:** M
**Reported:** 23/11/1994 **Weight:**
**Hospitalisation:** **Age:** 64Y
**Onset Date:** 17/11/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorexia<br>Confusional state<br>Hyperhidrosis | | | |

## Medicine Details:

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

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

**MORPHINE NOS (Other drug)** **Reason:** Pain
Oral application 600.0 Milligram Daily Oral
**Batch:** **Started:** 01/07/1994 **Stopped:** CONTIN

**CAPTOPRIL (Other drug)** **Reason:**
Tablet 100.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:** CONTIN

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

## Report Detail

**Case Number:** 97307 **Seq:** 1 **Gender:** M
**Reported:** 23/11/1994 **Weight:**
**Hospitalisation:** **Age:** 64Y
**Onset Date:** 17/11/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **FRUSEMIDE (Other drug)** | | | **Reason:** | | |
| Oral application | 40.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | | CONTIN |
| **RANITIDINE (Other drug)** | | | **Reason:** | Ulcer of duodenum w/o ment perf | |
| Tablet | 300.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | | CONTIN |
| **METOCLOPRAMIDE HYDROCHLORIDE (Other drug)** | | | **Reason:** | Nausea and vomiting | |
| | 3.0 | Dose Unspecified | Daily | | |
| **Batch:** | **Started:** 01/06/1994 | | **Stopped:** | | CONTIN |
| **PREDNISOLONE (Other drug)** | | | **Reason:** | | |
| | 10.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | | CONTIN |

## Laboratory Investigations:

## Additional Information:

the dosage start date is not necessarily accurate but indicates that start 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97307 **Seq:** 1 **Gender:** M
**Reported:** 23/11/1994 **Weight:**
**Hospitalisation:** **Age:** 64Y
**Onset Date:** 17/11/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
1.0 Dose Unspecified 1 time
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

the dosage start date is not necessarily accurate but indicates that start 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97316 **Seq:** 1 **Gender:** F
**Reported:** 23/11/1994 **Weight:** 55.00
**Hospitalisation:** **Age:** 41Y
**Onset Date:** 17/11/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Constipation<br>Eyelid ptosis<br>Fatigue | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 15/11/1994 **Stopped:** 20/11/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97348 **Seq:** 1
**Reported:** 28/11/1994
**Hospitalisation:**
**Onset Date:** 18/11/1994
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 55.00
**Age:** 23
**DOB:** 09/10/1971
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Libido increased<br>Anorgasmia<br>Yawning | | With every yawn, an orgasm. | Therapy changed to zoloft. |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 18/11/1994 **Stopped:** 24/11/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97413 **Seq:** 1 **Gender:** F
**Reported:** 29/11/1994 **Weight:** 54.00
**Hospitalisation:** **Age:** 79Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Confusional state<br>Depression | | | |

## Medicine Details:

**THYROXINE SODIUM (Other drug)** **Reason:**
50.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

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

**DIGOXIN (Other drug)** **Reason:**
125.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**MONOPRIL (Other drug)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Thyroid | | | | Increased tsh 40.5 |

## Additional Information:

Symptoms of thyrotoxicosis but biochemically hypothyroid

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97413 **Seq:** 1 **Gender:** F
**Reported:** 29/11/1994 **Weight:** 54.00
**Hospitalisation:** **Age:** 79Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 10/10/1994

## Laboratory Investigations:

## Additional Information:

Symptoms of thyrotoxicosis but biochemically hypothyroid

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97414 **Seq:** 1 **Gender:** F
**Reported:** 30/11/1994 **Weight:**
**Hospitalisation:** **Age:** 42Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mouth ulceration | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97416 **Seq:** 1 **Gender:** F
**Reported:** 30/11/1994 **Weight:**
**Hospitalisation:** **Age:** 42Y
**Onset Date:** 26/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pharyngitis<br>Upper respiratory tract infection | | | Antibiotics |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 24/08/1994 **Stopped:** 26/08/1994

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 97422 **Seq:** 1 **Gender:** F
**Reported:** 29/11/1994 **Weight:** 61.00
**Hospitalisation:** **Age:** 86Y
**Onset Date:** 31/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**PLENDIL ER (Other drug)** **Reason:** Essential benign hypertension
5.0 Milligram Daily
**Batch:** **Started:** 01/04/1994 **Stopped:** CONTIN

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 20/05/1994 **Stopped:** 22/10/1994

## Laboratory Investigations:

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

## Additional Information:

- 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97431 **Seq:** 1 **Gender:** F
**Reported:** 29/11/1994 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 09/11/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**OESTROGENS NOS (Other drug)** **Reason:** Menopausal symptoms
Implant 0.0 Subcutaneous
**Batch:** **Started:** **Stopped:**

**PRIMOLUT-N (Other drug)** **Reason:** Menopausal symptoms
5.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**TEMAZEPAM (Other drug)** **Reason:** Specific disorders of sleep
5.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97431 **Seq:** 1 **Gender:** F
**Reported:** 29/11/1994 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 09/11/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 08/11/1994 **Stopped:** 22/11/1994

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 97433 **Seq:** 1 **Gender:** M
**Reported:** 29/11/1994 **Weight:** 79.00
**Hospitalisation:** **Age:** 72Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Orthostatic hypotension | | | |

### Medicine Details:

**METAMUCIL (Other drug)** **Reason:**
Oral application 0.0 Oral
**Batch:** **Started:** **Stopped:**

**RANITIDINE (Other drug)** **Reason:** Peptic ulcer nos w/o ment perf
300.0 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**PANADOL (Other drug)** **Reason:**
500.0 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 19/11/1994 **Stopped:** 21/11/1994

### Laboratory Investigations:

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

### Additional Information:

## Report Detail

**Case Number:** 97490 **Seq:** 1
**Reported:** 01/12/1994
**Hospitalisation:** Admitted to hospital
**Onset Date:** 24/08/1994
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 46Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nystagmus | | Lateral gaze/scanning eye movements | |
| Convulsion | | Tonic clonic seizures | |
| Hypotonia | | Unresponsive | |
| Agitation | | | |
| Chills | | | |
| Coma | | | |
| Hyperreflexia | | | |
| Hypotension | | | |
| Mydriasis | | | Admitted to icu, ventilation, charcoal, benzodiazepines, iv fluids |
| Serotonin syndrome | | | |

## Medicine Details:

**IMIGRAN (Suspected)** **Reason:** Migraine
Tablet 200.0 Milligram 1 time Oral
**Batch:** **Started:** 22/08/1994 **Stopped:** 22/08/1994

**CHLORAL HYDRATE (Suspected)** **Reason:** Specific disorders of sleep
100.0 Millilitre 1 time
**Batch:** **Started:** 22/08/1994 **Stopped:** 22/08/1994

**PARNATE (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 100.0 Milligram Total Oral
**Batch:** **Started:** 22/08/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 10/08/1994 **Stopped:** 22/08/1994

## Laboratory Investigations:

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

## Additional Information:

Diagnosis was revised to serotonin syndrome.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97490 **Seq:** 1
**Reported:** 01/12/1994
**Hospitalisation:** Admitted to hospital
**Onset Date:** 24/08/1994
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 46Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tachycardia<br>Tremor | | | |

## Medicine Details:

**LITHICARB (Suspected)** **Reason:** Unspecified schizophrenia

Tablet 250.0 Milligram Daily Oral

**Batch:** **Started:** L TERM **Stopped:** 22/08/1994

## Laboratory Investigations:

## Additional Information:

Diagnosis was revised to serotonin syndrome.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97499 **Seq:** 1 **Gender:** F
**Reported:** 01/12/1994 **Weight:** 118.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 22/11/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea | Severe | | |

## Medicine Details:

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

Oral application 20.0 Milligram Daily Oral

**Batch:** **Started:** 21/11/1994 **Stopped:** 24/11/1994

## Laboratory Investigations:

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

## Additional Information:

Allergies:- marked jaw stiffness with sertraline

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97517 **Seq:** 1 **Gender:** F
**Reported:** 01/12/1994 **Weight:** 70.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 01/11/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97542 **Seq:** 1 **Gender:** M
**Reported:** 05/12/1994 **Weight:**
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 11/11/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Priapism<br>Ejaculation failure | | Sustained erection | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 07/11/1994 **Stopped:** 17/11/1994

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 97550 **Seq:** 1 **Gender:** F
**Reported:** 05/12/1994 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 28/11/1994 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash | | | Diprosone |

### Medicine Details:

**BETOPTIC (Other drug)** **Reason:**
Eye Drops 0.0 Ophthalmic
**Batch:** **Started:** 05/09/1993 **Stopped:**

**ESTRADERM (Other drug)** **Reason:**
2.0 Dose Unspecified Weekly
**Batch:** **Started:** 06/09/1993 **Stopped:**

**RIVOTRIL (Other drug)** **Reason:**
3.0 Dose Unspecified Daily
**Batch:** **Started:** 16/11/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
2.0 Dose Unspecified Daily
**Batch:** **Started:** 15/09/1994 **Stopped:** 29/11/1994

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 97560 **Seq:** 1 **Gender:** U
**Reported:** 07/12/1994 **Weight:**
**Hospitalisation:** **Age:** 52Y
**Onset Date:** 22/11/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Libido decreased | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 10/11/1994 **Stopped:** 30/11/1994

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97583 **Seq:** 1 **Gender:** F
**Reported:** 06/12/1994 **Weight:** 60.00
**Hospitalisation:** **Age:** 48Y
**Onset Date:** 19/09/1994 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary incontinence | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 25/07/1994 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97586 **Seq:** 1 **Gender:** F
**Reported:** 06/12/1994 **Weight:**
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 28/11/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome<br>Insomnia<br>Nausea | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

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

## Laboratory Investigations:

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

## Additional Information:

Missed 3 days of aropax 20 after successful 3 month treatment. reactions settled rapidly with resumption of dose

## Report Detail

**Case Number:** 97593 **Seq:** 1 **Gender:** F
**Reported:** 12/12/1994 **Weight:**
**Hospitalisation:** **Age:** 41Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**CARBAMAZEPINE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 05/10/1994 **Stopped:** 20/10/1994

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
10.0 Milligram 1 time
**Batch:** **Started:** 14/10/1994 **Stopped:** 14/10/1994

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 13/10/1994 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97599 **Seq:** 1 **Gender:** F
**Reported:** 08/12/1994 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 07/11/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Chills | | | |
| Coordination abnormal | | | |
| Drug withdrawal syndrome | | | |
| Dysarthria | Required Specialist Consultation | | |
| Nausea | | | |
| Sensory disturbance | | | |
| Vomiting | | | |

## Medicine Details:

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

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 15/01/1994 **Stopped:** 31/10/1994

## Laboratory Investigations:

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

## Additional Information:

History of sensitivity to clonazepam.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 97619 **Seq:** 1 **Gender:** M
**Reported:** 08/12/1994 **Weight:** 70.00
**Hospitalisation:** **Age:** 31Y
**Onset Date:** 08/11/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 07/10/1994 **Stopped:** 20/11/1994

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97722 **Seq:** 1 **Gender:** F
**Reported:** 12/12/1994 **Weight:** 57.00
**Hospitalisation:** **Age:**
**Onset Date:** 09/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 08/10/1994 **Stopped:** 30/10/1994

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 97831 **Seq:** 1 **Gender:** F
**Reported:** 14/12/1994 **Weight:** 75.00
**Hospitalisation:** **Age:** 67Y
**Onset Date:** 31/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Micturition disorder | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/06/1994 **Stopped:** 28/12/1994

**STELAZINE (Suspected)** **Reason:** Depression
Tablet 2.0 Milligram Daily Oral
**Batch:** **Started:** 01/06/1994 **Stopped:** 28/12/1994

### Laboratory Investigations:

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

### Additional Information:

Previous hesitancy of severe nature with retention with tricyclic antidepressants. unipolar depression 40 years. physically well but for arthritis. - 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97833 **Seq:** 1 **Gender:** M
**Reported:** 14/12/1994 **Weight:** 56.00
**Hospitalisation:** **Age:** 16Y
**Onset Date:** 24/11/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysuria | | Difficulty and burning on passing urine | |

## Medicine Details:

**PROZAC (Other drug)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 30/10/1994 **Stopped:** 23/11/1994

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 24/11/1994 **Stopped:** 01/12/1994

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 97859 **Seq:** 1 **Gender:** F
**Reported:** 16/12/1994 **Weight:**
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 28/09/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** 27/09/1994 **Stopped:** 25/11/1994

### Laboratory Investigations:

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

### Additional Information:

## Report Detail

**Case Number:** 97863 **Seq:** 1 **Gender:** F
**Reported:** 16/12/1994 **Weight:** 55.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 06/12/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | | |
| Periorbital oedema | | | |
| Pruritus | | | |
| Rash maculo-papular | Severe | | |

## Medicine Details:

**XANAX (Other drug)** **Reason:** Anxiety neurosis
0.0
**Batch:** **Started:** L TERM **Stopped:**

**SUXAMETHONIUM CHLORIDE (Other drug)** **Reason:** Depression
0.0
**Batch:** **Started:** 07/11/1994 **Stopped:** 05/12/1994

**PENTOTHAL (Other drug)** **Reason:**
7.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 18/11/1994 **Stopped:** 06/12/1994

## Laboratory Investigations:

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

## Additional Information:

Allergies:- agranulocytosis with mianserin and severe gingivitis subsequently with dothiepin.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 97887 **Seq:** 1 **Gender:** F
**Reported:** 15/12/1994 **Weight:** 70.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 13/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Extrapyramidal disorder | | | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 97894 **Seq:** 1 **Gender:** M
**Reported:** 15/12/1994 **Weight:** 68.00
**Hospitalisation:** **Age:** 47Y
**Onset Date:** 25/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash maculo-papular | | | |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 17/10/1994 **Stopped:** 25/10/1994

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97901 **Seq:** 1 **Gender:** F
**Reported:** 16/12/1994 **Weight:**
**Hospitalisation:** **Age:** 37Y
**Onset Date:** 26/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertonia | | Stiffness in tongue and mouth | |

## Medicine Details:

**PROPYLTHIOURACIL (Other drug)** **Reason:** Thyrotoxicosis w/o ment goiter
300.0 Milligram Daily
**Batch:** **Started:** 22/09/1994 **Stopped:** CONTIN

**CHLORPROMAZINE HYDROCHLORIDE (Other drug)** **Reason:**
Oral application 50.0 Milligram Daily Oral
**Batch:** **Started:** 18/10/1994 **Stopped:** CONTIN

**CARBAMAZEPINE (Other drug)** **Reason:**
Oral application 800.0 Milligram Daily Oral
**Batch:** **Started:** 16/09/1994 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 14/10/1994 **Stopped:** 07/11/1994

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 97922 **Seq:** 1 **Gender:** F
**Reported:** 19/12/1994 **Weight:** 63.00
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Apathy<br>Anorexia<br>Hyperhidrosis<br>Sleep disorder<br>Tremor<br>Weight increased | | Lack of volition | |

## Medicine Details:

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

**TRANXENE (Other drug)** **Reason:**
Capsule 0.0 Oral
**Batch:** **Started:** **Stopped:**

**ECOTRIN (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

**ZANTAC (Other drug)** **Reason:**
Tablet 2.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 97922 **Seq:** 1 **Gender:** F
**Reported:** 19/12/1994 **Weight:** 63.00
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **FLAGYL (Other drug)** | | | **Reason:** | | |
| Tablet | 3.0 | Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **PANADOL (Other drug)** | | | **Reason:** | | |
| Oral application | 4.0 | Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **BRUFEN (Other drug)** | | | **Reason:** | Psoriatic arthropathy | |
| Tablet | 1.6 | Gram | Daily | | Oral |
| **Batch:** | **Started:** | L TERM | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | | |
| Tablet | 20.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 09/08/1994 | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 97979 **Seq:** 1 **Gender:** F
**Reported:** 21/12/1994 **Weight:** 65.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 14/12/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Neurosis<br>Headache<br>Nausea<br>Palpitations | | Agoraphobia | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

**Batch:** **Started:** 13/12/1994 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 97996 **Seq:** 1 **Gender:** F
**Reported:** 23/12/1994 **Weight:** 75.00
**Hospitalisation:** **Age:** 67Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | | |
| Anorexia | | | |
| Asthenia | | | |
| Depression | | | |
| Hyponatraemia | | | |
| Inappropriate antidiuretic hormon | | | Fluid restriction, inf of hypertonic saline. |
| Malaise | | | |
| Sleep disorder | | | |

## Medicine Details:

**ATENOLOL (Other drug)** **Reason:** Essential benign hypertension

Tablet 50.0 Milligram Daily Oral

**Batch:** **Started:** L TERM **Stopped:**

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

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 30/11/1994 **Stopped:** 06/12/1994

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electrolytes | | | | Serum sodium level of 114 mmol/l (normal range 134 - 146mmol/l) and osmolality of 232mmol/kg (normal range 275 - 295 mmol/kg). urine osmolality was 372 mmol/kg and urine sodium concentration was 49mmol/l |

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 98007 **Seq:** 1 **Gender:** M
**Reported:** 29/12/1994 **Weight:** 76.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** 15/12/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Anxiety neurosis

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 14/12/1994 **Stopped:** 15/12/1994

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 98033 **Seq:** 1 **Gender:** F
**Reported:** 29/12/1994 **Weight:** 52.00
**Hospitalisation:** **Age:** 22Y
**Onset Date:** 21/12/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Depersonalisation<br>Dry mouth<br>Nausea<br>Stupor | | | |

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** 21/12/1994 **Stopped:** 21/12/1994

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 98166 **Seq:** 1 **Gender:** F
**Reported:** 06/01/1995 **Weight:**
**Hospitalisation:** **Age:** 43Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic function abnormal<br>Malaise<br>Myalgia<br>Purpura | | | |

## Medicine Details:

**ALCOHOL (Suspected)** **Reason:**
Oral application 0.0 Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
**Batch:** **Started:** 23/07/1994 **Stopped:** 21/11/1994

**NORDETTE NOS (Suspected)** **Reason:** Menopausal symptoms
Pill 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 08/07/1991 **Stopped:**

**PULMICORT (Suspected)** **Reason:** Asthma
Inhalation 4.0 Dose Unspecified Daily Inhalation
**Batch:** **Started:** 24/10/1994 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 98166 **Seq:** 1 **Gender:** F
**Reported:** 06/01/1995 **Weight:**
**Hospitalisation:** **Age:** 43Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **BRICANYL (Suspected)** | | | **Reason:** Asthma | | |
| Inhalation | 4.0 | Dose Unspecified | Daily | | Inhalation |
| **Batch:** | **Started:** 26/09/1991 | | | **Stopped:** | |
| **EUHYPNOS (Suspected)** | | | **Reason:** | | |
| Capsule | 10.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** 23/07/1994 | | | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:

### Report Detail

**Case Number:** 98214 **Seq:** 1 **Gender:** F
**Reported:** 09/01/1995 **Weight:** 61.00
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 01/01/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia<br>Anxiety<br>Confusional state<br>Dehydration<br>Diarrhoea<br>Dizziness<br>Hypotension<br>Ketosis<br>Nausea | | Aching limbs | |

### Medicine Details:

**SURMONTIL (Suspected)** **Reason:** Depression
50.0 Milligram Daily
**Batch:** **Started:** 30/12/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 31/12/1994 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 98231 **Seq:** 1 **Gender:** M
**Reported:** 10/01/1995 **Weight:**
**Hospitalisation:** **Age:** 55Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia | | | |
| Dizziness | | | |
| Fatigue | | | |
| Nausea | | | |
| Tremor | | | |

### Medicine Details:

**AROPAX (Interaction)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 22/07/1994 **Stopped:** 18/10/1994

**AURORIX (Interaction)** **Reason:** Depression
Tablet 600.0 Milligram Daily Oral
**Batch:** **Started:** 30/12/1993 **Stopped:** 21/07/1994

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 98233 **Seq:** 1 **Gender:** F
**Reported:** 10/01/1995 **Weight:** 68.00
**Hospitalisation:** **Age:** 53Y
**Onset Date:** 31/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**EVENING PRIMROSE OIL (Other drug)** **Reason:**
Oral application 4.0 Gram Daily Oral
**Batch:** **Started:** **Stopped:**

**TENORMIN (Other drug)** **Reason:**
Tablet 12.5 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**TAMOXIFEN CITRATE (Other drug)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/1994 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

- 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 98260 **Seq:** 1 **Gender:** M
**Reported:** 11/01/1995 **Weight:** 95.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 21/12/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Libido decreased | | | |

## Medicine Details:

**METHOTREXATE (Other drug)** **Reason:** Psoriatic arthropathy
25.0 Milligram Weekly
**Batch:** **Started:** 01/01/1990 **Stopped:**

**PANADEINE FORTE (Other drug)** **Reason:** Psoriatic arthropathy
1.0 Dose Unspecified As necessary
**Batch:** **Started:** 01/01/1990 **Stopped:**

**FENAC (Other drug)** **Reason:** Psoriatic arthropathy
150.0 Milligram Daily
**Batch:** **Started:** 01/01/1994 **Stopped:**

**PANAMAX (Other drug)** **Reason:** Psoriatic arthropathy
8.0 Dose Unspecified Daily
**Batch:** **Started:** 01/01/1990 **Stopped:**

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

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 98260 **Seq:** 1 **Gender:** M
**Reported:** 11/01/1995 **Weight:** 95.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 21/12/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | |
|---|---|---|---|
| **ZANTAC (Other drug)** | | **Reason:** | Other diseases of esophagus |
| | 300.0 Milligram | Daily | |
| **Batch:** | **Started:** 01/01/1990 | | **Stopped:** |
| **SCF (Other drug)** | | **Reason:** | Other diseases of esophagus |
| | 1.0 Gram | Daily | |
| **Batch:** | **Started:** 01/01/1992 | | **Stopped:** |
| **AROPAX (Suspected)** | | **Reason:** | Depression |
| | 20.0 Milligram | Daily | |
| **Batch:** | **Started:** 02/11/1994 | | **Stopped:** 28/12/1994 |

## Laboratory Investigations:

## Additional Information:

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 98305 **Seq:** 1 **Gender:** F
**Reported:** 12/01/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug ineffective<br>Weight increased | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

**Batch:** **Started:** 01/08/1994 **Stopped:** 28/11/1994

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 98313 **Seq:** 1 **Gender:** F
**Reported:** 13/01/1995 **Weight:** 85.00
**Hospitalisation:** **Age:** 60Y
**Onset Date:** 31/12/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysarthria<br>Somnolence<br>Tongue oedema | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
6.0 Dose Unspecified Total
**Batch:** **Started:** 01/12/1994 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Same pattern recurred on six seperate occasions after single tablet. - 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 98357 **Seq:** 1 **Gender:** F
**Reported:** 18/01/1995 **Weight:** 60.00
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 31/10/1994 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Haematuria<br>Hyperparathyroidism<br>Nephrolithiasis<br>Renal pain | | | |

### Medicine Details:

**PLENDIL (Suspected)** **Reason:**
Tablet 0.0 Oral
**Batch:** **Started:** 01/01/1990 **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** 06/06/1994 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Biochemistry<br>Intravenous | 10-65 | | | Parathyroid hormone level (pth) of 85. pth 17/10/94 6.9 pmol/l<br>Multiple renal calculi bilaterally |

### Additional Information:

Probable renal colic and calculus during second pregnancy (loin pain, abdominal pain , passage of small piece of "gravel" - not investigated at that time). - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

## Report Detail

**Case Number:** 98389 **Seq:** 1
**Reported:** 18/01/1995
**Hospitalisation:** Hospitalisation prolonged
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:**
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depression<br>Herpes zoster<br>Pancytopenia<br>Weight decreased | | | Acyclovir |

## Medicine Details:

**CLONAZEPAM (Other drug)** **Reason:**
500.0 Microgram As necessary
**Batch:** **Started:** **Stopped:**

**TEMAZEPAM (Other drug)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

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

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 14/02/1994 **Stopped:** 05/07/1994

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Haemoglobin | ( 115-165 G/L) | 09/02/1994 | 105 | |
| | Haemoglobin | ( 115-165 G/L) | 20/04/1994 | 118 | |
| | Haemoglobin | ( 115-165 G/L) | 21/07/1994 | 110 | |
| | Haemoglobin | ( 115-165 G/L) | 02/11/1994 | 119 | |
| | Haemoglobin | ( 115-165 G/L) | 18/08/1994 | 111 | |
| | Neutrophils | (1.7-8.2 X | 09/02/1994 | 1.3 | |
| | Neutrophils | (1.7-8.2 X | 02/11/1994 | 4.8 | |

## Additional Information:

## Report Detail

**Case Number:** 98389 **Seq:** 1
**Reported:** 18/01/1995
**Hospitalisation:** Hospitalisation prolonged
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:**
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | |
|---|---|---|---|
| **CLONAZEPAM (Other drug)** | | **Reason:** | |
| | 500.0 Microgram | As necessary | |
| **Batch:** | **Started:** | | **Stopped:** |
| **TEMAZEPAM (Other drug)** | | **Reason:** | |
| | 20.0 Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** |
| **ASPIRIN (Other drug)** | | **Reason:** | |
| | 150.0 Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | **Reason:** | |
| | 20.0 Milligram | Daily | |
| **Batch:** | **Started:** 14/02/1994 | | **Stopped:** 05/07/1994 |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Neutrophils | (1.7-8.2 X 10^9/L) | 18/08/1994 | 2.2 | |
| | Neutrophils | (1.7-8.2 X 10^9/L) | 20/04/1994 | 1.3 | |
| | Neutrophils | (1.7-8.2 X 10^9/L) | 21/07/1994 | 2.4 | |
| | Platelets | (150-400 10^9/L) | 09/02/1994 | 117 | |
| | Platelets | (150-400 10^9/L) | 20/04/1994 | 101 | |
| | Platelets | (150-400 10^9/L) | 18/08/1994 | 152 | |
| | Platelets | (150-400 10^9/L) | 02/11/1994 | 175 | |

## Additional Information:

## Report Detail

**Case Number:** 98389 **Seq:** 1
**Reported:** 18/01/1995
**Hospitalisation:** Hospitalisation prolonged
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:**
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | |
|---|---|---|---|
| **CLONAZEPAM (Other drug)** | | **Reason:** | |
| | 500.0 Microgram | As necessary | |
| **Batch:** | **Started:** | | **Stopped:** |
| **TEMAZEPAM (Other drug)** | | **Reason:** | |
| | 20.0 Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** |
| **ASPIRIN (Other drug)** | | **Reason:** | |
| | 150.0 Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | **Reason:** | |
| | 20.0 Milligram | Daily | |
| **Batch:** | **Started:** 14/02/1994 | | **Stopped:** 05/07/1994 |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Platelets | (150-400 10^9/L) | 21/07/1994 | 121 | |
| | White blood cells | ( 4-11 X 10) | 09/02/1994 | 2.9 | |
| | White blood cells | ( 4-11 X 10) | 20/04/1994 | 2.7 | |
| | White blood cells | ( 4-11 X 10) | 21/07/1994 | 4.9 | |
| | White blood cells | ( 4-11 X 10) | 18/08/1994 | 4.4 | |
| | White blood cells | ( 4-11 X 10) | 02/11/1994 | 6.3 | |

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 98494 **Seq:** 1 **Gender:** M
**Reported:** 24/01/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure<br>Insomnia<br>Libido decreased<br>Nausea | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 98500 **Seq:** 1 **Gender:** F
**Reported:** 24/01/1995 **Weight:** 53.00
**Hospitalisation:** **Age:** 36Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 80.0 Milligram Daily Oral
**Batch:** **Started:** 18/10/1994 **Stopped:** 12/12/1994

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 98505 **Seq:** 1 **Gender:** F
**Reported:** 24/01/1995 **Weight:** 67.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 17/03/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 17/03/1994 **Stopped:** 12/04/1994

### Laboratory Investigations:

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

### Additional Information:

Long standing bipolar swings.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 98506 **Seq:** 1 **Gender:** F
**Reported:** 24/01/1995 **Weight:**
**Hospitalisation:** **Age:** 34Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia | | Tightening of jaw | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/1994 **Stopped:** 28/11/1994

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 98507 **Seq:** 1 **Gender:** F
**Reported:** 24/01/1995 **Weight:** 50.00
**Hospitalisation:** **Age:** 24Y
**Onset Date:** 01/12/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Visual field defect | | Visual disturbances, tunnel vision | Aropax ceased by patient. |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 24/11/1994 **Stopped:** 17/12/1994

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 98510 **Seq:** 1 **Gender:** F
**Reported:** 05/01/1995 **Weight:** 82.00
**Hospitalisation:** **Age:** 41Y
**Onset Date:** 22/12/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Insomnia | | | |

### Medicine Details:

**CAFERGOT (Other drug)** **Reason:**
Suppository 1.0 Dose Unspecified As necessary Rectal
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**MS CONTIN (Other drug)** **Reason:**
30.0 Milligram Daily
**Batch:** **Started:** 06/09/1994 **Stopped:** CONTIN

**OGEN (Other drug)** **Reason:**
25.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 11/12/1994 **Stopped:** 23/12/1994

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 98527 **Seq:** 1 **Gender:** F
**Reported:** 27/01/1995 **Weight:** 90.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 31/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia<br>Libido decreased | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/10/1994 **Stopped:** 10/01/1995

### Laboratory Investigations:

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

### Additional Information:

- 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.

### Report Detail

**Case Number:** 98677 **Seq:** 1 **Gender:** F
**Reported:** 02/02/1995 **Weight:**
**Hospitalisation:** **Age:** 26Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Psychotic disorder | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Unspecified schizophrenia

Tablet 20.0 Milligram Daily Oral

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

### Laboratory Investigations:

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

### Additional Information:

### Report Detail

**Case Number:** 98678 **Seq:** 1 **Gender:** F
**Reported:** 02/02/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

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

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 98762 **Seq:** 1 **Gender:** M
**Reported:** 07/02/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension<br>Tachycardia | | | |

## Medicine Details:

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

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

**MINIPRESS (Other drug)** **Reason:**
Tablet 4.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

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

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 98762 **Seq:** 1 **Gender:** M
**Reported:** 07/02/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detai

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **AROPAX (Suspected)** | | | **Reason:** | |
| Tablet | 10.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:

### Report Detail

**Case Number:** 98763 **Seq:** 1 **Gender:** F
**Reported:** 08/02/1995 **Weight:**
**Hospitalisation:** Treated in outpatient department only. **Age:** 26Y
**Onset Date:** 07/12/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary retention | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 24/11/1994 **Stopped:** 07/12/1994

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 98855 **Seq:** 1 **Gender:** F
**Reported:** 09/02/1995 **Weight:** 57.00
**Hospitalisation:** **Age:** 36Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Alcohol intolerance | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**TENORMIN (Suspected)** **Reason:** Anxiety neurosis
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 98875 **Seq:** 1 **Gender:** F
**Reported:** 09/02/1995 **Weight:** 66.00
**Hospitalisation:** **Age:** 49Y
**Onset Date:** 31/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus<br>Purpura<br>Rash | | | |

## Medicine Details:

**XANAX (Other drug)** **Reason:** Anxiety neurosis
250.0 Microgram As necessary
**Batch:** **Started:** 19/07/1994 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 06/10/1994 **Stopped:** 24/12/1994

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Immunology | | | | Eb urine 1gm positive |

## Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

## Report Detail

**Case Number:** 98905 **Seq:** 1 **Gender:** F
**Reported:** 13/02/1995 **Weight:** 54.00
**Hospitalisation:** **Age:**
**Onset Date:** 31/08/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 80.0 Milligram Daily Oral
**Batch:** **Started:** 01/08/1994 **Stopped:** CONTIN

**PROLADONE (Suspected)** **Reason:** Lumbalgia
120.0 Milligram Daily
**Batch:** **Started:** 01/02/1993 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Reactions to most antidepressives tried-nausea tremor, headache. - 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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 98914 **Seq:** 1 **Gender:** F
**Reported:** 13/02/1995 **Weight:**
**Hospitalisation:** **Age:** AE
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Coma | | | Oxygen |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram 1 time Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Patient on a number of medications including oral hypoglycaemics.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 98922 **Seq:** 1 **Gender:** F
**Reported:** 13/02/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 26Y
**Onset Date:** 09/01/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Alcohol intolerance | | | |
| Nausea | Required Visit to Doctor | | |
| Vomiting | Required Visit to Doctor | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 09/01/1995 **Stopped:** CONTIN

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 98946 **Seq:** 1 **Gender:** F
**Reported:** 15/02/1995 **Weight:** 59.00
**Hospitalisation:** **Age:** 66Y
**Onset Date:** 06/12/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia<br>Tetany | | | |

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **HIPREX (Other drug)** | | | **Reason:** | |
| Tablet | 2.0 Gram | Daily | | Oral |
| **Batch:** | **Started:** 12/09/1994 | | **Stopped:** | |
| **ALODORM (Other drug)** | | | **Reason:** | |
| Tablet | 5.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 26/08/1994 | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** Depression | |
| Tablet | 40.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 16/11/1994 | | **Stopped:** 06/12/1994 | |

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 98963 **Seq:** 1 **Gender:** F
**Reported:** 15/02/1995 **Weight:** 65.00
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 31/01/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**ESTRADERM (Other drug)** **Reason:** Menopausal symptoms
Cream 2.0 Dose Unspecified Weekly Transdermal
**Batch:** **Started:** 22/10/1993 **Stopped:** CONTIN

**PROVERA (Other drug)** **Reason:** Menopausal symptoms
10.0 Milligram Daily
**Batch:** **Started:** 22/10/1993 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 31/01/1995 **Stopped:** CONTIN

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 99156 **Seq:** 1 **Gender:** F
**Reported:** 28/02/1995 **Weight:** 57.00
**Hospitalisation:** **Age:** 34Y
**Onset Date:** 10/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia | | Marked jaw and tongue dystonia | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 20/02/1995

## Laboratory Investigations:

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

## Additional Information:

Patient has been sensitive to a number of anti-depressents.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99161 **Seq:** 1 **Gender:** F
**Reported:** 27/02/1995 **Weight:**
**Hospitalisation:** **Age:** 86Y
**Onset Date:** 06/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br>Inappropriate antidiuretic hormon<br>Renal impairment | | | |

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **ANGININE (Other drug)** | | | **Reason:** | Angina pectoris w/o hyperten | |
| Tablet | 1.0 | Dose Unspecified | As necessary | Sublingual | |
| **Batch:** | **Started:** | | | **Stopped:** | CONTIN |
| **IMDUR (Other drug)** | | | **Reason:** | Angina pectoris w/o hyperten | |
| Tablet | 60.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | CONTIN |
| **COVERSYL (Other drug)** | | | **Reason:** | Congestive heart failure | |
| Tablet | 2.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | CONTIN |
| **CARTIA (Other drug)** | | | **Reason:** | | |
| Tablet | 1.0 | Dose Unspecified | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | CONTIN |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Creatinine | | 06/02/1995 | 69 | |
| | Creatinine | | 07/02/1995 | 77 | |
| | Creatinine | | 09/02/1995 | 98 | |
| | Creatinine | | 10/02/1995 | 163 | |
| | Creatinine | | 08/02/1995 | 79 | |
| | Creatinine | | 11/02/1995 | 137 | |
| | Creatinine | | 12/02/1995 | 126 | |

### Additional Information:

### Report Detail

**Case Number:** 99161 **Seq:** 1 **Gender:** F
**Reported:** 27/02/1995 **Weight:**
**Hospitalisation:** **Age:** 86Y
**Onset Date:** 06/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 22/01/1995 **Stopped:** 09/02/1995

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Creatinine | | 15/02/1995 | 115 | |
| | Creatinine | | 18/02/1995 | 124 | |
| | Creatinine | | 16/02/1995 | 110 | |
| | Creatinine | | 14/02/1995 | 111 | |
| | Creatinine | | 12/02/1995 | 128 | |
| | Other data | 275-295 | | | Osmolarity 7/2/95 233. urine: osmolarity 346 na+ 46. |
| | Sodium | 132-145 | 06/02/1995 | 118 | |

### Additional Information:

## Report Detail

**Case Number:** 99161 **Seq:** 1 **Gender:** F
**Reported:** 27/02/1995 **Weight:**
**Hospitalisation:** **Age:** 86Y
**Onset Date:** 06/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **ANGININE (Other drug)** | | | | **Reason:** | Angina pectoris w/o hyperten | |
| Tablet | 1.0 | Dose Unspecified | As necessary | | Sublingual | |
| **Batch:** | **Started:** | | | **Stopped:** | | CONTIN |
| **IMDUR (Other drug)** | | | | **Reason:** | Angina pectoris w/o hyperten | |
| Tablet | 60.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | | CONTIN |
| **COVERSYL (Other drug)** | | | | **Reason:** | Congestive heart failure | |
| Tablet | 2.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | | CONTIN |
| **CARTIA (Other drug)** | | | | **Reason:** | | |
| Tablet | 1.0 | Dose Unspecified | Daily | | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | | CONTIN |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | 132-145 MMOL/L | 07/02/1995 | 111 | |
| | Sodium | 132-145 MMOL/L | 08/02/1995 | 114 | |
| | Sodium | 132-145 MMOL/L | 09/02/1995 | 119 | |
| | Sodium | 132-145 MMOL/L | 10/02/1995 | 122 | |
| | Sodium | 132-145 MMOL/L | 11/02/1995 | 129 | |
| | Sodium | 132-145 MMOL/L | 12/02/1995 | 128 | |
| | Sodium | 132-145 MMOL/L | 13/02/1995 | 129 | |

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 99161 **Seq:** 1 **Gender:** F
**Reported:** 27/02/1995 **Weight:**
**Hospitalisation:** **Age:** 86Y
**Onset Date:** 06/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detai

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 22/01/1995 **Stopped:** 09/02/1995

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | 132-145 MMOL/L | 14/02/1995 | 132 | |
| | Sodium | 132-145 MMOL/L | 15/02/1995 | 131 | |
| | Sodium | 132-145 MMOL/L | 16/02/1995 | 130 | |
| | Sodium | 132-145 MMOL/L | 18/02/1995 | 133 | |

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 99251 **Seq:** 1 **Gender:** M
**Reported:** 28/02/1995 **Weight:**
**Hospitalisation:** **Age:** 42
**Onset Date:** 02/12/1994 **DOB:** 10/04/1952
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**CLONAZEPAM (Other drug)** **Reason:**
Oral application 1.0 Milligram Daily Oral
**Batch:** **Started:** 01/09/1992 **Stopped:**

**COLOXYL WITH SENNA (Other drug)** **Reason:** Constipation
Tablet 2.0 Dose Unspecified Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 24/06/1994 **Stopped:** 23/12/1994

**CLOZAPINE (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** 01/08/1994 **Stopped:**

## 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 99253 **Seq:** 1 **Gender:** F
**Reported:** 28/02/1995 **Weight:**
**Hospitalisation:** **Age:** 76
**Onset Date:** 15/01/1995 **DOB:** 20/11/1918
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Angina pectoris<br>Nausea<br>Vomiting | | | Fluids and metoclopramide |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram 1 time Oral
**Batch:** **Started:** 15/01/1995 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

See original report for other medication

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99268 **Seq:** 1 **Gender:** F
**Reported:** 28/02/1995 **Weight:** 59.00
**Hospitalisation:** **Age:** 82Y
**Onset Date:** 17/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state<br>Hyponatraemia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 14/02/1995 **Stopped:** 17/02/1995

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electrolytes | | | | After 3 days serum sodium 122 with major deterioration in |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99269 **Seq:** 1 **Gender:** F
**Reported:** 28/02/1995 **Weight:**
**Hospitalisation:** **Age:** 34Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99270 **Seq:** 1 **Gender:** F
**Reported:** 28/02/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis<br>Palpitations<br>Somnolence | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 99271 **Seq:** 1 **Gender:** F
**Reported:** 28/02/1995 **Weight:** 60.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 25/01/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Affect lability<br>Dizziness<br>Drug withdrawal syndrome<br>Insomnia<br>Muscle twitching | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/08/1994 **Stopped:** 24/01/1995

## 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99292 **Seq:** 1 **Gender:** F
**Reported:** 02/03/1995 **Weight:** 55.00
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 21/02/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia<br>Flushing<br>Myalgia<br>Nausea | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 20/02/1995 **Stopped:** 24/02/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99296 **Seq:** 1 **Gender:** F
**Reported:** 01/03/1995 **Weight:** 85.00
**Hospitalisation:** **Age:** 17Y
**Onset Date:** 21/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Bruxism<br>Asthenia<br>Dystonia<br>Nausea | | Involuntary clenching of back teeth. | |

### Medicine Details:

**PROVERA (Other drug)** **Reason:**
2.5 Milligram Daily
**Batch:** **Started:** 22/12/1994 **Stopped:**

**ESTIGYN (Other drug)** **Reason:**
10.0 Microgram Daily
**Batch:** **Started:** 22/12/1994 **Stopped:**

**CALCIUM CARBONATE (Other drug)** **Reason:**
600.0 Milligram Daily
**Batch:** **Started:** 22/12/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 21/02/1995 **Stopped:** 21/02/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99328 **Seq:** 1 **Gender:** F
**Reported:** 03/03/1995 **Weight:** 65.00
**Hospitalisation:** **Age:** 22Y
**Onset Date:** 08/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura Thrombocytopenia | | | prednisolone, intragam. |

### Medicine Details:

**STEMETIL (Other drug)** **Reason:** Nausea and vomiting
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/11/1994 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Histology | | | | A bone marrow done on 10/2/95 showed normal cellularity, thrombocytopenia with plentiful megakaryocyte numbers and findings consistent with peripheral destruction and/or sequestration of platelets |
| | Platelets | (X 10(9)/L) | 09/02/1995 | 1 | |
| | Platelets | (X 10(9)/L) | 10/02/1995 | 1 | |
| | Platelets | (X 10(9)/L) | 11/02/1995 | 1 | |
| | Platelets | (X 10(9)/L) | 13/02/1995 | 1 | |

### Additional Information:

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

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 99328 **Seq:** 1 **Gender:** F
**Reported:** 03/03/1995 **Weight:** 65.00
**Hospitalisation:** **Age:** 22Y
**Onset Date:** 08/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **STEMETIL (Other drug)** | | | **Reason:** | Nausea and vomiting |
| Tablet | 0.0 | | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **AROPAX (Suspected)** | | | **Reason:** | Depression |
| Tablet | 20.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 01/11/1994 | | | **Stopped:** |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Platelets | (X 10(9)/L) | 14/02/1995 | 21 | |
| | Platelets | (X 10(9)/L) | 15/02/1995 | 50 | |
| | Platelets | (X 10(9)/L) | 16/02/1995 | 101 | |
| | Platelets | (X 10(9)/L) | 17/02/1995 | 142 | |
| | Platelets | (X 10(9)/L) | 23/02/1995 | 231 | |

## Additional Information:

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99418 **Seq:** 1 **Gender:** M
**Reported:** 06/03/1995 **Weight:** 55.00
**Hospitalisation:** **Age:** 85Y
**Onset Date:** 07/02/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Leukopenia<br>Neutropenia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 16/01/1995 **Stopped:** 07/02/1995

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Lymphocytes | (1.0-4.0) | 06/02/1995 | 0.4 | |
| | Lymphocytes | (1.0-4.0) | 21/02/1995 | 0.5 | |
| | Neutrophils | (2.0-7.5)(2.0-8.0) | 06/02/1995 | 0.5 | |
| | Neutrophils | (2.0-7.5)(2.0-8.0) | 21/02/1995 | 0.9* | |
| | White blood cells | ( 4-11) | 06/02/1995 | 1.8 | |
| | White blood cells | ( 4-11) | 21/02/1995 | 1.7 | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 99451 **Seq:** 1 **Gender:** M
**Reported:** 08/03/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 99470 **Seq:** 1 **Gender:** M
**Reported:** 08/03/1995 **Weight:**
**Hospitalisation:** **Age:** 50Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/12/1994 **Stopped:**

## 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 99473 **Seq:** 1 **Gender:** M
**Reported:** 08/03/1995 **Weight:**
**Hospitalisation:** **Age:** 34Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypoaesthesia<br>Penis disorder | | Numbness of penis | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 22/02/1995 **Stopped:** 28/02/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99488 **Seq:** 1 **Gender:** M
**Reported:** 10/03/1995 **Weight:** 80.00
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia | | Pain in upper limbs and between shoulder | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 2M

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99489 **Seq:** 1 **Gender:** F
**Reported:** 10/03/1995 **Weight:** 57.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | Severe | | Dispirin and migral. |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 20.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99540 **Seq:** 1 **Gender:** F
**Reported:** 13/03/1995 **Weight:** 59.00
**Hospitalisation:** **Age:** 83Y
**Onset Date:** 14/12/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety<br>Insomnia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 14/12/1994 **Stopped:** 20/02/1995

### Laboratory Investigations:

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

### Additional Information:

Patient rechallenged on aropax resulting in symptoms occuring again. see original report for other drugs.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99578 **Seq:** 1 **Gender:** F
**Reported:** 14/03/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia<br>Hyperhidrosis | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 02/02/1995 **Stopped:** 09/03/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99614 **Seq:** 1 **Gender:** F
**Reported:** 16/03/1995 **Weight:** 33.00
**Hospitalisation:** **Age:** 17Y
**Onset Date:** 21/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia | | Acute orobuccal dystonia | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 21/02/1995 **Stopped:** 21/02/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99617 **Seq:** 1 **Gender:** F
**Reported:** 16/03/1995 **Weight:**
**Hospitalisation:** **Age:** 31Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 13/12/1994 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

## Report Detail

**Case Number:** 99619 **Seq:** 1 **Gender:** F
**Reported:** 16/03/1995 **Weight:**
**Hospitalisation:** **Age:** 37Y
**Onset Date:** 24/02/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**LEXOTAN (Other drug)** **Reason:**
Tablet 18.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

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

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 15/02/1995 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99624 **Seq:** 1 **Gender:** F
**Reported:** 16/03/1995 **Weight:** 55.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 09/01/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Nausea | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/06/1994 **Stopped:** 02/01/1995

### Laboratory Investigations:

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

### Additional Information:

Patient was gradually weened of aropax without problems. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99650 **Seq:** 1 **Gender:** F
**Reported:** 17/03/1995 **Weight:**
**Hospitalisation:** Treated in outpatient department only. **Age:** 35Y
**Onset Date:** 11/03/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety<br>Chest pain<br>Dyspnoea<br>Flushing<br>Hyperhidrosis | Severe | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 09/03/1995 **Stopped:** 11/03/1995

### Laboratory Investigations:

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

### Additional Information:

### Report Detail

**Case Number:** 99656 **Seq:** 1 **Gender:** F
**Reported:** 20/03/1995 **Weight:** 64.00
**Hospitalisation:** **Age:** 74Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence | Severe | | |

### Medicine Details:

**XANAX (Other drug)** **Reason:**
Tablet 2.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/09/1994 **Stopped:**

### 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 99700 **Seq:** 1 **Gender:** F
**Reported:** 22/03/1995 **Weight:**
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 05/03/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 20/02/1995 **Stopped:** 11/03/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99815 **Seq:** 1 **Gender:** F
**Reported:** 29/03/1995 **Weight:** 80.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 07/01/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**BREVINOR-1 (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** 01/12/1994 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### 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.

## Report Detail

**Case Number:** 99817 **Seq:** 1 **Gender:** F
**Reported:** 27/03/1995 **Weight:**
**Hospitalisation:** **Age:** 92Y
**Onset Date:** 16/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion<br>Hypotension | | | <br>Iv fluids. |

## Medicine Details:

**FLUDROCORTISONE (Other drug)** **Reason:** Hypotension
100.0 Microgram Daily
**Batch:** **Started:** **Stopped:**

**LACTULOSE (Other drug)** **Reason:**
60.0 Millilitre Daily
**Batch:** **Started:** **Stopped:**

**COLOXYL WITH SENNA (Other drug)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**ASPIRIN (Other drug)** **Reason:** Chron isch heart dis no hyper
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Episode after dose doubled.

## Report Detail

**Case Number:** 99817 **Seq:** 1 **Gender:** F
**Reported:** 27/03/1995 **Weight:**
**Hospitalisation:** **Age:** 92Y
**Onset Date:** 16/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | |
|---|---|---|---|
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | **Reason:** | Depression |
| | 10.0 Milligram | | Daily |
| **Batch:** | **Started:** 08/02/1995 | | **Stopped:** 15/02/1995 |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | **Reason:** | Depression |
| | 20.0 Milligram | | Daily |
| **Batch:** | **Started:** 16/02/1995 | | **Stopped:** 17/02/1995 |

## Laboratory Investigations:

## Additional Information:

Episode after dose doubled.

### Report Detail

**Case Number:** 99836 **Seq:** 1 **Gender:** F
**Reported:** 29/03/1995 **Weight:** 47.00
**Hospitalisation:** **Age:** 26Y
**Onset Date:** 10/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

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

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 25/07/1994 **Stopped:** CONTIN

### Laboratory Investigations:

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

### Additional Information:

Alcohol tolerance improved

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 99901 **Seq:** 1 **Gender:** M
**Reported:** 30/03/1995 **Weight:** 92.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 21/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache<br>Erectile dysfunction | Severe | Pre-ejaculatory headache | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** 08/09/1994 **Stopped:** 26/10/1994

### Laboratory Investigations:

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

### Additional Information:

Rechallenge produced identical symptoms and signs

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100055 **Seq:** 1 **Gender:** F
**Reported:** 04/04/1995 **Weight:**
**Hospitalisation:** **Age:** A3
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/09/1994 **Stopped:** 28/02/1995

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100056 **Seq:** 1 **Gender:** F
**Reported:** 04/04/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Weight increased | | | |

### Medicine Details:

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100085 **Seq:** 1 **Gender:** F
**Reported:** 06/04/1995 **Weight:**
**Hospitalisation:** **Age:** 73Y
**Onset Date:** 30/03/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence<br>Dry mouth<br>Hyperhidrosis<br>Visual disturbance | | Very sleepy | |

## Medicine Details:

**DISPRIN (Other drug)** **Reason:**
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**TEMAZEPAM (Other drug)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**TETRACYCLINE (Other drug)** **Reason:**
Oral application 1.0 Gram Daily Oral
**Batch:** **Started:** **Stopped:**

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

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 100085 **Seq:** 1 **Gender:** F
**Reported:** 06/04/1995 **Weight:**
**Hospitalisation:** **Age:** 73Y
**Onset Date:** 30/03/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **PANADOL (Other drug)** | | | **Reason:** | | |
| Tablet | 6.0 | Gram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **NAPROSYN SR 750 (Other drug)** | | | **Reason:** | | |
| Tablet | 750.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 20.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

### Report Detail

**Case Number:** 100179 **Seq:** 1 **Gender:** F
**Reported:** 10/04/1995 **Weight:**
**Hospitalisation:** **Age:** 25Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Eye pain | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 10.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100180 **Seq:** 1 **Gender:** F
**Reported:** 10/04/1995 **Weight:** 59.00
**Hospitalisation:** **Age:** 49Y
**Onset Date:** 27/01/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paralysis<br>Dizziness<br>Hyperhidrosis<br>Hypoaesthesia<br>Palpitations | | Inablitiy to move | |

### Medicine Details:

**RENITEC (Other drug)** **Reason:** Essential benign hypertension
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**TENORMIN (Other drug)** **Reason:** Essential benign hypertension
50.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram 1 time Oral
**Batch:** **Started:** 27/01/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100181 **Seq:** 1 **Gender:** F
**Reported:** 10/04/1995 **Weight:**
**Hospitalisation:** **Age:** 33Y
**Onset Date:** 01/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 14/12/1994 **Stopped:** 02/02/1995

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100182 **Seq:** 1 **Gender:** F
**Reported:** 10/04/1995 **Weight:**
**Hospitalisation:** **Age:** 41Y
**Onset Date:** 10/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 08/11/1994 **Stopped:** 14/02/1995

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 100186 **Seq:** 1 **Gender:** M
**Reported:** 10/04/1995 **Weight:**
**Hospitalisation:** **Age:** AD
**Onset Date:** 31/12/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Coordination abnormal<br>Insomnia | | Walking sideways | |

## Medicine Details:

**MORPHINE NOS (Other drug)** **Reason:** Pain
Injection 0.0 Intravenous
**Batch:** **Started:** **Stopped:**

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

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

## Laboratory Investigations:

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

## Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100221 **Seq:** 1 **Gender:** F
**Reported:** 11/04/1995 **Weight:** 56.00
**Hospitalisation:** **Age:** 55Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 0.5 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Reaction occured after each dose of aropax.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100224 **Seq:** 1 **Gender:** F
**Reported:** 11/04/1995 **Weight:** 100.00
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Skin discolouration | | Ability to tan when not previously present. | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/06/1994 **Stopped:**

## 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.

## Report Detail

**Case Number:** 100235 **Seq:** 1 **Gender:** F
**Reported:** 13/04/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 76Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence | | Slept all the time | |

## Medicine Details:

**MINIPRESS (Other drug)** **Reason:** Essential benign hypertension
3.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**INDERAL (Other drug)** **Reason:** Essential benign hypertension
20.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**SEREPAX (Other drug)** **Reason:** Essential benign hypertension
45.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 31/03/1995 **Stopped:** 09/04/1995

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 100252 **Seq:** 1 **Gender:** F
**Reported:** 12/04/1995 **Weight:**
**Hospitalisation:** **Age:** 76Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**ASIG (Other drug)** **Reason:** Essential benign hypertension
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** 05/10/1993 **Stopped:**

**ROCALTROL (Other drug)** **Reason:** Osteoarthritis
Capsule 2.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 25/11/1993 **Stopped:**

**CALTRATE (Other drug)** **Reason:** Osteoarthritis
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 10/11/1991 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 06/11/1994 **Stopped:** 22/03/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100261 **Seq:** 1
**Reported:** 18/04/1995
**Hospitalisation:** Admitted to hospital
**Onset Date:** 23/03/1995
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 35Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura<br>Thrombocytopenia | | | <br>Prednisone |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 17/03/1995 **Stopped:** 26/03/1995

**LITHICARB (Suspected)** **Reason:** Depression
1.0 Gram Daily
**Batch:** **Started:** 17/03/1995 **Stopped:** 26/03/1995

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Platelets | | 13/03/1995 | 336 | |
| | Platelets | | 27/03/1995 | 14 | |
| | Platelets | | 05/04/1995 | 580 | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100299 **Seq:** 1
**Reported:** 19/04/1995
**Hospitalisation:**
**Onset Date:** 12/03/1995
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 75.00
**Age:** 45Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dry mouth<br>Erectile dysfunction<br>Yawning | | | |

## Medicine Details:

**ALDECIN (Other drug)** **Reason:** Chronic nasopharyngitis
Spray 100.0 Microgram Daily Nasal
**Batch:** **Started:** **Stopped:** 07D

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 09/03/1995 **Stopped:** 06/04/1995

## Laboratory Investigations:

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

## Additional Information:

Allergies: amoxyl - diarrhoea lomotil - cease breathing

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100345 **Seq:** 1 **Gender:** F
**Reported:** 24/04/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 15/03/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/10/1994 **Stopped:** 20/04/1995

## 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100347 **Seq:** 1 **Gender:** F
**Reported:** 19/04/1995 **Weight:** 106.00
**Hospitalisation:** **Age:** 62Y
**Onset Date:** 08/04/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthralgia | Severe | | |
| Back pain | Severe | | |
| Headache | Severe | | |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 08/04/1995 **Stopped:** 10/04/1995

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100382 **Seq:** 1
**Reported:** 27/04/1995
**Hospitalisation:**
**Onset Date:** 21/04/1995
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 60.00
**Age:** 25Y
**DOB:**
**Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Nausea<br>Sleep disorder<br>Tremor | | Fidgity | |

## Medicine Details:

**AURORIX (Other drug)** **Reason:** Depression
3.0 Dose Unspecified Daily
**Batch:** **Started:** 31/03/1995 **Stopped:** 20/04/1995

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 21/04/1995 **Stopped:** 21/04/1995

## Laboratory Investigations:

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

## Additional Information:

Reaction began 24 hours post dose

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100400 **Seq:** 1 **Gender:** M
**Reported:** 24/04/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Renal impairment | | | |

## Medicine Details:

**CYCLOSPORIN-A (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

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

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Creatinine | | | | Creatinine levels have increased from 70-80mmol/l to 104mmol/l |

## Additional Information:

### Report Detail

**Case Number:** 100458 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:** 50.00
**Hospitalisation:** **Age:** 48Y
**Onset Date:** 14/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety<br>Drug withdrawal syndrome<br>Nausea<br>Suicide attempt<br>Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** 22/12/1994 **Stopped:** 14/02/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100465 **Seq:** 1 **Gender:** M
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:** AE
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100468 **Seq:** 1 **Gender:** M
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:** 43Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sensory disturbance<br>Drug withdrawal syndrome | | Electric flashes to various parts of body. | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 3M

### Laboratory Investigations:

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

### Additional Information:

Reaction has ocurred each time (twice) that the patient has tried stopping aropax 20.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100469 **Seq:** 1 **Gender:** M
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

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

## Medicine Details:

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

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

## Laboratory Investigations:

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

## Additional Information:

Seizures in a patient taking aropax 20 who had recently had a few beers.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100470 **Seq:** 1 **Gender:** U
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus<br>Rash | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100472 **Seq:** 1 **Gender:** U
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus<br>Rash | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100473 **Seq:** 1 **Gender:** U
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus<br>Rash | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100474 **Seq:** 1 **Gender:** M
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 15/12/1994 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome<br>Hyperhidrosis<br>Insomnia<br>Tremor | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 11/12/1994

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100475 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysphonia<br>Chills | | Shakey voice<br>Terrible body shakes | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100476 **Seq:** 1 **Gender:** M
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysuria<br>Nausea | | Stinging urine | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100481 **Seq:** 1 **Gender:** U
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Extrapyramidal disorder | | | |

## Medicine Details:

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

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100482 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary retention | | | |

## Medicine Details:

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

**AROPAX (Suspected)** **Reason:**
40.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100483 **Seq:** 1 **Gender:** M
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:** 25Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Eczema | | | Changed to prozac. |

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **MELLERIL (Other drug)** | | | **Reason:** | |
| Tablet | 50.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |
| **STELAZINE (Other drug)** | | | **Reason:** | |
| Tablet | 6.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression |
| Tablet | 20.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | 26/07/1994 | **Stopped:** | 08/12/1994 |

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100485 **Seq:** 1 **Gender:** U
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash | | Rash over chest and lower abdomen | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 20.0 Milligram Daily Oral

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100486 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:** A5
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100489 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pollakiuria<br>Polyuria | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
30.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Reaction ocurred after increasing dose of aropax 20 from 20 mg to 30 mg daily.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100491 **Seq:** 1 **Gender:** M
**Reported:** 01/05/1995 **Weight:** 80.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 31/08/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**STELAZINE (Other drug)** **Reason:**
15.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 3M

## Laboratory Investigations:

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

## Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100492 **Seq:** 1 **Gender:** U
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100494 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary incontinence | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
5.0 Milligram Daily
**Batch:** **Started:** 01/06/1994 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Patient was rechallenged on aropax with same reaction occurring. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100496 **Seq:** 1 **Gender:** M
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detai

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

**Batch:** **Started:** **Stopped:** 03W

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100497 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**TRYPTANOL (Other drug)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:** 30Y

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

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** 50D

## Laboratory Investigations:

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

## Additional Information:

Patient was on tryptanol for 30 years - stopped abruptly before starting aropax 20.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100498 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 31/07/1994 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100499 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis<br>Tremor | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Patient had similar reaction to tryptanol.

## Report Detail

**Case Number:** 100500 **Seq:** 1 **Gender:** M
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100501 **Seq:** 1 **Gender:** M
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 100503 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Amenorrhoea<br>Galactorrhoea | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100505 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

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

## Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100508 **Seq:** 1 **Gender:** U
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detai

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

### Medicine Details:

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

**TEGRETOL (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100512 **Seq:** 1 **Gender:** U
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100513 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:** 22Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Visual disturbance | Severe | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** CONTIN

**HALOPERIDOL (Suspected)** **Reason:** Depression
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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100514 **Seq:** 1 **Gender:** U
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100515 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Parosmia | | Awful smell in nose | |
| Dysgeusia | | Awful taste in mouth | |

### Medicine Details:

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100526 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 100572 **Seq:** 1 **Gender:** F
**Reported:** 03/05/1995 **Weight:** 76.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 28/12/1994 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis<br>Weight increased | | | |

### Medicine Details:

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

**BREVINOR-1 (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 100692 **Seq:** 1 **Gender:** F
**Reported:** 08/05/1995 **Weight:** 85.00
**Hospitalisation:** **Age:**
**Onset Date:** 15/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fatigue | | Sluggish mind and body. | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 15/02/1995 **Stopped:** 01/03/1995

### Laboratory Investigations:

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

### Additional Information:

Patient symptoms occured each day after taking aropax.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

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### Report Detail

**Case Number:** 100706 **Seq:** 1 **Gender:** M
**Reported:** 10/05/1995 **Weight:** 87.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 08/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure<br>Yawning | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/02/1995 **Stopped:** 09/02/1995

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100714 **Seq:** 1 **Gender:** F
**Reported:** 08/05/1995 **Weight:** 56.00
**Hospitalisation:** **Age:** 21Y
**Onset Date:** 01/03/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 13/01/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/03/1995 **Stopped:** 05/04/1995

**COGENTIN (Suspected)** **Reason:**
Tablet 2.0 Milligram Daily Oral
**Batch:** **Started:** 16/08/1994 **Stopped:**

**LITHIUM CARBONATE (Suspected)** **Reason:**
Tablet 1.0 Gram Daily Oral
**Batch:** **Started:** 20/09/1994 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 100714 **Seq:** 1
**Reported:** 08/05/1995
**Hospitalisation:**
**Onset Date:** 01/03/1995
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 56.00
**Age:** 21Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **PIMOZIDE (Suspected)** | | | **Reason:** | |
| Tablet | 4.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | 20/10/1994 | **Stopped:** | |
| **THIORIDAZINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | |
| Tablet | 200.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | 07/12/1992 | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100720 **Seq:** 1 **Gender:** M
**Reported:** 09/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100727 **Seq:** 1 **Gender:** F
**Reported:** 10/05/1995 **Weight:** 55.00
**Hospitalisation:** **Age:** 26Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus<br>Pyrexia<br>Rash erythematous | | | |

## Medicine Details:

**ORAL CONTRACEPTIVE NOS (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram 1 time Oral
**Batch:** **Started:** 26/04/1995 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 100747 **Seq:** 1 **Gender:** F
**Reported:** 11/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depersonalisation<br>Nausea | | Feels "out of it" | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 100792 **Seq:** 1 **Gender:** F
**Reported:** 15/05/1995 **Weight:** 65.00
**Hospitalisation:** **Age:** 27Y
**Onset Date:** 30/03/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Libido decreased | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 26/03/1995 **Stopped:** CONTIN

### Laboratory Investigations:

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

### Additional Information:

Pre-existing depressive syndrome did not include reduced libido.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100830 **Seq:** 1 **Gender:** M
**Reported:** 15/05/1995 **Weight:** 55.00
**Hospitalisation:** **Age:** 33Y
**Onset Date:** 26/03/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Alcohol intolerance<br>Grand mal convulsion | | | |

## Medicine Details:

**ALCOHOL (Other drug)** **Reason:**
Oral application 8.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 25/03/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 21/03/1995 **Stopped:** 26/03/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100831 **Seq:** 1 **Gender:** F
**Reported:** 15/03/1995 **Weight:** 60.00
**Hospitalisation:** **Age:** 30Y
**Onset Date:** 22/01/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Menorrhagia<br>Platelet aggregation abnormal<br>Purpura | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily Oral
**Batch:** **Started:** 21/01/1995 **Stopped:** 27/01/1995

**CLONAZEPAM (Suspected)** **Reason:**
1.0 Milligram Daily Oral
**Batch:** **Started:** 21/01/1995 **Stopped:** 10/02/1995

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 17/12/2002 | Haematology | ( 50-100 ) | 22/01/2007 | <10% | Arachidonic acid 7.5 |
| 17/12/2002 | Haematology | ( 50-100 ) | 22/01/2007 | 10% | Arachidonic acid 7.5 |
| 17/12/2002 | Haematology | ( 50-100 ) | 22/01/2007 | 67% | Arachidonic acid 7.5 |

## Additional Information:

## Report Detail

**Case Number:** 100839 **Seq:** 1 **Gender:** M
**Reported:** 16/05/1995 **Weight:** 70.00
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depersonalisation<br>Tinnitus | | Felt like he was outsde his body.<br>Noises like a cicada in head. | |

## Medicine Details:

**PRIMOTESTON DEPOT (Other drug)** **Reason:**
Injection 0.0 Intramuscular
**Batch:** **Started:** **Stopped:**

**DIABEX (Other drug)** **Reason:**
1.0 Gram Daily
**Batch:** **Started:** **Stopped:**

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100887 **Seq:** 1 **Gender:** F
**Reported:** 18/05/1995 **Weight:** 89.00
**Hospitalisation:** **Age:** 56Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**NORMISON (Other drug)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
50.0 Milligram Daily
**Batch:** **Started:** 01/12/1994 **Stopped:** 01/05/1995

## 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 100953 **Seq:** 1 **Gender:** F
**Reported:** 22/05/1995 **Weight:** 52.00
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 16/05/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Oculogyration | | Eyes staring | |
| Paraesthesia | | Tingling in arms | |
| Dystonia | | | |
| Tremor | | | |

## Medicine Details:

**OESTROGENS NOS (Other drug)** **Reason:** Menopausal symptoms
Implant 0.0 Subcutaneous
**Batch:** **Started:** **Stopped:** CONTIN

**PREMARIN (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 15/05/1995 **Stopped:** 16/05/1995

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 101039 **Seq:** 1 **Gender:** M
**Reported:** 22/05/1995 **Weight:**
**Hospitalisation:** **Age:** 73
**Onset Date:** 28/02/1995 **DOB:** 17/07/1921
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Extrapyramidal disorder | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 13/02/1995 **Stopped:** 23/02/1995

**NEULACTIL (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 28/02/1995

**LITHIUM CARBONATE (Suspected)** **Reason:**
750.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 28/02/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101067 **Seq:** 1 **Gender:** M
**Reported:** 25/05/1995 **Weight:** 84.00
**Hospitalisation:** **Age:** 70Y
**Onset Date:** 04/04/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle spasms | | Cramps in legs | |

### Medicine Details:

**NUELIN (Other drug)** **Reason:**
500.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

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

**LOSEC (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 17/03/1995 **Stopped:** 06/04/1995

### Laboratory Investigations:

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

### Additional Information:

### Report Detail

**Case Number:** 101101 **Seq:** 1 **Gender:** F
**Reported:** 22/05/1995 **Weight:** 57.00
**Hospitalisation:** **Age:** 20Y
**Onset Date:** 21/04/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 10/03/1995 **Stopped:** 28/04/1995

**LITHIUM CARBONATE (Suspected)** **Reason:**

Tablet 1.0 Gram Daily Oral

**Batch:** **Started:** 07/11/1994 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101102 **Seq:** 1 **Gender:** M
**Reported:** 26/05/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 04/05/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain<br>Diarrhoea | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram 1 time Oral

**Batch:** **Started:** 04/05/1995 **Stopped:** 04/05/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101108 **Seq:** 1 **Gender:** F
**Reported:** 22/05/1995 **Weight:** 56.00
**Hospitalisation:** **Age:** 41Y
**Onset Date:** 20/03/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 21/02/1995 **Stopped:** 02/04/1995

**LITHIUM CARBONATE (Suspected)** **Reason:** Depression
Tablet 1.0 Gram Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Serum drug level | | | | Paroxetine serum level on 40mg was 169 mcg/l. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101111 **Seq:** 1 **Gender:** M
**Reported:** 29/05/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 24/05/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**TIMOLOL MALEATE EYE DROPS (Suspected)** **Reason:**
Eye Drops 0.0 Ophthalmic
**Batch:** **Started:** 18/05/1995 **Stopped:**

**ZUCLOPENTHIXOL DECANOATE (Suspected)** **Reason:** Unspecified schizophrenia
Injection 800.0 Milligram Weekly Intramuscular
**Batch:** **Started:** 08/03/1995 **Stopped:**

**LARGACTIL (Suspected)** **Reason:** Unspecified schizophrenia
Oral application 1.2 Gram Daily Oral
**Batch:** **Started:** 08/03/1995 **Stopped:**

**CLONAZEPAM (Suspected)** **Reason:** Otr spec symp psychopathol nec
Oral application 1.0 Milligram Daily Oral
**Batch:** **Started:** 10/04/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 101111 **Seq:** 1 **Gender:** M
**Reported:** 29/05/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 24/05/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Otr spec symp psychopathol nec

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 17/05/1995 **Stopped:**

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101114 **Seq:** 1 **Gender:** F
**Reported:** 29/05/1995 **Weight:**
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 25/05/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination<br>Anxiety<br>Dry mouth | | Vivid visual hallucinations | |

### Medicine Details:

**VALIUM (Other drug)** **Reason:**
Tablet 2.5 Milligram Daily Oral
**Batch:** **Started:** 15/05/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 15/05/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** 09/05/1995 **Stopped:** 15/05/1995

### Laboratory Investigations:

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

### Additional Information:

## Report Detail

**Case Number:** 101154 **Seq:** 1 **Gender:** F
**Reported:** 26/05/1995 **Weight:** 50.00
**Hospitalisation:** **Age:** 78Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Anxiety<br>Delirium | | | |

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **SINEMET (Other drug)** | | | **Reason:** | | |
| Tablet | 3.0 | Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 20.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **AURORIX (Suspected)** | | | **Reason:** | | |
| Tablet | 300.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 101162 **Seq:** 1
**Reported:** 29/05/1995
**Hospitalisation:** Hospitalisation prolonged
**Onset Date:** 30/04/1995
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 82Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Somnolence | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 29/04/1995 **Stopped:** 02/05/1995

**HALOPERIDOL (Suspected)** **Reason:** Otr spec symp psychopathol nec

Oral application 2.5 Milligram Daily Oral
**Batch:** **Started:** 22/04/1995 **Stopped:** 02/05/1995

### Laboratory Investigations:

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

### Additional Information:

## Report Detail

**Case Number:** 101188 **Seq:** 1
**Reported:** 29/05/1995
**Hospitalisation:**
**Onset Date:** 22/05/1995
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 69.00
**Age:** 48Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

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

5.0 Milligram Daily

**Batch:** **Started:** L TERM **Stopped:** CONTIN

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

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 21/04/1995 **Stopped:** 25/05/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101192 **Seq:** 1 **Gender:** M
**Reported:** 26/05/1995 **Weight:** 80.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** 20/04/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome<br>Fatigue<br>Headache | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 10/01/1995 **Stopped:** 20/04/1995

### Laboratory Investigations:

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

### Additional Information:

Similar withdrawal noted after cessation of zoloft.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101193 **Seq:** 1 **Gender:** F
**Reported:** 26/05/1995 **Weight:** 80.00
**Hospitalisation:** **Age:** 33Y
**Onset Date:** 14/04/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia | | Loss of sexual climax | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 20/03/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101200 **Seq:** 1 **Gender:** M
**Reported:** 31/05/1995 **Weight:**
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 31/03/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure<br>Nausea<br>Somnolence | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 14/03/1995 **Stopped:** 26/04/1995

### Laboratory Investigations:

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

### Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101207 **Seq:** 1 **Gender:** F
**Reported:** 31/05/1995 **Weight:**
**Hospitalisation:** **Age:** 33Y
**Onset Date:** 17/01/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Libido decreased | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 10/01/1995 **Stopped:** 24/01/1995

### Laboratory Investigations:

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

### Additional Information:

Prior to aropax, anafranil stopped due to constipation and reduced sex drive.

### Report Detail

**Case Number:** 101209 **Seq:** 1 **Gender:** M
**Reported:** 31/05/1995 **Weight:**
**Hospitalisation:** **Age:** 39Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 06/01/1995 **Stopped:** 07/04/1995

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 07/04/1995 **Stopped:** CONTIN

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 101218 **Seq:** 1
**Reported:** 26/05/1995
**Hospitalisation:**
**Onset Date:** 31/03/1995
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 79.00
**Age:** 63Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypothyroidism | Severe | | Thyroxine |

## Medicine Details:

**LITHICARB (Suspected)** **Reason:** Depression
500.0 Milligram Daily
**Batch:** **Started:** 02/09/1994 **Stopped:** 26/04/1995

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 06/01/1995 **Stopped:** CONTIN

**TOLVON (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/01/1993 **Stopped:** CONTIN

**MELLERIL (Suspected)** **Reason:**
25.0 Milligram Daily
**Batch:** **Started:** 01/01/1993 **Stopped:** 28/04/1995

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Other data | | | | Very high thyroid autoantibodies - tsh 100, t4 2.4. |

## Additional Information:

Patient is recovering. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 101321 **Seq:** 1 **Gender:** F
**Reported:** 05/06/1995 **Weight:** 65.00
**Hospitalisation:** **Age:** 72Y
**Onset Date:** 16/05/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

## Reaction Detail

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

## Medicine Details:

**DYMADON (Other drug)** **Reason:** Headache
0.0 As necessary
**Batch:** **Started:** **Stopped:**

**MURELAX (Other drug)** **Reason:** Anxiety neurosis
15.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**NORVASC (Other drug)** **Reason:** Essential benign hypertension
5.0 Milligram Daily
**Batch:** **Started:** 01/01/1993 **Stopped:**

**OROXINE (Other drug)** **Reason:** Othr&unspec metabolic diseases
50.0 Microgram Daily
**Batch:** **Started:** 01/04/1995 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Patient experienced same reaction with every dose of aropax. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

### Report Detail

**Case Number:** 101321 **Seq:** 1 **Gender:** F
**Reported:** 05/06/1995 **Weight:** 65.00
**Hospitalisation:** **Age:** 72Y
**Onset Date:** 16/05/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **ZANTAC (Other drug)** | | | **Reason:** | Other diseases of esophagus |
| | 150.0 Milligram | Daily | | |
| **Batch:** | **Started:** 01/01/1994 | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression |
| Tablet | 20.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 16/05/1995 | | **Stopped:** | 19/05/1995 |

### Laboratory Investigations:

### Additional Information:

Patient experienced same reaction with every dose of aropax. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 101366 **Seq:** 1 **Gender:** F
**Reported:** 05/06/1995 **Weight:** 103.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 05/05/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urticaria | | | Changed to sertraline. |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 1.0 Dose Unspecified Daily Oral

**Batch:** **Started:** 28/03/1995 **Stopped:** 24/05/1995

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 101472 **Seq:** 1 **Gender:** M
**Reported:** 13/06/1995 **Weight:** 90.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** 23/05/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysuria<br>Ejaculation failure<br>Nausea<br>Somnolence | | Micturition difficult | |

## Medicine Details:

**DIAZEPAM (Other drug)** **Reason:**
15.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 17/05/1995 **Stopped:** 23/05/1995

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 101519 **Seq:** 1 **Gender:** F
**Reported:** 14/06/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis<br>Palpitations | | | Periactin |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Endogenous depression.has had similar reactions on aurorix, prothiaden, zoloft also taking the pill and iron supplement.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101521 **Seq:** 1 **Gender:** F
**Reported:** 14/06/1995 **Weight:** 64.00
**Hospitalisation:** **Age:** 51Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia<br>Constipation<br>Libido decreased<br>Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 24/03/1994 **Stopped:** CONTIN

### Laboratory Investigations:

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

### Additional Information:

Reaction to aropax decreased with decrease of dose to 20 mg and increased with increase to 50 mg. see original report for other drugs.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101522 **Seq:** 1 **Gender:** F
**Reported:** 14/06/1995 **Weight:** 65.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 10/04/1995 **Stopped:** 22/05/1995

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 101525 **Seq:** 1 **Gender:** F
**Reported:** 14/06/1995 **Weight:**
**Hospitalisation:** **Age:** 74Y
**Onset Date:** 14/05/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vaginal haemorrhage | | | |

## Medicine Details:

**PREMARIN (Other drug)** **Reason:**
Tablet 625.0 Microgram Daily Oral
**Batch:** **Started:** **Stopped:**

**PROVERA (Other drug)** **Reason:**
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

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

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/03/1995 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Histology | | | | Hysteroscopy which showed an entirely normal uterus and an endometrial biopsy at the time showed some active endometritis, but only with faily inactive endometrium. |

## Additional Information:

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101536 **Seq:** 1 **Gender:** F
**Reported:** 14/06/1995 **Weight:** 60.00
**Hospitalisation:** **Age:** 47Y
**Onset Date:** 28/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1995 **Stopped:** 28/04/1995

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101538 **Seq:** 1 **Gender:** F
**Reported:** 14/06/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia<br>Nightmare | | | |

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **FLUVAX (Other drug)** | | | **Reason:** | |
| Injection | 0.0 | | | Intramuscular |
| **Batch:** | **Started:** | | **Stopped:** | |
| **NICABATE (Other drug)** | | | **Reason:** | |
| Cream | 0.0 | | | Transdermal |
| **Batch:** | **Started:** 01/01/1995 | | **Stopped:** | 28/04/1995 |
| **ESTRADERM (Other drug)** | | | **Reason:** | |
| Cream | 50.0 Microgram | Daily | | Transdermal |
| **Batch:** | **Started:** 01/01/1994 | | **Stopped:** | 28/01/1995 |
| **AROPAX (Suspected)** | | | **Reason:** | |
| Tablet | 20.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 13/01/1995 | | **Stopped:** | |

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

## Report Detail

**Case Number:** 101540 **Seq:** 1 **Gender:** M
**Reported:** 14/06/1995 **Weight:**
**Hospitalisation:** **Age:** 59Y
**Onset Date:** 31/01/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash maculo-papular<br>Pruritus | | Rash on shoulder | |

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **DIAZEPAM (Other drug)** | | | **Reason:** | | |
| Oral application | 10.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | CONTIN |
| **LORAZEPAM (Other drug)** | | | **Reason:** | | |
| Tablet | 1.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 20.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | 16/12/1994 | | **Stopped:** | 24/02/1995 |
| **AROPAX (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 40.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | 24/02/1995 | | **Stopped:** | 07/03/1995 |

## Laboratory Investigations:

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

## Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101556 **Seq:** 1 **Gender:** U
**Reported:** 15/06/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detai

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

### Medicine Details:

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

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 101560 **Seq:** 1 **Gender:** F
**Reported:** 15/06/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia | | Pins and needles and body goes numb. | |
| Dystonia | | Tongue and jaw go hard | |
| Anorexia | | | |
| Anxiety | | | |
| Fatigue | | | |
| Nausea | | | |
| Tremor | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101595 **Seq:** 1 **Gender:** M
**Reported:** 19/06/1995 **Weight:** 90.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 16/05/1995 **Stopped:** 06/06/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101690 **Seq:** 1 **Gender:** M
**Reported:** 22/06/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tinnitus | | Rushing in ear | |
| Micturition disorder | | Slowing of urine | |
| Urine analysis abnormal | | Urine darker in colour | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101693 **Seq:** 1 **Gender:** F
**Reported:** 22/06/1995 **Weight:** 65.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 28/04/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Neurosis | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 27/04/1995 **Stopped:** 28/04/1995

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

Oral application 150.0 Milligram Daily Oral

**Batch:** **Started:** 23/06/1994 **Stopped:** 23/03/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101695 **Seq:** 1 **Gender:** F
**Reported:** 22/06/1995 **Weight:**
**Hospitalisation:** **Age:** 23Y
**Onset Date:** 01/06/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Meningism<br>Dizziness<br>Drug withdrawal syndrome<br>Nausea | | Stiff neck | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 25/01/1995 **Stopped:** 01/06/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101725 **Seq:** 1 **Gender:** F
**Reported:** 26/06/1995 **Weight:** 55.00
**Hospitalisation:** **Age:** 14Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 12/04/1995 **Stopped:** 30/05/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101759 **Seq:** 1 **Gender:** M
**Reported:** 27/06/1995 **Weight:** 51.00
**Hospitalisation:** **Age:** 79Y
**Onset Date:** 30/05/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Extrapyramidal disorder | | | |

### Medicine Details:

**COVERSYL (Other drug)** **Reason:** Congestive heart failure
Tablet 1.0 Milligram Daily Oral
**Batch:** **Started:** 04/01/1995 **Stopped:** CONTIN

**FELDENE (Other drug)** **Reason:** Osteoarthritis
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**FRUSEMIDE (Other drug)** **Reason:** Congestive heart failure
40.0 Milligram Daily
**Batch:** **Started:** 04/01/1995 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 09/03/1995 **Stopped:** 15/06/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101760 **Seq:** 1 **Gender:** F
**Reported:** 27/06/1995 **Weight:** 45.00
**Hospitalisation:** **Age:** 85Y
**Onset Date:** 29/05/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Extrapyramidal disorder | | | |

### Medicine Details:

**PANADOL (Other drug)** **Reason:** Pain
2.0 Dose Unspecified As necessary
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**RIVOTRIL (Other drug)** **Reason:** Pain
500.0 Microgram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**ADALAT (Other drug)** **Reason:** Angina pectoris w/o hyperten
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**ZANTAC (Other drug)** **Reason:** Other diseases of esophagus
300.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 101760 **Seq:** 1
**Reported:** 27/06/1995
**Hospitalisation:**
**Onset Date:** 29/05/1995
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 45.00
**Age:** 85Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **NORMISON (Other drug)** | | | **Reason:** | Specific disorders of sleep | | |
| | 10.0 | Milligram | Daily | | | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | CONTIN | | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression | | |
| Tablet | 20.0 | Milligram | Daily | Oral | | |
| **Batch:** | **Started:** | 05/05/1995 | **Stopped:** | 31/05/1995 | | |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 101924 **Seq:** 1 **Gender:** F
**Reported:** 03/07/1995 **Weight:**
**Hospitalisation:** **Age:** 37Y
**Onset Date:** 31/01/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperkinesia<br>Anorgasmia<br>Dystonia<br>Micturition disorder<br>Tremor | | Restless feet | |

### Medicine Details:

**ALPRAZOLAM (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 01/01/1995 **Stopped:** 28/06/1995

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 01/01/1995 **Stopped:** 28/06/1995

### Laboratory Investigations:

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

### Additional Information:

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

## Report Detail

**Case Number:** 101933 **Seq:** 1 **Gender:** M
**Reported:** 03/07/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102016 **Seq:** 1 **Gender:** F
**Reported:** 07/07/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 34Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Proctitis<br>Rectal haemorrhage | | | |

## Medicine Details:

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

**MINOCYCLINE HYDROCHLORIDE (Suspected)** **Reason:** Other acne of sebaceous glands
0.0
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Histology<br>Other data | | | | Biopsy: non- specific colitis.<br>Proctitis, rectal haemorrhage revealed on sigmoidoscopy and |

## Additional Information:

Previous history of proctitis and has been on other antidepresssants also.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102017 **Seq:** 1 **Gender:** M
**Reported:** 07/07/1995 **Weight:** 74.00
**Hospitalisation:** **Age:** 41Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperacusis | Required Visit to Doctor | Sensitivity to sounds. | |
| Anxiety | Required Visit to Doctor | | |
| Drug withdrawal syndrome | | | |
| Fatigue | Required Specialist Consultation | | |
| Insomnia | Required Specialist Consultation | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 13/12/1994 **Stopped:** 28/04/1995

### Laboratory Investigations:

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

### Additional Information:

Reaction ocurred after ceasing aropax - symptoms resolved when aropax restarted. patient subsequently able to stop drug. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102017 **Seq:** 1
**Reported:** 07/07/1995
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 74.00
**Age:** 41Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vertigo | Required Visit to Doctor | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 13/12/1994 **Stopped:** 28/04/1995

## Laboratory Investigations:

## Additional Information:

Reaction ocurred after ceasing aropax - symptoms resolved when aropax restarted. patient subsequently able to stop drug. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102139 **Seq:** 1 **Gender:** F
**Reported:** 12/07/1995 **Weight:** 60.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 28/06/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**ASPALGIN (Other drug)** **Reason:** Pain
Tablet 2.0 Dose Unspecified As necessary Oral
**Batch:** **Started:** 01/01/1993 **Stopped:**

**AROPAX (Suspected)** **Reason:** Pain
20.0 Milligram Daily
**Batch:** **Started:** 28/06/1995 **Stopped:** 03/07/1995

### Laboratory Investigations:

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

### Additional Information:

Previous exposure to prothiadene with same effect. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102158 **Seq:** 1 **Gender:** F
**Reported:** 13/07/1995 **Weight:** 62.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 06/03/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle twitching<br>Thirst | | | |

## Medicine Details:

**METHOTREXATE (Other drug)** **Reason:**
Tablet 12.0 Milligram Weekly Oral
**Batch:** **Started:** 01/01/1993 **Stopped:**

**PREDNISOLONE (Other drug)** **Reason:**
Oral application 5.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1989 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 04/03/1995 **Stopped:** 10/03/1995

## Laboratory Investigations:

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

## Additional Information:

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102159 **Seq:** 1 **Gender:** M
**Reported:** 13/07/1995 **Weight:**
**Hospitalisation:** **Age:** 53Y
**Onset Date:** **DOB:**
**Outcome:** Recovered with sequelae **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tooth disorder | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** 16/08/1994 **Stopped:** 13/06/1995

### Laboratory Investigations:

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

### Additional Information:

Patient complained of cracked teeth since taking aropax 20mg/day. fillings replaced 04/05/1995 and 18/05/95.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102162 **Seq:** 1 **Gender:** F
**Reported:** 13/07/1995 **Weight:** 50.00
**Hospitalisation:** **Age:** 74Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**CARDIPRIN 100 (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**BETALOC (Other drug)** **Reason:** Essential benign hypertension
Tablet 25.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**SEREPAX (Other drug)** **Reason:**
7.5 Milligram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/02/1995 **Stopped:** 2W

## 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102186 **Seq:** 1 **Gender:** M
**Reported:** 17/07/1995 **Weight:** 83.00
**Hospitalisation:** **Age:** 64Y
**Onset Date:** 25/02/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 02/02/1995 **Stopped:** 23/02/1995

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102221 **Seq:** 1 **Gender:** F
**Reported:** 17/07/1995 **Weight:** 67.00
**Hospitalisation:** **Age:** 27Y
**Onset Date:** 10/07/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Bruxism | | Teeth chattering and tight jaw muscles. | |

## Medicine Details:

**LITHICARB (Other drug)** **Reason:** Manic-depression psycho,manic
3.0 Dose Unspecified Daily
**Batch:** **Started:** 22/06/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** 10/07/1995 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102222 **Seq:** 1 **Gender:** M
**Reported:** 19/07/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 08/07/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety<br>Disturbance in attention | | Nerves on edge | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 06/07/1995 **Stopped:** 11/07/1995

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102260 **Seq:** 1 **Gender:** M
**Reported:** 19/07/1995 **Weight:** 66.00
**Hospitalisation:** **Age:** 58Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

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

**CYCLOSPORIN-A (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**DILTIAZEM HYDROCHLORIDE (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

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

## Laboratory Investigations:

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

## Additional Information:

History of allergy to prothiaden.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102260 **Seq:** 1 **Gender:** M
**Reported:** 19/07/1995 **Weight:** 66.00
**Hospitalisation:** **Age:** 58Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

## Additional Information:

History of allergy to prothiaden.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102261 **Seq:** 1 **Gender:** F
**Reported:** 19/07/1995 **Weight:** 60.00
**Hospitalisation:** **Age:** 19Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Oculogyration | | Eyes rolled up | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

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

## Laboratory Investigations:

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

## Additional Information:

Simmilar reaction occured with halloperidol in past.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102262 **Seq:** 1 **Gender:** F
**Reported:** 19/07/1995 **Weight:**
**Hospitalisation:** **Age:** 47Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

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

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1995 **Stopped:**

## 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.

### Report Detail

**Case Number:** 102263 **Seq:** 1 **Gender:** F
**Reported:** 19/07/1995 **Weight:** 50.00
**Hospitalisation:** **Age:** 49Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

**Batch:** **Started:** 30/11/1994 **Stopped:** 17/01/1995

### Laboratory Investigations:

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

### Additional Information:

## Report Detail

**Case Number:** 102303 **Seq:** 1 **Gender:** F
**Reported:** 20/07/1995 **Weight:** 45.00
**Hospitalisation:** **Age:** 83Y
**Onset Date:** 13/06/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Extrapyramidal disorder | | | |

## Medicine Details:

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

**TEMAZEPAM (Other drug)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 02/06/1995 **Stopped:** 08/06/1995

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 08/06/1995 **Stopped:** 13/06/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102323 **Seq:** 1 **Gender:** F
**Reported:** 21/07/1995 **Weight:** 48.00
**Hospitalisation:** **Age:** 29Y
**Onset Date:** 26/06/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyskinesia | | Repetitive jaw movement causing teeth | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram 1 time Oral

**Batch:** **Started:** 26/06/1995 **Stopped:** 26/06/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102324 **Seq:** 1 **Gender:** F
**Reported:** 21/07/1995 **Weight:**
**Hospitalisation:** **Age:** 41Y
**Onset Date:** 12/07/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea<br>Flatulence<br>Nausea<br>Thinking abnormal | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram 1 time Oral

**Batch:** **Started:** 12/07/1995 **Stopped:** 12/07/1995

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102327 **Seq:** 1 **Gender:** F
**Reported:** 21/07/1995 **Weight:** 55.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 28/06/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome<br>Vertigo | | | |

## Medicine Details:

**MICROGYNON 30 ED (Other drug)** **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Othr&unspec metabolic diseases
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 27/03/1995 **Stopped:** 24/06/1995

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102328 **Seq:** 1 **Gender:** M
**Reported:** 21/07/1995 **Weight:** 98.00
**Hospitalisation:** **Age:** 51Y
**Onset Date:** 01/07/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**PANADEINE FORTE (Other drug)** **Reason:** Lumbalgia
2.0 Dose Unspecified As necessary
**Batch:** **Started:** 01/01/1990 **Stopped:**

**SEREPAX (Other drug)** **Reason:** Anxiety neurosis
30.0 Milligram Daily
**Batch:** **Started:** 01/01/1990 **Stopped:**

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

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

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102330 **Seq:** 1 **Gender:** F
**Reported:** 21/07/1995 **Weight:** 75.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 29/04/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Erythema multiforme<br>Lymphadenopathy<br>Myalgia<br>Rash maculo-papular | | | |

## Medicine Details:

**OROXINE (Other drug)** **Reason:**
Tablet 115.0 Microgram Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Othr&unspec metabolic diseases
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1995 **Stopped:** 29/04/1995

## 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102335 **Seq:** 1 **Gender:** M
**Reported:** 24/07/1995 **Weight:**
**Hospitalisation:** **Age:** 87Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia<br>Nightmare | | | Serepax. |

## Medicine Details:

**TAGAMET (Suspected)** **Reason:** Peptic ulcer nos w/o ment perf
Tablet 600.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1988 **Stopped:** 28/05/1995

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 12/04/1995 **Stopped:** 06/07/1995

## 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102407 **Seq:** 1 **Gender:** M
**Reported:** 26/07/1995 **Weight:** 80.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 08/06/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Erectile dysfunction | | | |

### Medicine Details:

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

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

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/06/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102445 **Seq:** 1
**Reported:** 28/07/1995
**Hospitalisation:**
**Onset Date:** 16/07/1995
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 65.00
**Age:** 66Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Diarrhoea<br>Speech disorder<br>Tremor | | | |

## Medicine Details:

**ISOPTIN SR (Other drug)** **Reason:** Otr&nos disord of heart rhythm
240.0 Milligram Daily
**Batch:** **Started:** 01/01/1988 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 10/07/1995 **Stopped:** 17/07/1995

## 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102457 **Seq:** 1 **Gender:** F
**Reported:** 28/07/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 29Y
**Onset Date:** 07/06/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 11/10/1994 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

## Report Detail

**Case Number:** 102458 **Seq:** 1 **Gender:** F
**Reported:** 28/07/1995 **Weight:**
**Hospitalisation:** **Age:** 36Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**MICROLUT (Other drug)** **Reason:** Contraception
Tablet 30.0 Microgram Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1995 **Stopped:**

## 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102479 **Seq:** 1 **Gender:** F
**Reported:** 31/07/1995 **Weight:** 84.00
**Hospitalisation:** **Age:** 69Y
**Onset Date:** 19/07/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache<br>Palpitations | | | |

### Medicine Details:

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

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

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102582 **Seq:** 1 **Gender:** U
**Reported:** 01/08/1995 **Weight:** 65.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle contractions involuntary | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

**Batch:** **Started:** 01/06/1995 **Stopped:**

### 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.

## Report Detail

**Case Number:** 102600 **Seq:** 1 **Gender:** F
**Reported:** 02/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Hyperhidrosis | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102601 **Seq:** 1 **Gender:** M
**Reported:** 02/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Hallucination<br>Tachycardia | | | |

## Medicine Details:

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

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 23/07/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102605 **Seq:** 1 **Gender:** F
**Reported:** 03/08/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 41Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Euphoric mood<br>Hallucination<br>Psychotic disorder | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram 1 time Oral

**Batch:** **Started:** 01/09/1994 **Stopped:** 28/09/1994

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102670 **Seq:** 1 **Gender:** F
**Reported:** 07/08/1995 **Weight:**
**Hospitalisation:** **Age:** 65Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 30/03/1995 **Stopped:** 21/04/1995

## Laboratory Investigations:

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

## Additional Information:

Patient was rechallenged on aropax with reaction occurring again.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102671 **Seq:** 1 **Gender:** F
**Reported:** 07/08/1995 **Weight:**
**Hospitalisation:** **Age:** 65Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vaginal infection | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 06/05/1995 **Stopped:** 06/07/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102672 **Seq:** 1 **Gender:** M
**Reported:** 07/08/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 68Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Amnesia<br>Confusional state<br>Drug withdrawal syndrome | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 10/02/1995 **Stopped:** 29/05/1995

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102675 **Seq:** 1 **Gender:** F
**Reported:** 07/08/1995 **Weight:** 55.00
**Hospitalisation:** **Age:** 61Y
**Onset Date:** 18/07/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Syncope | | | |

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **CYANOCOBALAMIN (Other drug)** | | | **Reason:** | |
| Injection | 0.0 | | | Intravenous |
| **Batch:** | **Started:** | | | **Stopped:** |
| **ASIG (Other drug)** | | | **Reason:** | |
| Tablet | 10.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **OROXINE (Other drug)** | | | **Reason:** | |
| Tablet | 200.0 | Microgram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **PREMARIN (Other drug)** | | | **Reason:** | |
| Tablet | 200.0 | Microgram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 102675 **Seq:** 1 **Gender:** F
**Reported:** 07/08/1995 **Weight:** 55.00
**Hospitalisation:** **Age:** 61Y
**Onset Date:** 18/07/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **AROPAX (Suspected)** | | | **Reason:** | |
| Tablet | 20.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |

### Laboratory Investigations:

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102676 **Seq:** 1 **Gender:** F
**Reported:** 07/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | | | Panadol, panadeine, aspirin, deseril, periactin, ergodryl, |

## Medicine Details:

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

## Laboratory Investigations:

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

## Additional Information:

Reaction to aropax occurs after taking dose and improves by the time the next dose is due, but they don't fully resolve.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102677 **Seq:** 1 **Gender:** M
**Reported:** 07/08/1995 **Weight:** 80.00
**Hospitalisation:** **Age:** 65Y
**Onset Date:** 16/06/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia<br>Dyspnoea<br>Hypoaesthesia | | | |

### Medicine Details:

**MOGADON (Other drug)** **Reason:**
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**QUINATE (Other drug)** **Reason:**
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram 1 time Oral
**Batch:** **Started:** 16/06/1995 **Stopped:** 16/06/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102678 **Seq:** 1 **Gender:** F
**Reported:** 07/08/1995 **Weight:** 82.00
**Hospitalisation:** **Age:** 30Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sensory disturbance<br>Visual disturbance | | Electric shock like feeling in head. | Changed to zoloft. |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 07/07/1994 **Stopped:** 11/10/1994

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102730 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 11/01/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorexia<br>Dry mouth<br>Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 28/11/1994 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102731 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 40.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102735 **Seq:** 1 **Gender:** M
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis<br>Libido decreased | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102737 **Seq:** 1 **Gender:** M
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 102738 **Seq:** 1 **Gender:** M
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Photosensitivity reaction | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

### Laboratory Investigations:

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

### Additional Information:

History of allergy to tetracycline - photosensitivity.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102739 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | | | |

## Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102740 **Seq:** 1 **Gender:** M
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Constipation<br>Dry mouth<br>Muscle twitching<br>Tremor | | | |

### Medicine Details:

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

### Laboratory Investigations:

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

### Additional Information:

### Report Detail

**Case Number:** 102741 **Seq:** 1 **Gender:** M
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure<br>Insomnia | | | |

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **AROPAX (Suspected)** | | | **Reason:** | |
| Tablet | 20.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **AROPAX (Suspected)** | | | **Reason:** | |
| Tablet | 40.0 | 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102743 **Seq:** 1 **Gender:** M
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

### Medicine Details:

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102744 **Seq:** 1 **Gender:** M
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102745 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:** A7
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102746 **Seq:** 1 **Gender:** M
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 17/03/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 16/03/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102747 **Seq:** 1 **Gender:** U
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ageusia<br>Chills | | | |

## Medicine Details:

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

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 102748 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:** AD
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Breast enlargement<br>Metrorrhagia | | | |

## Medicine Details:

**RIVOTRIL (Suspected)** **Reason:**

0.0

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

**AROPAX (Suspected)** **Reason:**

Tablet 30.0 Milligram Daily Oral

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102751 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1995 **Weight:** 52.00
**Hospitalisation:** **Age:** 51Y
**Onset Date:** 23/03/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorexia | | | |
| Asthenia | | | |
| Chest pain | | | |
| Diarrhoea | | | |
| Dizziness | | | |
| Fatigue | | | |
| Insomnia | | | |
| Nausea | | | |
| Pyrexia | | | |
| Vomiting | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 1.0 Dose Unspecified 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102753 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1995 **Weight:** 60.00
**Hospitalisation:** **Age:** 60
**Onset Date:** **DOB:** 27/11/1934
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthralgia<br>Mania<br>Myalgia | | | |

### Medicine Details:

**FELDENE (Other drug)** **Reason:**
Capsule 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**PREMARIN (Other drug)** **Reason:**
Tablet 625.0 Microgram Daily Oral
**Batch:** **Started:** **Stopped:**

**SIMVASTATIN (Other drug)** **Reason:**
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**TEMAZEPAM (Other drug)** **Reason:**
Oral application 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

## Report Detail

**Case Number:** 102753 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1995 **Weight:** 60.00
**Hospitalisation:** **Age:** 60
**Onset Date:** **DOB:** 27/11/1934
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **TOFRANIL (Other drug)** | | | **Reason:** | | |
| Tablet | 75.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 20.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 01/10/1994 | | **Stopped:** | 28/02/1995 |

## Laboratory Investigations:

## Additional Information:

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

## Report Detail

**Case Number:** 102755 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:** 63
**Onset Date:** **DOB:** 06/12/1931
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea | Severe | | |

## Medicine Details:

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

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram 1 time Oral
**Batch:** **Started:** 19/04/1995 **Stopped:** 20/04/1995

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102756 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia<br>Dysuria<br>Extrasystoles<br>Hyperhidrosis<br>Tremor | | | |

## Medicine Details:

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

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102758 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:** 60Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome<br>Nausea | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Other&unspecified epilepsy
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 28/12/1994 **Stopped:** 20/07/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102759 **Seq:** 1 **Gender:** M
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:** 77Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fatigue<br>Hypertonia | | | |

### Medicine Details:

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

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

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

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

### Laboratory Investigations:

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

### Additional Information:

Patient experiences same reaction after each dose of aropax 20.

### Report Detail

**Case Number:** 102759 **Seq:** 1 **Gender:** M
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:** 77Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

### Reaction Detai

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **ZANTAC (Other drug)** | | | **Reason:** | |
| | 0.0 | | | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **AROPAX (Suspected)** | | | **Reason:** | |
| Tablet | 40.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |

### Laboratory Investigations:

### Additional Information:
Patient experiences same reaction after each dose of aropax 20.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102778 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:** 48Y
**Onset Date:** 28/07/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Angioedema | | | Icu, hydrocortisone, adrenaline. |

### Medicine Details:

**ENALAPRIL MALEATE (Suspected)** **Reason:** Essential benign hypertension
5.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**STELAZINE (Suspected)** **Reason:** Depression
2.0 Milligram Daily
**Batch:** **Started:** 27/07/1995 **Stopped:** 28/07/1995

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 27/07/1995 **Stopped:** 28/07/1995

**PREMARIN (Suspected)** **Reason:** Menopausal symptoms
1.2 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

### Laboratory Investigations:

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

### Additional Information:

Patient had reaction to morphine= difficulty breathing.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102796 **Seq:** 1 **Gender:** U
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | Severe | | |
| Nausea | Severe | | |
| Vomiting | Severe | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102797 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 102798 **Seq:** 1 **Gender:** U
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102799 **Seq:** 1 **Gender:** U
**Reported:** 09/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cardiac arrest<br>Electrocardiogram QT prolonged<br>Torsade de pointes | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** 3M

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102808 **Seq:** 1 **Gender:** F
**Reported:** 11/08/1995 **Weight:** 62.00
**Hospitalisation:** **Age:** 47Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 01/05/1995 **Stopped:**

**PROZAC (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1994 **Stopped:** 28/04/1995

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 102904 **Seq:** 1 **Gender:** F
**Reported:** 16/08/1995 **Weight:**
**Hospitalisation:** **Age:** 34Y
**Onset Date:** 11/08/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | | Diazepam 5mg, cogentin 1mg |

### Medicine Details:

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

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

**FENTANYL CITRATE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103028 **Seq:** 1
**Reported:** 22/08/1995
**Hospitalisation:** Admitted to hospital
**Onset Date:** 01/08/1995
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 96.00
**Age:** 51Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura Thrombocytopenia | | | Prednisolone |

## Medicine Details:

**DOXYCYCLINE HYDROCHLORIDE (Suspected)** **Reason:** Other diseases of lung
Oral application 0.0 Daily Oral
**Batch:** **Started:** **Stopped:** 1W

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 19/06/1995 **Stopped:** 14/08/1995

**ERYTHROMYCIN (Suspected)** **Reason:** Other diseases of lung
Oral application 0.0 Daily Oral
**Batch:** **Started:** **Stopped:** 1W

**CEPHALEXIN (Suspected)** **Reason:** Other diseases of lung
Oral application 0.0 Daily Oral
**Batch:** **Started:** **Stopped:** 2D

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Platelets | | | | Platelet count on admission 21 x 109/l. at discharge after treatment with prednisolone platelet-67 x 109/l. |

## Additional Information:

Tonic water 1 drink daily.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103050 **Seq:** 1
**Reported:** 23/08/1995
**Hospitalisation:** Admitted to hospital
**Onset Date:** 25/07/1995
**Outcome:** Recovered

**Gender:** M
**Weight:**
**Age:** 67Y
**DOB:**
**Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion<br>Tremor | | | |

## Medicine Details:

**CYPROTERONE ACETATE (Other drug)** **Reason:** Malignant neoplasm of prostate
0.0
**Batch:** **Started:** L TERM **Stopped:**

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

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/05/1995 **Stopped:**

## 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103055 **Seq:** 1 **Gender:** M
**Reported:** 28/08/1995 **Weight:** 118.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination<br>Drug withdrawal syndrome<br>Hyperhidrosis<br>Nightmare | | Hypnagogic hallucinations-as if | |

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 28/02/1995

**DOXEPIN HYDROCHLORIDE (Suspected)** **Reason:**
25.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 28/02/1995

## Laboratory Investigations:

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

## Additional Information:

Reaction occured two days after ceasing paroxetine and resolved when restared paroxetine again. two days later, less than 24 hours after ceasing doxepin, similar phenomena for 3 days, resolved when restarted doxepin. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103098 **Seq:** 1 **Gender:** F
**Reported:** 28/08/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 20/12/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis<br>Insomnia<br>Pruritus<br>Pyrexia<br>Rash | | | |

## Medicine Details:

**TEMAZEPAM (Other drug)** **Reason:**
10.0 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 16/12/1994 **Stopped:** 27/12/1994

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 103251 **Seq:** 1 **Gender:** M
**Reported:** 04/09/1995 **Weight:** 92.00
**Hospitalisation:** **Age:** 67Y
**Onset Date:** 05/08/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**COVERSYL (Other drug)** **Reason:** Essential benign hypertension
Tablet 4.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1994 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 03/08/1995 **Stopped:** 11/08/1995

### 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.

## Report Detail

**Case Number:** 103357 **Seq:** 1 **Gender:** M
**Reported:** 07/09/1995 **Weight:** 49.00
**Hospitalisation:** **Age:** 80Y
**Onset Date:** 24/08/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**DIAZEPAM (Other drug)** **Reason:**
Oral application 4.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**CALCITRIOL (Other drug)** **Reason:** Osteoporosis
Capsule 0.2 Microgram Daily Oral
**Batch:** **Started:** **Stopped:**

**ASPIRIN (Other drug)** **Reason:** Acute,ill-def cerebrovascular disease w/o hyperte
Oral application 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**COLOXYL (Other drug)** **Reason:** Constipation
Tablet 2.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103357 **Seq:** 1 **Gender:** M
**Reported:** 07/09/1995 **Weight:** 49.00
**Hospitalisation:** **Age:** 80Y
**Onset Date:** 24/08/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 17/08/1995 **Stopped:** 24/08/1995

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103414 **Seq:** 1 **Gender:** F
**Reported:** 08/09/1995 **Weight:**
**Hospitalisation:** **Age:** 19Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103415 **Seq:** 1 **Gender:** F
**Reported:** 08/09/1995 **Weight:** 85.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 30/01/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Neurosis<br>Agitation<br>Arthralgia<br>Chest pain<br>Dizziness<br>Drug withdrawal syndrome<br>Nausea<br>Palpitations | | Claustrophobia | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 22/12/1994 **Stopped:** 28/01/1995

### Laboratory Investigations:

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

### Additional Information:

Anxiety disorder, benzodiazepine dependence. was on heavy doses of benzodiazepines and stopped this in june 1995. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103416 **Seq:** 1 **Gender:** M
**Reported:** 08/09/1995 **Weight:**
**Hospitalisation:** **Age:** 62Y
**Onset Date:** 31/07/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Retinal disorder | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/07/1995 **Stopped:** 1M

### Laboratory Investigations:

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

### Additional Information:

- 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103417 **Seq:** 1 **Gender:** F
**Reported:** 08/09/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea | | | |
| Headache | | | |
| Nausea | | | |
| Tinnitus | | | |
| Vomiting | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/01/1995 **Stopped:** 08/08/1995

### 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.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103418 **Seq:** 1 **Gender:** M
**Reported:** 08/09/1995 **Weight:**
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 29/06/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea<br>Urticaria | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 3D

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103422 **Seq:** 1 **Gender:** F
**Reported:** 08/09/1995 **Weight:** 49.00
**Hospitalisation:** **Age:** 27Y
**Onset Date:** 11/08/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia<br>Coordination abnormal<br>Mydriasis<br>Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 10/08/1995 **Stopped:** 23/08/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103423 **Seq:** 1 **Gender:** M
**Reported:** 08/09/1995 **Weight:**
**Hospitalisation:** **Age:** 46
**Onset Date:** **DOB:** 17/04/1949
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 1W

### Laboratory Investigations:

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

### Additional Information:

## Report Detail

**Case Number:** 103425 **Seq:** 1 **Gender:** F
**Reported:** 08/09/1995 **Weight:** 50.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain | Severe | | |
| Insomnia | | | |
| Nausea | Severe | | |

## Medicine Details:

**BECOTIDE (Other drug)** **Reason:**
Inhalation 8.0 Dose Unspecified Daily Inhalation
**Batch:** **Started:** **Stopped:**

**RIVOTRIL (Other drug)** **Reason:**
1.5 Milligram Daily
**Batch:** **Started:** **Stopped:**

**THEO-DUR (Other drug)** **Reason:**
Tablet 600.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**VENTOLIN (Other drug)** **Reason:**
Inhalation 8.0 Dose Unspecified Daily Inhalation
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103425 **Seq:** 1 **Gender:** F
**Reported:** 08/09/1995 **Weight:** 50.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| AROPAX (Suspected) | | | Reason: | |
|---|---|---|---|---|
| Tablet | 40.0 | Milligram | Daily | Oral |
| Batch: | Started: | | Stopped: | |

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103426 **Seq:** 1 **Gender:** F
**Reported:** 08/09/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 31/05/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/04/1995 **Stopped:** 1M

## Laboratory Investigations:

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

## Additional Information:

- 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.

### Report Detail

**Case Number:** 103429 **Seq:** 1 **Gender:** F
**Reported:** 08/09/1995 **Weight:** 60.00
**Hospitalisation:** **Age:** 16Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis<br>Leukopenia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 12M

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103452 **Seq:** 1 **Gender:** F
**Reported:** 11/09/1995 **Weight:** 63.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 03/09/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 01/04/1995 **Stopped:** 03/09/1995

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103500 **Seq:** 1 **Gender:** M
**Reported:** 12/09/1995 **Weight:** 50.00
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 08/09/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis<br>Somnolence<br>Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/04/1995 **Stopped:** 18/08/1995

### 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103606 **Seq:** 1 **Gender:** F
**Reported:** 18/09/1995 **Weight:**
**Hospitalisation:** **Age:** 37Y
**Onset Date:** 31/07/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Dizziness<br>Drug withdrawal syndrome<br>Nausea<br>Palpitations<br>Tinnitus | | | Temazepam |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/02/1995 **Stopped:**

## 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103607 **Seq:** 1 **Gender:** F
**Reported:** 18/09/1995 **Weight:** 65.00
**Hospitalisation:** **Age:** 45
**Onset Date:** **DOB:** 21/07/1950
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Blepharospasm<br>Yawning | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 09/03/1995 **Stopped:** 18/04/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103610 **Seq:** 1 **Gender:** M
**Reported:** 18/09/1995 **Weight:** 76.00
**Hospitalisation:** **Age:** 70Y
**Onset Date:** 20/07/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

0.0

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103657 **Seq:** 1 **Gender:** M
**Reported:** 21/09/1995 **Weight:**
**Hospitalisation:** **Age:** 48Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Therapeutic response unexpecte<br>Tinnitus | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 21/06/1995 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Hair regrowth on bald scalp.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103695 **Seq:** 1 **Gender:** F
**Reported:** 25/09/1995 **Weight:**
**Hospitalisation:** **Age:** 60Y
**Onset Date:** 18/09/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 18/09/1995 **Stopped:** 21/09/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103707 **Seq:** 1 **Gender:** M
**Reported:** 26/09/1995 **Weight:**
**Hospitalisation:** **Age:** 24Y
**Onset Date:** 18/09/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dry mouth<br>Somnolence | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 11/09/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103828 **Seq:** 1 **Gender:** F
**Reported:** 03/10/1995 **Weight:**
**Hospitalisation:** **Age:** 69Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 06M

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103829 **Seq:** 1 **Gender:** F
**Reported:** 03/10/1995 **Weight:** 60.00
**Hospitalisation:** **Age:** 36Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depersonalisation<br>Drug withdrawal syndrome<br>Hyperhidrosis<br>Libido decreased<br>Tinnitus | Severe | Floaty, disjointed physical feeling | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/12/1994 **Stopped:** 28/07/1995

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103830 **Seq:** 1 **Gender:** F
**Reported:** 03/10/1995 **Weight:** 80.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 31/12/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pain | | Feeling of electric shock. | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/06/1994 **Stopped:** 28/05/1995

### Laboratory Investigations:

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

### Additional Information:

- 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103831 **Seq:** 1 **Gender:** M
**Reported:** 03/10/1995 **Weight:**
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 09/07/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dry skin | | Dryness, rash at back of ankles | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 03/07/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

## Report Detail

**Case Number:** 103855 **Seq:** 1 **Gender:** M
**Reported:** 05/10/1995 **Weight:** 85.00
**Hospitalisation:** **Age:** 69Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysuria<br>Micturition disorder<br>Penis disorder<br>Pollakiuria<br>Urethral disorder<br>Urinary incontinence | | | Noroxin. |

## Medicine Details:

**SIMVASTATIN (Other drug)** **Reason:** Othr&unspec metabolic diseases
20.0 Milligram Daily
**Batch:** **Started:** 01/01/1994 **Stopped:**

**DILTIAZEM HYDROCHLORIDE (Other drug)** **Reason:** Chron isch heart dis no hyper
Oral application 270.0 Milligram Daily Oral
**Batch:** **Started:** 01/04/1995 **Stopped:**

**ATENOLOL (Other drug)** **Reason:** Chron isch heart dis no hyper
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** 01/04/1995 **Stopped:**

**IMDUR (Other drug)** **Reason:** Chron isch heart dis no hyper
Oral application 120.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1993 **Stopped:**

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

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103855 **Seq:** 1 **Gender:** M
**Reported:** 05/10/1995 **Weight:** 85.00
**Hospitalisation:** **Age:** 69Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **ASPIRIN (Other drug)** | | | **Reason:** | Chron isch heart dis no hyper |
| Oral application | 100.0 Milligram | | Daily | Oral |
| **Batch:** | **Started:** 01/01/1993 | | | **Stopped:** |
| **DILANTIN (Other drug)** | | | **Reason:** | |
| Oral application | 200.0 Milligram | | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | Depression |
| Tablet | 20.0 Milligram | | Daily | Oral |
| **Batch:** | **Started:** 01/04/1995 | | | **Stopped:** 20/09/1995 |

## Laboratory Investigations:

## Additional Information:

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

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103924 **Seq:** 1 **Gender:** F
**Reported:** 09/10/1995 **Weight:** 80.00
**Hospitalisation:** **Age:** 77Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Delusion<br>Hallucination<br>Psychotic disorder | | | |

## Medicine Details:

**LOSEC (Suspected)** **Reason:** Ulcer of duodenum w/o ment perf
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 28/05/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/02/1995 **Stopped:**

## 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103928 **Seq:** 1 **Gender:** F
**Reported:** 06/10/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 67Y
**Onset Date:** 15/09/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **PREMARIN (Other drug)** | | | **Reason:** | Menopausal symptoms |
| Tablet | 625.0 | Microgram | Daily | Oral |
| **Batch:** | **Started:** | 01/01/1993 | **Stopped:** | |
| **PROVERA (Other drug)** | | | **Reason:** | Menopausal symptoms |
| Tablet | 5.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | 01/01/1993 | **Stopped:** | |
| **DUCENE (Other drug)** | | | **Reason:** | Anxiety neurosis |
| Tablet | 2.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression |
| Tablet | 20.0 | Milligram | Daily | Oral |
| **Batch:** | **Started:** | 08/09/1995 | **Stopped:** | 30/09/1995 |

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

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 103960 **Seq:** 1 **Gender:** F
**Reported:** 09/10/1995 **Weight:**
**Hospitalisation:** **Age:** 33Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia<br>Libido decreased | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 20/09/1995 **Stopped:** 04/10/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 103973 **Seq:** 1 **Gender:** F
**Reported:** 11/10/1995 **Weight:** 75.00
**Hospitalisation:** **Age:** 41Y
**Onset Date:** 10/08/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 01/03/1995 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Eosinophils | | 10/08/1995 | 2.01 | |
| | Eosinophils | | 26/09/1995 | 0.96 | |

### Additional Information:

### Report Detail

**Case Number:** 104015 **Seq:** 1 **Gender:** F
**Reported:** 12/10/1995 **Weight:**
**Hospitalisation:** **Age:** 24Y
**Onset Date:** 21/09/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Face oedema | | | |

### Medicine Details:

**NORDETTE NOS (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 3D

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 104072 **Seq:** 1 **Gender:** F
**Reported:** 16/10/1995 **Weight:** 71.00
**Hospitalisation:** **Age:** 34Y
**Onset Date:** 25/09/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 0.0 Oral
**Batch:** **Started:** 14/08/1995 **Stopped:** 04/10/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 104242 **Seq:** 1 **Gender:** F
**Reported:** 27/10/1995 **Weight:**
**Hospitalisation:** **Age:** 32
**Onset Date:** **DOB:** 20/09/1963
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Electrocardiogram abnormal<br>Extrasystoles | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 02/06/1995 **Stopped:** 04/10/1995

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electrocardiograph | | | | Ecg changes -st/t changes nonspecific plus atrial |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 104252 **Seq:** 1 **Gender:** F
**Reported:** 27/10/1995 **Weight:** 53.00
**Hospitalisation:** **Age:** 21Y
**Onset Date:** 01/04/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary incontinence | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** 22/02/1995 **Stopped:** 22/04/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 104269 **Seq:** 1 **Gender:** F
**Reported:** 30/10/1995 **Weight:** 81.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 31/08/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura<br>Hepatosplenomegaly | | Bleeding and bruising. | |

### Medicine Details:

**ATIVAN (Other drug)** **Reason:**
Tablet 0.5 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**CISAPRIDE (Other drug)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

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

**LOSEC (Other drug)** **Reason:**
Capsule 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | GGT = SGGT = | | | | Ggt - 51, improved after sertraline was ceased - 36. esr - 17. |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104269 **Seq:** 1
**Reported:** 30/10/1995
**Hospitalisation:**
**Onset Date:** 31/08/1995
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 81.00
**Age:** 50Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **SERTRALINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | |
| | 0.0 | | | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | |
| Tablet | 20.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 11/04/1995 | | **Stopped:** | 11/09/1995 |

## Laboratory Investigations:

## Additional Information:

### Report Detail

**Case Number:** 104273 **Seq:** 1
**Reported:** 30/10/1995
**Hospitalisation:**
**Onset Date:** 12/10/1995
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 75.00
**Age:** 55Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Eczema<br>Rash | | | |

### Medicine Details:

**SEREPAX (Other drug)** **Reason:** Anxiety neurosis
2.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 09/10/1995 **Stopped:** 23/10/1995

### Laboratory Investigations:

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

### Additional Information:

### Report Detail

**Case Number:** 104303 **Seq:** 1 **Gender:** M
**Reported:** 31/10/1995 **Weight:**
**Hospitalisation:** **Age:** 45
**Onset Date:** 31/07/1995 **DOB:** 04/10/1949
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
10.0 Milligram Daily
**Batch:** **Started:** 01/07/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

- 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104304 **Seq:** 1 **Gender:** F
**Reported:** 31/10/1995 **Weight:** 62.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 21/09/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Micturition disorder<br>Urinary incontinence | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

**Batch:** **Started:** 18/08/1995 **Stopped:** 04/10/1995

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104306 **Seq:** 1 **Gender:** M
**Reported:** 31/10/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104320 **Seq:** 1 **Gender:** F
**Reported:** 30/10/1995 **Weight:** 52.00
**Hospitalisation:** **Age:** 30Y
**Onset Date:** 20/10/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorexia<br>Anxiety<br>Insomnia<br>Nausea | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 19/10/1995 **Stopped:** 27/10/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 104407 **Seq:** 1 **Gender:** F
**Reported:** 02/11/1995 **Weight:**
**Hospitalisation:** **Age:** 40Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/08/1995 **Stopped:**

### 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.

## Report Detail

**Case Number:** 104438 **Seq:** 1 **Gender:** F
**Reported:** 03/11/1995 **Weight:**
**Hospitalisation:** **Age:** 70Y
**Onset Date:** 01/02/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia<br>Insomnia<br>Libido increased | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/11/1994 **Stopped:** 16/10/1995

**LORAZEPAM (Suspected)** **Reason:** Anxiety neurosis
Tablet 1.5 Milligram Daily Oral
**Batch:** **Started:** 01/11/1994 **Stopped:** 16/10/1995

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

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104675 **Seq:** 1 **Gender:** F
**Reported:** 17/11/1995 **Weight:** 58.00
**Hospitalisation:** **Age:** 29
**Onset Date:** **DOB:** 03/11/1966
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 22/08/1995 **Stopped:** 28/10/1995

## Laboratory Investigations:

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

## Additional Information:

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 104692 **Seq:** 1 **Gender:** F
**Reported:** 17/11/1995 **Weight:**
**Hospitalisation:** **Age:** 34Y
**Onset Date:** 01/11/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anhidrosis<br>Anxiety<br>Insomnia<br>Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
60.0 Milligram Daily
**Batch:** **Started:** 01/10/1995 **Stopped:**

### 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104693 **Seq:** 1 **Gender:** F
**Reported:** 17/11/1995 **Weight:** 73.00
**Hospitalisation:** **Age:** 20Y
**Onset Date:** 28/09/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash maculo-papular<br>Dizziness<br><br><br>Pruritus | <br>Required Specialist Consultation | Over body | |

## Medicine Details:

**DOTHIEPIN HYDROCHLORIDE (Other drug)** **Reason:** Specific disorders of sleep
25.0 Milligram Daily
**Batch:** **Started:** 28/08/1995 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 21/09/1995 **Stopped:** 28/09/1995

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 104706 **Seq:** 1 **Gender:** F
**Reported:** 20/11/1995 **Weight:** 55.00
**Hospitalisation:** **Age:** 54Y
**Onset Date:** 15/09/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | | |
| Dizziness | | | |
| Dry mouth | | | |
| Dysgeusia | | | |
| Dystonia | | | |
| Nausea | | | |
| Paraesthesia | | | |
| Tremor | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 15/09/1995 **Stopped:** 15/09/1995

**CLOMIPRAMINE HYDROCHLORIDE (Suspected)** **Reason:**
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 13/09/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 104709 **Seq:** 1 **Gender:** M
**Reported:** 20/11/1995 **Weight:**
**Hospitalisation:** **Age:** 58
**Onset Date:** **DOB:** 08/11/1937
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Erectile dysfunction | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 04/09/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 104725 **Seq:** 1 **Gender:** F
**Reported:** 21/11/1995 **Weight:** 87.00
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 28/10/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Hyperhidrosis<br>Hypertonia<br>Nausea<br>Throat tightness | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
20.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 104730 **Seq:** 1 **Gender:** F
**Reported:** 21/11/1995 **Weight:** 70.00
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 13/04/1995 **Stopped:** 11/08/1995

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104731 **Seq:** 1 **Gender:** F
**Reported:** 21/11/1995 **Weight:**
**Hospitalisation:** **Age:** 74Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache<br>Constipation<br>Dystonia | | Tightness of forehead | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 2W

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104812 **Seq:** 1 **Gender:** F
**Reported:** 23/11/1995 **Weight:**
**Hospitalisation:** **Age:** 47Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypoaesthesia<br>Paraesthesia<br>Depersonalisation<br>Drug withdrawal syndrome | | Numbness of mouth and lips.<br>Pins and needles of mouth and lips. | |

## Medicine Details:

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

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

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104843 **Seq:** 1
**Reported:** 23/11/1995
**Hospitalisation:**
**Onset Date:** 05/09/1995
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 90.00
**Age:** 51Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | Delayed ejaculation | |
| Arthralgia | | | |
| Fatigue | | | |
| Flatulence | | | |
| Folliculitis | | | |
| Hyperhidrosis | | | |
| Myalgia | | | |
| Pruritus | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

**Batch:** **Started:** 29/08/1995 **Stopped:** CONTIN

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104894 **Seq:** 1 **Gender:** F
**Reported:** 28/11/1995 **Weight:**
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 31/10/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | | Nocturnal sweats | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/10/1995 **Stopped:** 28/10/1995

## Laboratory Investigations:

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

## Additional Information:

- 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104921 **Seq:** 1 **Gender:** F
**Reported:** 28/11/1995 **Weight:** 49.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 16/11/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dry mouth<br>Headache<br>Nausea | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 16/11/1995 **Stopped:** 16/11/1995

## Laboratory Investigations:

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

## Additional Information:

Patient died 24/11/95.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104930 **Seq:** 1 **Gender:** F
**Reported:** 29/11/1995 **Weight:** 80.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain | | | |
| Dyspnoea | | | |
| Fatigue | | | |
| Headache | | | |
| Hepatic function abnormal | | | |
| Hyperhidrosis | | | |
| Vomiting | | | |

## Medicine Details:

**PROTHIADEN (Other drug)** **Reason:** Depression
150.0 Milligram Daily
**Batch:** **Started:** 01/03/1995 **Stopped:** CONTIN

**LOSEC (Other drug)** **Reason:** Other diseases of esophagus
20.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**PREMARIN (Other drug)** **Reason:** Menopausal symptoms
625.0 Microgram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:**
Tablet 2.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:** 7D

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | | | | 54 |
| | AST = SGOT | | | | 45 |
| | GGT = SGGT = | | | | 93 |
| | SAP = ALP | | | | 209 |

## Additional Information:

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

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104932 **Seq:** 1
**Reported:** 29/11/1995
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 74.00
**Age:** 17Y
**DOB:**
**Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Dizziness<br>Headache<br>Nausea<br>Syncope | | Paraesthesia of arms and legs. | |

## Medicine Details:

**MICROVAL (Other drug)** **Reason:** Contraception
Pill 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 23/11/1995 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:**
1.0 Dose Unspecified 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 104998 **Seq:** 1 **Gender:** F
**Reported:** 30/11/1995 **Weight:**
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 25/08/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash<br>Anaphylactoid reaction<br><br>Chest pain<br>Dyspnoea<br>Pruritus | | Rash on trunk and limbs. | Ventolin, phenergan, adrenaline, hydrocortisone. |

## Medicine Details:

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

**COLOFAC (Other drug)** **Reason:** Irritable colon
Tablet 405.0 Milligram Daily Oral
**Batch:** **Started:** 01/07/1995 **Stopped:**

**MICROGYNON 30 ED (Other drug)** **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 01/01/1993 **Stopped:**

**PLAQUENIL (Other drug)** **Reason:** Otr&unsp difuse connec tis dis
Tablet 200.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1995 **Stopped:**

## 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:** 104998 **Seq:** 1 **Gender:** F
**Reported:** 30/11/1995 **Weight:**
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 25/08/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **CECLOR (Suspected)** | | | **Reason:** | Otr&nos infec&parasit diseases |
| Oral application | 0.0 | | | Oral |
| **Batch:** | **Started:** | 20/08/1995 | **Stopped:** | 25/08/1995 |
| **AROPAX (Suspected)** | | | **Reason:** | Depression |
| Tablet | 20.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 23/08/1995 | **Stopped:** | 25/08/1995 |

### Laboratory Investigations:

### Additional Information:
the dosage start date is not accurate but indicates that start occurred sometime during the year.

### Report Detail

**Case Number:** 104999 **Seq:** 1 **Gender:** F
**Reported:** 30/11/1995 **Weight:** 85.00
**Hospitalisation:** **Age:** 53Y
**Onset Date:** 31/08/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary incontinence | | | |

### Medicine Details:

**SEDATIVE NOS (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

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

### Report Detail

**Case Number:** 105000 **Seq:** 1 **Gender:** F
**Reported:** 30/11/1995 **Weight:** 65.00
**Hospitalisation:** **Age:** 75Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary incontinence | | | Probanthine given for some |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**CHLOTRIDE (Suspected)** **Reason:**
Tablet 500.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**RENITEC (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

## Report Detail

**Case Number:** 105001 **Seq:** 1 **Gender:** F
**Reported:** 30/11/1995 **Weight:** 76.00
**Hospitalisation:** **Age:** 80Y
**Onset Date:** 08/11/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**SEREPAX (Other drug)** **Reason:** Anxiety neurosis
22.5 Milligram Daily
**Batch:** **Started:** 01/01/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
50.0 Milligram Daily
**Batch:** **Started:** 01/06/1995 **Stopped:** 08/11/1995

## Laboratory Investigations:

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

## Additional Information:

On paroxetine since june 1995 - increased slowly to 50mg over several months. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105002 **Seq:** 1 **Gender:** F
**Reported:** 30/11/1995 **Weight:** 50.00
**Hospitalisation:** **Age:** 43Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Headache<br>Hyperhidrosis<br>Tremor | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 2M

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105016 **Seq:** 1 **Gender:** M
**Reported:** 01/12/1995 **Weight:** 80.00
**Hospitalisation:** **Age:** 56Y
**Onset Date:** 10/11/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**DI-GESIC (Other drug)** **Reason:** Pain
Tablet 2.0 Dose Unspecified Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**NORMISON (Other drug)** **Reason:** Specific disorders of sleep
1.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Pain
1.0 Dose Unspecified Daily
**Batch:** **Started:** 08/11/1995 **Stopped:** 18/11/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105028 **Seq:** 1 **Gender:** F
**Reported:** 01/12/1995 **Weight:**
**Hospitalisation:** **Age:** 43
**Onset Date:** 31/08/1995 **DOB:** 07/10/1951
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura | | | Changed to aurorix. |

### Medicine Details:

**ATIVAN (Other drug)** **Reason:**
Tablet 1.0 Milligram Daily Oral
**Batch:** **Started:** 29/01/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/03/1995 **Stopped:** 12/10/1995

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Biochemistry | 20 - 250 NG/ML | 07/10/1995 | 10 | Serum ferritin |

### Additional Information:

Allergies to maxolon-dystonia, tetracycline-rash. - 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105131 **Seq:** 1 **Gender:** M
**Reported:** 06/12/1995 **Weight:**
**Hospitalisation:** **Age:** 49
**Onset Date:** 11/10/1995 **DOB:** 10/08/1946
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

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

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

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

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

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | 0 - 60 U/L | 27/10/1995 | 289 | |
| | ALT = SGPT | 0 - 60 U/L | 30/10/1995 | 205 | |
| | ALT = SGPT | 0 - 60 U/L | 03/11/1995 | 190 | |
| | ALT = SGPT | 0 - 60 U/L | 05/12/1995 | 40 | |
| | AST = SGOT | 0 - 50 U/L | 27/10/1995 | 500 | |
| | AST = SGOT | 0 - 50 U/L | 30/10/1995 | 383 | |
| | AST = SGOT | 0 - 50 U/L | 05/12/1995 | 39 | |

### Additional Information:

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105131 **Seq:** 1 **Gender:** M
**Reported:** 06/12/1995 **Weight:**
**Hospitalisation:** **Age:** 49
**Onset Date:** 11/10/1995 **DOB:** 10/08/1946
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

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

**LIPEX (Other drug)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** 01/01/1994 **Stopped:**

**TENORMIN (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** 01/01/1994 **Stopped:**

**CARDIZEM (Other drug)** **Reason:**
180.0 Milligram Daily
**Batch:** **Started:** 01/06/1995 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | AST = SGOT | 0 - 50 U/L | 03/11/1995 | 222 | |
| | Albumin | | 11/10/1995 | 34 | |
| | Bilirubin | 0 -21 UMOL/L | 27/10/1995 | 128 | |
| | Bilirubin | 0 -21 UMOL/L | 30/10/1995 | 211 | |
| | Bilirubin | 0 -21 UMOL/L | 03/11/1995 | 72 | |
| | Bilirubin | 0 -21 UMOL/L | 05/12/1995 | 23 | |
| | GGT = SGGT = | 0 - 70 U/L | 27/10/1995 | 2238 | |

### Additional Information:

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

## Report Detail

**Case Number:** 105131 **Seq:** 1 **Gender:** M
**Reported:** 06/12/1995 **Weight:**
**Hospitalisation:** **Age:** 49
**Onset Date:** 11/10/1995 **DOB:** 10/08/1946
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 21/09/1995 **Stopped:** 29/10/1995

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | GGT = SGGT = SGOTD | 0 - 70 U/L | 30/10/1995 | 2666 | |
| | GGT = SGGT = SGOTD | 0 - 70 U/L | 03/11/1995 | 1673 | |
| | GGT = SGGT = SGOTD | 0 - 70 U/L | 05/12/1995 | 431 | |
| | Protein | | 11/10/1995 | 62 | |
| | SAP = ALP | 0 - 120 U/L | 27/10/1995 | 351 | |
| | SAP = ALP | 0 - 120 U/L | 30/10/1995 | 370 | |
| | SAP = ALP | 0 - 120 U/L | 03/11/1995 | 352 | |

## Additional Information:

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

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105131 **Seq:** 1 **Gender:** M
**Reported:** 06/12/1995 **Weight:**
**Hospitalisation:** **Age:** 49
**Onset Date:** 11/10/1995 **DOB:** 10/08/1946
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

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

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

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

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

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | SAP = ALP | 0 - 120 U/L | 05/12/1995 | 106 | |

## Additional Information:

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

## Report Detail

**Case Number:** 105131 **Seq:** 1 **Gender:** M
**Reported:** 06/12/1995 **Weight:**
**Hospitalisation:** **Age:** 49
**Onset Date:** 11/10/1995 **DOB:** 10/08/1946
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | |
|---|---|---|---|
| **COLCHICINE (Other drug)** | | **Reason:** | |
| | 0.0 | | |
| **Batch:** | **Started:** | | **Stopped:** |
| **LIPEX (Other drug)** | | **Reason:** | |
| | 10.0 Milligram | Daily | |
| **Batch:** | **Started:** 01/01/1994 | | **Stopped:** |
| **TENORMIN (Other drug)** | | **Reason:** | |
| | 1.0 Dose Unspecified | Daily | |
| **Batch:** | **Started:** 01/01/1994 | | **Stopped:** |
| **CARDIZEM (Other drug)** | | **Reason:** | |
| | 180.0 Milligram | Daily | |
| **Batch:** | **Started:** 01/06/1995 | | **Stopped:** |

## Laboratory Investigations:

## Additional Information:

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

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105131 **Seq:** 1 **Gender:** M
**Reported:** 06/12/1995 **Weight:**
**Hospitalisation:** **Age:** 49
**Onset Date:** 11/10/1995 **DOB:** 10/08/1946
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 21/09/1995 **Stopped:** 29/10/1995

## Laboratory Investigations:

## Additional Information:

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105147 **Seq:** 1 **Gender:** M
**Reported:** 07/12/1995 **Weight:**
**Hospitalisation:** **Age:** 75Y
**Onset Date:** 10/11/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | | Fluid restriction; stop drug |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 08/11/1995 **Stopped:** 10/11/1995

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | | | Na fell from 132 to 124 mmol/l |

### Additional Information:

## Report Detail

**Case Number:** 105214 **Seq:** 1 **Gender:** F
**Reported:** 08/12/1995 **Weight:** 65.00
**Hospitalisation:** **Age:** 67Y
**Onset Date:** 04/08/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Platelet disorder<br>Haematuria<br>Purpura | | Platelet dysfunction | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Anxiety neurosis

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 04/07/1995 **Stopped:** 04/08/1995

**ASCORBIC ACID (Suspected)** **Reason:**

Oral application 1.0 Gram 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105216 **Seq:** 1 **Gender:** F
**Reported:** 08/12/1995 **Weight:** 73.00
**Hospitalisation:** **Age:** 34Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/09/1995 **Stopped:** 15/11/1995

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105217 **Seq:** 1 **Gender:** F
**Reported:** 08/12/1995 **Weight:** 73.00
**Hospitalisation:** **Age:** 34Y
**Onset Date:** 16/11/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Anxiety<br>Drug withdrawal syndrome<br>Nausea<br>Vertigo | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/09/1995 **Stopped:** 15/11/1995

### Laboratory Investigations:

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

### Additional Information:

Symptoms resolved in 1-2 days when patient restarted aropax 20 on 24/11/95 the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105348 **Seq:** 1 **Gender:** F
**Reported:** 15/12/1995 **Weight:**
**Hospitalisation:** **Age:** 38Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 02/11/1995 **Stopped:** 28/11/1995

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105353 **Seq:** 1 **Gender:** F
**Reported:** 15/12/1995 **Weight:** 70.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthralgia | | Affecting joints of fingers, both hands. | |
| Myalgia | | Pain in calf muscle | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1994 **Stopped:**

## 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.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105384 **Seq:** 1 **Gender:** U
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105388 **Seq:** 1 **Gender:** M
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

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

## Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105389 **Seq:** 1 **Gender:** F
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** Admitted to hospital **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105394 **Seq:** 1 **Gender:** M
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:** 94Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** 01/10/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Patient experienced diarrhoea after taking fluoxetine and sertaline previously the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105396 **Seq:** 1 **Gender:** U
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detai

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

### Medicine Details:

**THYROXINE SODIUM (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105399 **Seq:** 1 **Gender:** U
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary incontinence<br>Urinary retention | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105400 **Seq:** 1 **Gender:** F
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** 2M

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105401 **Seq:** 1 **Gender:** F
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome<br>Headache<br>Nervousness | | | Ativan |

## Medicine Details:

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105402 **Seq:** 1 **Gender:** M
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105403 **Seq:** 1 **Gender:** U
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypercholesterolaemia<br>Hypertriglyceridaemia | | | |

### Medicine Details:

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105405 **Seq:** 1 **Gender:** M
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Increased appetite | | Developed a desire for sweet foods. | |

## Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105406 **Seq:** 1 **Gender:** U
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Orthostatic hypotension | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105418 **Seq:** 1 **Gender:** U
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105423 **Seq:** 1 **Gender:** F
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache<br>Nausea<br>Tremor<br>Weight decreased | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 03W

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105428 **Seq:** 1 **Gender:** F
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Flushing<br>Menstrual disorder | | | Duphaston dose increased. |

### Medicine Details:

**DUPHASTON (Other drug)** **Reason:**
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

**ESTIGYN (Other drug)** **Reason:**
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 0.0 Oral
**Batch:** **Started:** 03/05/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105431 **Seq:** 1 **Gender:** M
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Patient feels tired all the time, this became more pronounced when dose of aropax was increased to two tablets.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105433 **Seq:** 1 **Gender:** M
**Reported:** 18/12/1995 **Weight:**
**Hospitalisation:** **Age:** 53Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105492 **Seq:** 1 **Gender:** F
**Reported:** 21/12/1995 **Weight:** 81.00
**Hospitalisation:** **Age:** 65Y
**Onset Date:** 11/09/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**RENITEC (Other drug)** **Reason:** Essential benign hypertension
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/02/1992 **Stopped:**

**BETALOC (Other drug)** **Reason:** Essential benign hypertension
Tablet 100.0 Milligram Daily Oral
**Batch:** **Started:** 12/04/1988 **Stopped:**

**CARTIA (Other drug)** **Reason:**
Tablet 100.0 Milligram Daily Oral
**Batch:** **Started:** 01/02/1995 **Stopped:**

**NORMISON (Other drug)** **Reason:** Specific disorders of sleep
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 16/08/1990 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105492 **Seq:** 1 **Gender:** F
**Reported:** 21/12/1995 **Weight:** 81.00
**Hospitalisation:** **Age:** 65Y
**Onset Date:** 11/09/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 14/07/1995 **Stopped:**

## Laboratory Investigations:

## Additional Information:

## Report Detail

**Case Number:** 105502 **Seq:** 1 **Gender:** F
**Reported:** 21/12/1995 **Weight:**
**Hospitalisation:** **Age:** 52Y
**Onset Date:** 17/12/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**PREMARIN (Other drug)** **Reason:** Menopausal symptoms
300.0 Microgram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 17/12/1995 **Stopped:** 18/12/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105549 **Seq:** 1 **Gender:** F
**Reported:** 28/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash | | Over most of the body | |

### Medicine Details:

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

**THYROXINE SODIUM (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 6M

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105550 **Seq:** 1 **Gender:** F
**Reported:** 28/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Psychotic disorder | | | |

## Medicine Details:

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

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105553 **Seq:** 1 **Gender:** M
**Reported:** 28/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Micturition disorder | | | |

## Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105554 **Seq:** 1 **Gender:** F
**Reported:** 28/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash | | On both elbows; blistering rash on hands | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105555 **Seq:** 1 **Gender:** F
**Reported:** 28/12/1995 **Weight:** 58.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 27/06/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Nervousness<br>Paraesthesia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 23/01/1995 **Stopped:** 23/06/1995

**SURGAM (Suspected)** **Reason:**
Tablet 200.0 Milligram Daily Oral
**Batch:** **Started:** 01/06/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105556 **Seq:** 1 **Gender:** U
**Reported:** 28/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Paraesthesia | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105557 **Seq:** 1 **Gender:** U
**Reported:** 28/12/1995 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Paraesthesia | | | |

## Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105559 **Seq:** 1 **Gender:** F
**Reported:** 28/12/1995 **Weight:**
**Hospitalisation:** **Age:** 48
**Onset Date:** **DOB:** 31/03/1947
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash<br>Pruritus | | Initially to legs; spread to rest of body | |

### Medicine Details:

**ADALAT (Other drug)** **Reason:** Essential benign hypertension
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 07/05/1992 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 19/05/1995 **Stopped:** 16/11/1995

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105605 **Seq:** 1 **Gender:** F
**Reported:** 02/01/1996 **Weight:** 59.00
**Hospitalisation:** **Age:** 51Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/01/1993 **Stopped:** 31/01/1994

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Neutrophils | (1.8 X 10^9/L) | 10/04/1995 | 39 | |
| | Neutrophils | (1.8 X 10^9/L) | 19/09/1995 | 39 | |

## Additional Information:

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

## Report Detail

**Case Number:** 105607 **Seq:** 1
**Reported:** 02/01/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 12/10/1995
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 82Y
**DOB:**
**Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**ASCORBIC ACID (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**PANAMAX (Other drug)** **Reason:**
0.0 As necessary
**Batch:** **Started:** **Stopped:**

**BETAMIN (Other drug)** **Reason:**
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**CARDIPRIN 100 (Other drug)** **Reason:**
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | 12/10/1995 | 124 | |
| | Sodium | | 18/10/1995 | 136 | |

## Additional Information:

## Report Detail

**Case Number:** 105607 **Seq:** 1
**Reported:** 02/01/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 12/10/1995
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 82Y
**DOB:**
**Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **COLOXYL (Other drug)** | | | **Reason:** | | |
| | 2.0 | Dose Unspecified | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **METAMUCIL (Other drug)** | | | **Reason:** | | |
| | 1.0 | Dose Unspecified | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **NAPROSYN SR (Other drug)** | | | **Reason:** | | |
| Tablet | 750.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | 12/10/1995 |
| **TOLVON (Suspected)** | | | **Reason:** | | |
| | 0.0 | | | | |
| **Batch:** | **Started:** | | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105607 **Seq:** 1
**Reported:** 02/01/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 12/10/1995
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 82Y
**DOB:**
**Causality:** Causality probable

## Reaction Detail

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/09/1995 **Stopped:** 4W

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105620 **Seq:** 1
**Reported:** 02/01/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 75Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash maculo-papular | | | Moisturizing cream, |

### Medicine Details:

**ATENOLOL (Suspected)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:** 12/12/1995

**CHLORAL HYDRATE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 31/10/1995 **Stopped:** 11/12/1995

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 11/11/1995 **Stopped:** 11/12/1995

**TRIMETHOPRIM (Suspected)** **Reason:** Othr diseases of urinary tract
300.0 Milligram Daily
**Batch:** **Started:** 27/11/1995 **Stopped:** 11/12/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105635 **Seq:** 1 **Gender:** F
**Reported:** 02/01/1996 **Weight:**
**Hospitalisation:** **Age:** 41Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Libido decreased | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/11/1995 **Stopped:**

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105817 **Seq:** 1 **Gender:** F
**Reported:** 12/01/1996 **Weight:**
**Hospitalisation:** **Age:** 62Y
**Onset Date:** 04/01/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash | | Rash on legs and hip area | |

### Medicine Details:

**ZANTAC (Other drug)** **Reason:**
Oral application 150.0 Milligram As necessary Oral
**Batch:** **Started:** 01/01/1993 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 20/12/1995 **Stopped:**

### 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.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 105891 **Seq:** 1 **Gender:** F
**Reported:** 17/01/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety<br>Dizziness<br>Drug withdrawal syndrome | | | |

## Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105898 **Seq:** 1 **Gender:** F
**Reported:** 17/01/1996 **Weight:**
**Hospitalisation:** **Age:** 21Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 105906 **Seq:** 1 **Gender:** F
**Reported:** 17/01/1996 **Weight:** 51.00
**Hospitalisation:** **Age:** 36Y
**Onset Date:** 19/10/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Nausea<br>Vertigo | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

**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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106048 **Seq:** 1 **Gender:** F
**Reported:** 22/01/1996 **Weight:** 58.00
**Hospitalisation:** **Age:** 61Y
**Onset Date:** 05/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

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

### Medicine Details:

**DI-GESIC (Other drug)** **Reason:**
0.0 As necessary
**Batch:** **Started:** **Stopped:**

**BECOTIDE (Other drug)** **Reason:**
Inhalation 2.0 Dose Unspecified Daily Inhalation
**Batch:** **Started:** 01/01/1995 **Stopped:**

**LIPEX (Other drug)** **Reason:** Othr&unspec metabolic diseases
10.0 Milligram Daily
**Batch:** **Started:** 01/01/1995 **Stopped:** CONTIN

**ZOTON (Other drug)** **Reason:** Ulcer of duodenum w/o ment perf
30.0 Milligram Daily
**Batch:** **Started:** 01/01/1995 **Stopped:** CONTIN

### Laboratory Investigations:

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

### Additional Information:

Patient was rechallenged on aropax with same reaction occurring. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106048 **Seq:** 1 **Gender:** F
**Reported:** 22/01/1996 **Weight:** 58.00
**Hospitalisation:** **Age:** 61Y
**Onset Date:** 05/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
50.0 Milligram Daily
**Batch:** **Started:** 02/01/1996 **Stopped:** 05/01/1996

### Laboratory Investigations:

### Additional Information:

Patient was rechallenged on aropax with same reaction occurring. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106051 **Seq:** 1 **Gender:** U
**Reported:** 23/01/1996 **Weight:**
**Hospitalisation:** Admitted to hospital **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura Thrombocytopenia | | | Prednisolone |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 24/10/1995 **Stopped:** 15/12/1995

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Platelets | | 15/12/1995 | 2 | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106072 **Seq:** 1 **Gender:** M
**Reported:** 29/01/1996 **Weight:**
**Hospitalisation:** **Age:** 37Y
**Onset Date:** 13/01/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure<br>Priapism | | | |

## Medicine Details:

**ANTABUSE (Other drug)** **Reason:**
0.0
**Batch:** **Started:** 27/12/1995 **Stopped:**

**DIAZEPAM (Other drug)** **Reason:** Specific disorders of sleep
10.0 Milligram Daily
**Batch:** **Started:** 27/12/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 11/01/1996 **Stopped:** 18/01/1996

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106109 **Seq:** 1 **Gender:** F
**Reported:** 22/01/1996 **Weight:** 75.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 17/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia<br>Opisthotonus | Severe | | Cogentin, morphine. |

## Medicine Details:

**LIGNOCAINE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 16/01/1996 **Stopped:**

**PROPOFOL (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 16/01/1996 **Stopped:**

**STEMETIL (Suspected)** **Reason:**
25.0 Milligram Total
**Batch:** **Started:** 16/01/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/10/1995 **Stopped:**

## 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106148 **Seq:** 1 **Gender:** F
**Reported:** 25/01/1996 **Weight:** 63.00
**Hospitalisation:** **Age:** 25Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/07/1995 **Stopped:** 28/01/1996

### Laboratory Investigations:

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

### Additional Information:

Patient also developed headaches on aurorix and prozac therapy. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106150 **Seq:** 1
**Reported:** 25/01/1996
**Hospitalisation:**
**Onset Date:** 08/11/1995
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 62.00
**Age:** 26
**DOB:** 11/03/1969
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia<br>Drug withdrawal syndrome<br>Headache<br>Hypoaesthesia<br>Nausea<br>Paraesthesia<br>Paresis<br>Visual disturbance | | Aching shoulders and elbow. | |

## Medicine Details:

**ZOLOFT (Other drug)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** 01/02/1995 **Stopped:** 28/06/1995

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/07/1995 **Stopped:** 07/11/1995

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

### Report Detail

**Case Number:** 106154 **Seq:** 1 **Gender:** M
**Reported:** 25/01/1996 **Weight:** 80.00
**Hospitalisation:** **Age:** 60Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Priapism<br>Ejaculation failure | | Erection prolonged | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 2M

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106155 **Seq:** 1 **Gender:** F
**Reported:** 25/01/1996 **Weight:**
**Hospitalisation:** **Age:** 38
**Onset Date:** **DOB:** 26/03/1957
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia | Severe | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram 1 time Oral
**Batch:** **Started:** 01/09/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Sensitive to other medications eg: visual disturbances with clomipramine, hallucinations with buscopan, anxiety with alprazolam. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106158 **Seq:** 1 **Gender:** M
**Reported:** 25/01/1996 **Weight:** 103.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Priapism<br>Ejaculation failure | | Erection prolonged | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Pain

Tablet 40.0 Milligram Daily Oral

**Batch:** **Started:** 01/09/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Patient on decreased dose of apropax 20 mg daily.

## Report Detail

**Case Number:** 106168 **Seq:** 1 **Gender:** F
**Reported:** 25/01/1996 **Weight:**
**Hospitalisation:** **Age:** 37Y
**Onset Date:** 04/12/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypoaesthesia<br>Asthenia<br>Dyskinesia<br>Dysphagia<br>Dystonia<br>Grand mal convulsion<br>Paraesthesia<br>Tremor | | Numbness l lower leg & back l hand up to | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 02/11/1995 **Stopped:** 04/12/1995

**XANAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 250.0 Microgram Daily Oral
**Batch:** **Started:** 30/11/1995 **Stopped:** 04/12/1995

## Laboratory Investigations:

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

## Additional Information:

Recurrent depression, jaw tightness on prozac. from 5/10/95 when on aropax 20 mg daily, jaw tightness and muscle twitching in arms and legs.

## Report Detail

**Case Number:** 106169 **Seq:** 1 **Gender:** F
**Reported:** 31/01/1996 **Weight:**
**Hospitalisation:** **Age:** 95Y
**Onset Date:** 20/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety<br>Dizziness<br>Hyperhidrosis<br>Hypertension<br>Syncope | | | |

## Medicine Details:

**LASIX (Other drug)** **Reason:** Congestive heart failure
20.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**MIDAMOR (Other drug)** **Reason:** Congestive heart failure
1.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**LANOXIN (Other drug)** **Reason:** Congestive heart failure
125.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**KINIDIN DURULES (Other drug)** **Reason:** Congestive heart failure
2.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

## Laboratory Investigations:

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

## Additional Information:

### Report Detail

**Case Number:** 106169 **Seq:** 1 **Gender:** F
**Reported:** 31/01/1996 **Weight:**
**Hospitalisation:** **Age:** 95Y
**Onset Date:** 20/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **ISOPTIN (Other drug)** | | | **Reason:** | Congestive heart failure | |
| | 1.0 | Dose Unspecified | Daily | | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | CONTIN | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 10.0 | Milligram | 1 time | Oral | |
| **Batch:** | **Started:** | 20/01/1996 | **Stopped:** | 20/01/1996 | |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106188 **Seq:** 1 **Gender:** F
**Reported:** 01/02/1996 **Weight:** 75.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** 21/12/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 0.0 Oral
**Batch:** **Started:** 13/10/1995 **Stopped:** 28/11/1995

### Laboratory Investigations:

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

### Additional Information:

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106218 **Seq:** 1 **Gender:** F
**Reported:** 02/02/1996 **Weight:**
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 31/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety | | | |
| Dyspepsia | Severe | | |
| Vomiting | Severe | | |

### Medicine Details:

**PROZAC (Suspected)** **Reason:** Depression
20.0 Milligram 1 time
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram 1 time
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106230 **Seq:** 1 **Gender:** F
**Reported:** 02/02/1996 **Weight:** 60.00
**Hospitalisation:** **Age:** 70Y
**Onset Date:** 21/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**PREMARIN (Other drug)** **Reason:** Menopausal symptoms
Tablet 625.0 Microgram Daily Oral
**Batch:** **Started:** **Stopped:**

**SOLPRIN (Other drug)** **Reason:** Angina pectoris w/o hyperten
150.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**VALIUM (Other drug)** **Reason:** Anxiety neurosis
2.5 Milligram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
10.0 Milligram Daily
**Batch:** **Started:** 16/01/1996 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106258 **Seq:** 1 **Gender:** F
**Reported:** 05/02/1996 **Weight:** 50.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 31/12/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 23/11/1995 **Stopped:** CONTIN

### Laboratory Investigations:

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

### Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106279 **Seq:** 1 **Gender:** F
**Reported:** 05/02/1996 **Weight:** 60.00
**Hospitalisation:** **Age:** 84Y
**Onset Date:** 31/07/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Extrapyramidal disorder | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/07/1995 **Stopped:** 28/09/1995

### Laboratory Investigations:

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

### Additional Information:

- 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

### Report Detail

**Case Number:** 106290 **Seq:** 1 **Gender:** F
**Reported:** 07/02/1996 **Weight:**
**Hospitalisation:** **Age:** 46Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depression<br>Suicide attempt<br>Weight increased | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**TEGRETOL (Suspected)** **Reason:**
3.0 Dose Unspecified 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106291 **Seq:** 1
**Reported:** 07/02/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 46Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urticaria | | Contact urticaria | |
| Vomiting | | Nocturnal vomiting (every 2nd night) | |
| Rash maculo-papular | | Over arms and legs | Iv steroids |
| Anxiety | | | |
| Gravitational oedema | | | |
| Mania | | | |

## Medicine Details:

**CHLORPROMAZINE HYDROCHLORIDE (Other drug)** **Reason:** Depression
Tablet 400.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**PHENERGAN (Other drug)** **Reason:** Depression
Oral application 25.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 01/12/1995 **Stopped:**

**TEGRETOL (Suspected)** **Reason:** Depression
3.0 Dose Unspecified Daily
**Batch:** **Started:** 01/11/1995 **Stopped:**

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106299 **Seq:** 1 **Gender:** F
**Reported:** 07/02/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus<br>Purpura | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 01/01/1995 **Stopped:** 21/08/1995

**SINEQUAN (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 01/07/1995 **Stopped:**

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106300 **Seq:** 1 **Gender:** F
**Reported:** 07/02/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

**Batch:** **Started:** 01/01/1995 **Stopped:** 21/08/1995

### Laboratory Investigations:

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

### Additional Information:

Patient missed 2 doses sometime in 4/95 and experienced similar symptoms. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106317 **Seq:** 1 **Gender:** M
**Reported:** 07/02/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106319 **Seq:** 1 **Gender:** F
**Reported:** 07/02/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

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

**CHLORPROMAZINE HYDROCHLORIDE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** 05/09/1995

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106323 **Seq:** 1
**Reported:** 07/02/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** U
**Weight:**
**Age:** AC
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Psychotic disorder | Severe | Acute toxic psychosis | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

### Laboratory Investigations:

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

### Additional Information:

Patient was also on anticonvulsant therapy possibly gabapentin or vigabatrin.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106330 **Seq:** 1 **Gender:** F
**Reported:** 07/02/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Weight increased | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/03/1995 **Stopped:**

## 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.

## Report Detail

**Case Number:** 106332 **Seq:** 1 **Gender:** F
**Reported:** 07/02/1996 **Weight:** 70.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 08/01/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Gravitational oedema | | Ankle, leg, thigh | |

## Medicine Details:

**ROHYPNOL (Other drug)** **Reason:** Specific disorders of sleep
2.0 Milligram As necessary
**Batch:** **Started:** 01/06/1995 **Stopped:**

**MERSYNDOL (Other drug)** **Reason:** Migraine
0.0 As necessary
**Batch:** **Started:** **Stopped:**

**PALFIUM (Other drug)** **Reason:** Migraine
6.0 Milligram Daily
**Batch:** **Started:** 01/11/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 21/12/1995 **Stopped:** 10/01/1996

## Laboratory Investigations:

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

## Additional Information:

Patient has a clotting defect the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

### Report Detail

**Case Number:** 106334 **Seq:** 1 **Gender:** F
**Reported:** 07/02/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

### Reaction Detai

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

### Laboratory Investigations:

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

### Additional Information:

Patient was rechallenged on aropax with same reaction accurring.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106336 **Seq:** 1 **Gender:** F
**Reported:** 07/02/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Vertigo | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 3M

## Laboratory Investigations:

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

## Additional Information:

Dr thinks it may have been caused by viral inner ear infection.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106342 **Seq:** 1 **Gender:** F
**Reported:** 07/02/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 106368 **Seq:** 1 **Gender:** F
**Reported:** 09/02/1996 **Weight:** 95.00
**Hospitalisation:** **Age:** 53Y
**Onset Date:** 31/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Amnesia | | | |
| Cough | | | |
| Fatigue | | | |
| Libido decreased | | | |
| Somnolence | | | |

## Medicine Details:

**ESTRADERM (Other drug)** **Reason:** Menopausal symptoms
Cream 0.0 Transdermal
**Batch:** **Started:** 01/08/1994 **Stopped:**

**FELDENE (Other drug)** **Reason:** Unspecified arthritis
Oral application 20.0 Milligram As necessary Oral
**Batch:** **Started:** 01/10/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/11/1995 **Stopped:** 01/02/1996

## Laboratory Investigations:

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

## Additional Information:

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106407 **Seq:** 1 **Gender:** F
**Reported:** 12/02/1996 **Weight:** 52.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 29/01/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 25/01/1996 **Stopped:** 05/02/1996

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106461 **Seq:** 1
**Reported:** 15/02/1996
**Hospitalisation:**
**Onset Date:** 31/01/1996
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 63.00
**Age:** 46
**DOB:** 17/06/1949
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthralgia<br>Insomnia<br>Muscle twitching<br>Myalgia<br>Rhinitis | | Pain | |

### Medicine Details:

**PANADEINE FORTE (Other drug)** **Reason:** Lumbalgia

Tablet 2.0 Dose Unspecified As necessary Oral

**Batch:** **Started:** 01/01/1992 **Stopped:**

**AROPAX (Suspected)** **Reason:**

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106472 **Seq:** 1 **Gender:** M
**Reported:** 16/02/1996 **Weight:** 75.00
**Hospitalisation:** **Age:** 34Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle twitching | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/03/1995 **Stopped:** 28/10/1995

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106473 **Seq:** 1 **Gender:** F
**Reported:** 16/02/1996 **Weight:** 70.00
**Hospitalisation:** **Age:** 37Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Drug withdrawal syndrome | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

**Batch:** **Started:** 01/04/1995 **Stopped:** 28/11/1995

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106487 **Seq:** 1 **Gender:** M
**Reported:** 16/02/1996 **Weight:**
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 31/10/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle twitching<br>Nightmare<br>Tongue ulceration | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/09/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

- 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106500 **Seq:** 1 **Gender:** F
**Reported:** 19/02/1996 **Weight:** 65.00
**Hospitalisation:** **Age:** 30Y
**Onset Date:** 10/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 08/12/1995 **Stopped:** 16/12/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106553 **Seq:** 1 **Gender:** M
**Reported:** 19/02/1996 **Weight:**
**Hospitalisation:** **Age:** 57Y
**Onset Date:** 31/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 02/11/1995 **Stopped:** 28/01/1996

### Laboratory Investigations:

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

### Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106571 **Seq:** 1 **Gender:** F
**Reported:** 21/02/1996 **Weight:** 54.00
**Hospitalisation:** **Age:** 75Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysgeusia<br>Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 12/09/1995 **Stopped:** 06/02/1996

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106617 **Seq:** 1 **Gender:** F
**Reported:** 23/02/1996 **Weight:** 55.00
**Hospitalisation:** **Age:** 25Y
**Onset Date:** 13/02/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Encephalopathy<br>Psychotic disorder | | | |

### Medicine Details:

**BENZTROPINE MESYLATE (Suspected)** **Reason:**
2.0 Milligram Daily
**Batch:** **Started:** 13/02/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** 01/09/1995 **Stopped:**

**CHLORPROMAZINE HYDROCHLORIDE (Suspected)** **Reason:** Unspecified psychosis
400.0 Milligram Daily
**Batch:** **Started:** 01/12/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Brain syndrome developed within hours of taking benztropin the dosage start date is not necessarily accurate but indicates that start 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106619 **Seq:** 1 **Gender:** F
**Reported:** 22/02/1996 **Weight:** 68.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 14/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety | | | |
| Diarrhoea | | | |
| Faecal incontinence | | | |
| Nausea | | | |
| Tremor | | | |

## Medicine Details:

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

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 10/01/1996 **Stopped:** 08/02/1996

## Laboratory Investigations:

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

## Additional Information:

## Report Detail

**Case Number:** 106647 **Seq:** 1 **Gender:** F
**Reported:** 23/02/1996 **Weight:** 63.00
**Hospitalisation:** **Age:** 57Y
**Onset Date:** 06/08/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Sleep disorder<br>Tremor | | | |

## Medicine Details:

**ESTRADERM (Other drug)** **Reason:** Menopausal symptoms
100.0 Microgram Weekly
**Batch:** **Started:** 05/05/1992 **Stopped:** CONTIN

**BECONASE (Other drug)** **Reason:** Chronic sinusitis
Spray 1.0 Dose Unspecified Daily Nasal
**Batch:** **Started:** 20/10/1994 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** 04/08/1995 **Stopped:** 13/08/1995

## Laboratory Investigations:

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

## Additional Information:

Previous exposure to aropax in november 1994 for 6 days with similar adverse reaction description.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106659 **Seq:** 1 **Gender:** F
**Reported:** 26/02/1996 **Weight:** 70.00
**Hospitalisation:** **Age:** 26Y
**Onset Date:** 31/01/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Amnesia<br>Disturbance in attention | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 01/12/1995 **Stopped:**

**PROTHIADEN (Suspected)** **Reason:** Depression
Oral application 75.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1995 **Stopped:** 28/02/1996

### Laboratory Investigations:

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

### Additional Information:

Chronic cabinabinoid effect. - 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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106691 **Seq:** 1 **Gender:** M
**Reported:** 26/02/1996 **Weight:** 70.00
**Hospitalisation:** **Age:**
**Onset Date:** 31/08/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/08/1994 **Stopped:**

**LITHIUM CARBONATE (Suspected)** **Reason:** Unspecified psychosis
Tablet 500.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

- 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106754 **Seq:** 1 **Gender:** F
**Reported:** 28/02/1996 **Weight:** 71.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** 13/02/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aphasia<br>Arthralgia<br>Nausea<br>Vertigo | | | |

### Medicine Details:

**INDERAL (Other drug)** **Reason:** Migraine
Tablet 240.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/1995 **Stopped:**

**ASPIRIN (Other drug)** **Reason:** Migraine
Oral application 150.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** 01/08/1995 **Stopped:** 19/02/1996

### 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. the dosage start date is not necessarily accurate but indicates that start 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106817 **Seq:** 1 **Gender:** F
**Reported:** 01/03/1996 **Weight:** 65.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 23/02/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state<br>Dry mouth<br>Dysgeusia<br>Nervousness<br>Tremor | | | |

## Medicine Details:

**ARISTOCORT (Other drug)** **Reason:** Otr ecz&der due otr&unsp cause
0.0 As necessary
**Batch:** **Started:** **Stopped:**

**DIPROSONE (Other drug)** **Reason:** Otr ecz&der due otr&unsp cause
0.0 As necessary
**Batch:** **Started:** **Stopped:**

**TRIPHASIL (Other drug)** **Reason:** Contraception
Pill 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106820 **Seq:** 1 **Gender:** F
**Reported:** 01/03/1996 **Weight:** 72.00
**Hospitalisation:** **Age:** 29Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome<br>Increased appetite<br>Nausea | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 02/01/1996 **Stopped:** 20/02/1996

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106821 **Seq:** 1 **Gender:** F
**Reported:** 01/03/1996 **Weight:** 53.00
**Hospitalisation:** **Age:** 37Y
**Onset Date:** 23/02/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | | |
| Asthenia | | | |
| Dizziness | | | |
| Dry mouth | | | |
| Hallucination | | | |
| Hyperhidrosis | | | |
| Mydriasis | | | |
| Paraesthesia | | | |
| Tremor | | | |

## Medicine Details:

**CALTRATE (Other drug)** **Reason:**
Tablet 600.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1990 **Stopped:**

**VITAMIN NOS (Other drug)** **Reason:**
Oral application 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 01/12/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 21/01/1996 **Stopped:** 23/02/1996

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106888 **Seq:** 1
**Reported:** 05/03/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 25/02/1996
**Outcome:** Recovered

**Gender:** F
**Weight:** 60.00
**Age:** 64Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br>Urinary retention | | | <br>Idc, fluid restriction |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 25/01/1996 **Stopped:** 25/02/1996

**MENOPREM (Suspected)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** 18/02/1996 **Stopped:** 25/02/1996

**KEFLEX (Suspected)** **Reason:** Othr diseases of urinary tract
2.0 Gram Daily
**Batch:** **Started:** 18/02/1996 **Stopped:** 25/02/1996

**URAL (Suspected)** **Reason:** Othr diseases of urinary tract
4.0 Dose Unspecified Daily
**Batch:** **Started:** 18/02/1996 **Stopped:** 25/02/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Serum osmolality | | 25/02/1996 | 0.238 | |
| | Sodium | MMOL/L | 25/02/1996 | 119 | |
| | Urine osmolality | | 25/02/1996 | 0.268 | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106906 **Seq:** 1 **Gender:** M
**Reported:** 06/03/1996 **Weight:** 70.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

### Medicine Details:

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

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/01/1995 **Stopped:** 31/01/1995

### 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. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106921 **Seq:** 1 **Gender:** M
**Reported:** 06/03/1996 **Weight:** 74.00
**Hospitalisation:** **Age:** 33
**Onset Date:** 08/12/1995 **DOB:** 22/09/1962
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Amnesia<br>Ejaculation failure<br>Insomnia<br>Libido decreased<br>Somnolence | | | |

### Medicine Details:

**BRICANYL (Other drug)** **Reason:** Asthma
Inhalation 0.0 As necessary Inhalation
**Batch:** **Started:** **Stopped:**

**PULMICORT (Other drug)** **Reason:** Asthma
Inhalation 400.0 Microgram Daily Inhalation
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 23/08/1995 **Stopped:** 01/01/1996

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 106922 **Seq:** 1 **Gender:** M
**Reported:** 06/03/1996 **Weight:** 74.00
**Hospitalisation:** **Age:** 33
**Onset Date:** **DOB:** 22/09/1962
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Disturbance in attention<br>Amnesia<br>Drug withdrawal syndrome<br>Thinking abnormal<br>Tinnitus | | Concenration impaired, high pitched sibilant cresendo and decresendo buzz in head, thinking abnormal, withdrawal syndrom and amnesia. | Changed to Aaurorix. |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 08/01/1996 **Stopped:** 01/02/1996

### Laboratory Investigations:

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

### Additional Information:

Other drugs taken: Bricanyl and Pulmicort. Aropax was reduced to 10mg for 1 week, then 5mg for 1-2 weeks then stopped.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 106933 **Seq:** 1 **Gender:** M
**Reported:** 07/03/1996 **Weight:** 78.00
**Hospitalisation:** **Age:** 67Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

## Medicine Details:

**MINIDIAB (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 05/12/1995 **Stopped:** 02/02/1996

## Laboratory Investigations:

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

## Additional Information:

Ejaculation returned when off aropax. rechallenged 8/2/96 et seq with return of reaction.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 107006 **Seq:** 1 **Gender:** F
**Reported:** 12/03/1996 **Weight:** 75.00
**Hospitalisation:** **Age:** 24Y
**Onset Date:** 05/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 30.0 Milligram Daily Oral

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

## Laboratory Investigations:

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

## Additional Information:

Aropax reduced to 20 mg from 30mg.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107060 **Seq:** 1 **Gender:** F
**Reported:** 13/03/1996 **Weight:**
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 26/02/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 16/02/1996 **Stopped:** 10/03/1996

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107084 **Seq:** 1 **Gender:** F
**Reported:** 15/03/1996 **Weight:**
**Hospitalisation:** **Age:** 58Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Accommodation disorder | | Marked difficulty in focussing | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 07/02/1996 **Stopped:** 21/02/1996

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 107086 **Seq:** 1 **Gender:** F
**Reported:** 15/03/1996 **Weight:** 80.00
**Hospitalisation:** **Age:** 31Y
**Onset Date:** 28/02/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Bruxism | | | |

## Medicine Details:

**VENTOLIN (Other drug)** **Reason:** Asthma
8.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:**

**PULMICORT (Other drug)** **Reason:** Asthma
4.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 27/02/1996 **Stopped:** 02/03/1996

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107117 **Seq:** 1
**Reported:** 19/03/1996
**Hospitalisation:**
**Onset Date:** 07/03/1996
**Outcome:** Recovered with sequelae

**Gender:** M
**Weight:** 80.00
**Age:** AD
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyskinesia<br>Hypertonia | | | Diazepam, benztropiine |

### Medicine Details:

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

Tablet 60.0 Milligram Daily Oral

**Batch:** **Started:** 05/03/1996 **Stopped:** 07/03/1996

### Laboratory Investigations:

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

### Additional Information:

Involuntary movements persisted for 2-3 days after medication stopped. sequelae: painful joints after spasms.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107147 **Seq:** 1 **Gender:** U
**Reported:** 20/03/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperaesthesia<br>Paraesthesia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107149 **Seq:** 1 **Gender:** M
**Reported:** 19/03/1996 **Weight:**
**Hospitalisation:** **Age:** 25Y
**Onset Date:** 31/03/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 0.5 Dose Unspecified Daily Oral
**Batch:** **Started:** 16/03/1995 **Stopped:** 06/03/1996

### Laboratory Investigations:

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

### Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107155 **Seq:** 1 **Gender:** U
**Reported:** 20/03/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Hallucination | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107157 **Seq:** 1 **Gender:** F
**Reported:** 20/03/1996 **Weight:** 0.00
**Hospitalisation:** **Age:** 82
**Onset Date:** **DOB:** 26/04/1913
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br><br>Constipation<br>Dysgeusia<br>Inappropriate antidiuretic hormon<br>Nausea | | Sodium levels dropped to low 20's, suspected SIADH | |

### Medicine Details:

**COLOXYL WITH SENNA (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

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

**ASPIRIN (Other drug)** **Reason:**
Oral application 150.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**CISAPRIDE (Other drug)** **Reason:**
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 17/12/2002 | Sodium | MMOL/L | 13/08/2003 | 127 | |
| 17/12/2002 | Sodium | MMOL/L | 13/08/2003 | 128 | |
| 17/12/2002 | Sodium | MMOL/L | 13/08/2003 | 122 | |
| 17/12/2002 | Sodium | MMOL/L | 13/08/2003 | 121 | |
| 17/12/2002 | Sodium | MMOL/L | 13/08/2003 | 131 | |
| 17/12/2002 | Sodium | MMOL/L | 13/08/2003 | 126 | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 107157 **Seq:** 1 **Gender:** F
**Reported:** 20/03/1996 **Weight:** 0.00
**Hospitalisation:** **Age:** 82
**Onset Date:** **DOB:** 26/04/1913
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **LISINOPRIL (Other drug)** | | | **Reason:** | | | |
| Tablet | 5.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | | |
| **TRANSIDERM-NITRO (Other drug)** | | | **Reason:** | | | |
| Cream | 25.0 | Milligram | Daily | | Transdermal | |
| **Batch:** | **Started:** | | | **Stopped:** | | |
| **ZANTAC (Other drug)** | | | **Reason:** | | | |
| Tablet | 300.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression | | |
| Tablet | 2.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | 20/10/1995 | | **Stopped:** | 26/10/1995 | |

## Laboratory Investigations:

## Additional Information:

## Report Detail

**Case Number:** 107157 **Seq:** 1 **Gender:** F
**Reported:** 20/03/1996 **Weight:** 0.00
**Hospitalisation:** **Age:** 82
**Onset Date:** **DOB:** 26/04/1913
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **NATRILIX (Suspected)** | | | **Reason:** | | |
| Tablet | 2.5 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | 12/10/1995 |
| **SERTRALINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 50.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 02/11/1995 | | **Stopped:** | 12/11/1995 |

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 107159 **Seq:** 1 **Gender:** U
**Reported:** 20/03/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

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

## Laboratory Investigations:

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

## Additional Information:

Reaction occurred when medication dose reduced by half.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107163 **Seq:** 1 **Gender:** U
**Reported:** 20/03/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 06/11/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

### Report Detail

**Case Number:** 107164 **Seq:** 1 **Gender:** F
**Reported:** 20/03/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Menstrual disorder | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107166 **Seq:** 1
**Reported:** 20/03/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:**
**Age:**
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pharyngitis<br>Weight decreased | Severe | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 0.0 Oral

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

### Laboratory Investigations:

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

### Additional Information:

### Report Detail

**Case Number:** 107168 **Seq:** 1 **Gender:** M
**Reported:** 20/03/1996 **Weight:**
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 18/11/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Accommodation disorder<br>Ejaculation failure<br>Fatigue<br>Somnolence | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Transient situational disturb
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 18/11/1995 **Stopped:** 20/11/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107169 **Seq:** 1 **Gender:** F
**Reported:** 20/03/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 25/11/1995

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 107223 **Seq:** 1 **Gender:** F
**Reported:** 22/03/1996 **Weight:**
**Hospitalisation:** **Age:** 26Y
**Onset Date:** 01/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | Jittery and feeling tremulous | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/11/1995 **Stopped:** 29/02/1996

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 107231 **Seq:** 1 **Gender:** F
**Reported:** 21/03/1996 **Weight:** 88.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 29/02/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache<br>Muscle spasms | | | |

## Medicine Details:

**WARFARIN SODIUM (Other drug)** **Reason:** Embol&thromb otr&unsp arteries
6.0 Milligram Daily
**Batch:** **Started:** 24/04/1992 **Stopped:**

**INDERAL (Other drug)** **Reason:** Essential benign hypertension
200.0 Milligram Daily
**Batch:** **Started:** 29/12/1989 **Stopped:**

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107236 **Seq:** 1 **Gender:** F
**Reported:** 22/03/1996 **Weight:**
**Hospitalisation:** **Age:** 32Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 2M

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 107238 **Seq:** 1 **Gender:** F
**Reported:** 22/03/1996 **Weight:** 70.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Dizziness<br>Drug withdrawal syndrome<br>Nightmare | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/06/1994 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Rechallenge: reaction occurred when aropax reduced to less than 10mg; dose has been tapered - 20mg to 10mg to 5mg, even alternate nights, but these symptoms always intervene. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107272 **Seq:** 1 **Gender:** M
**Reported:** 25/03/1996 **Weight:** 55.00
**Hospitalisation:** **Age:** 76Y
**Onset Date:** 25/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 21/01/1996 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 107316 **Seq:** 1
**Reported:** 26/03/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 22/01/1996
**Outcome:** Recovered

**Gender:** F
**Weight:** 52.00
**Age:** 78Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia<br>Fatigue<br>Hyponatraemia<br>Somnolence | | | Hospital and fluid restriction |

## Medicine Details:

**STEMETIL (Other drug)** **Reason:** Nausea and vomiting
Tablet 5.0 Milligram As necessary Oral
**Batch:** **Started:** 03/01/1996 **Stopped:**

**OROXINE (Other drug)** **Reason:** Myxedema
Tablet 100.0 Microgram Daily Oral
**Batch:** **Started:** 01/01/1980 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 15/01/1996 **Stopped:** 25/01/1996

**TRIPRIM (Suspected)** **Reason:** Othr diseases of urinary tract
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 17/01/1996 **Stopped:** 23/01/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | 25/01/1996 | 116 | |

## Additional Information:

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107346 **Seq:** 1 **Gender:** M
**Reported:** 27/03/1996 **Weight:** 70.00
**Hospitalisation:** **Age:** 68Y
**Onset Date:** 18/03/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain<br>Cystitis | | | |

### Medicine Details:

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

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

**MONOPRIL (Other drug)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**VASTIN (Other drug)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

### Report Detail

**Case Number:** 107346 **Seq:** 1 **Gender:** M
**Reported:** 27/03/1996 **Weight:** 70.00
**Hospitalisation:** **Age:** 68Y
**Onset Date:** 18/03/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 16/03/1996 **Stopped:** 19/03/1996

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107349 **Seq:** 1 **Gender:** F
**Reported:** 27/03/1996 **Weight:**
**Hospitalisation:** **Age:** 72Y
**Onset Date:** 12/03/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain<br>Nausea<br>Paresis<br>Vertigo | | | |

### Medicine Details:

**STEMETIL (Other drug)** **Reason:** Vertigo
15.0 Milligram Daily
**Batch:** **Started:** **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 12/03/1996 **Stopped:** 13/03/1996

**MURELAX (Suspected)** **Reason:** Specific disorders of sleep
Tablet 15.0 Milligram Daily Oral
**Batch:** **Started:** 12/03/1996 **Stopped:** CONTIN

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107357 **Seq:** 1 **Gender:** F
**Reported:** 27/03/1996 **Weight:**
**Hospitalisation:** **Age:** 56Y
**Onset Date:** 31/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/09/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

- 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107359 **Seq:** 1 **Gender:** F
**Reported:** 27/03/1996 **Weight:**
**Hospitalisation:** **Age:** 70Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 01/05/1995 **Stopped:** 28/02/1996

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107385 **Seq:** 1 **Gender:** F
**Reported:** 28/03/1996 **Weight:** 75.00
**Hospitalisation:** **Age:** 41Y
**Onset Date:** 26/12/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Photosensitivity reaction | | Very dark even tan | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/11/1995 **Stopped:**

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107430 **Seq:** 1 **Gender:** F
**Reported:** 29/03/1996 **Weight:** 140.00
**Hospitalisation:** **Age:** 47Y
**Onset Date:** 12/03/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination<br>Disturbance in attention<br>Drug withdrawal syndrome<br>Hyperhidrosis | | Auditory and visual hallucinations | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107477 **Seq:** 1 **Gender:** F
**Reported:** 29/03/1996 **Weight:**
**Hospitalisation:** **Age:** 63Y
**Onset Date:** 20/07/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | Severe | | |

### Medicine Details:

**BETALOC (Other drug)** **Reason:** Essential benign hypertension
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

**ODRIK (Other drug)** **Reason:** Essential benign hypertension
Tablet 2.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 10/07/1995 **Stopped:** 20/07/1995

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107683 **Seq:** 1 **Gender:** F
**Reported:** 02/04/1996 **Weight:**
**Hospitalisation:** **Age:** A4
**Onset Date:** 28/03/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicide attempt<br>Drug ineffective | | Swallowed packet of demazine repetabs | Charcoal powder |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
60.0 Milligram Daily
**Batch:** **Started:** 01/02/1996 **Stopped:** CONTIN

### Laboratory Investigations:

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

### Additional Information:

Patient deteriorated markedly on high dose of aropax (in excess of therapeutic levels) the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 107695 **Seq:** 1 **Gender:** F
**Reported:** 03/04/1996 **Weight:** 50.00
**Hospitalisation:** **Age:** 27Y
**Onset Date:** 20/03/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Face oedema<br><br>Gravitational oedema | Required Specialist Consultation | | |

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** 01/01/1996 **Stopped:**

**TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)** **Reason:** Unspecified psychosis
30.0 Milligram Daily
**Batch:** **Started:** 01/12/1995 **Stopped:**

**RISPERIDONE (Suspected)** **Reason:** Unspecified psychosis
2.0 Milligram Daily
**Batch:** **Started:** 10/03/1996 **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Patient allegic to disprin. the dosage start date is not necessarily accurate but indicates that start 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 107697 **Seq:** 1 **Gender:** F
**Reported:** 02/04/1996 **Weight:** 79.00
**Hospitalisation:** **Age:** 37Y
**Onset Date:** 31/12/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 16/06/1995 **Stopped:** 26/02/1996

## Laboratory Investigations:

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

## Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107736 **Seq:** 1 **Gender:** F
**Reported:** 04/04/1996 **Weight:** 60.00
**Hospitalisation:** **Age:** 26Y
**Onset Date:** 31/10/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1995 **Stopped:** 28/10/1995

### Laboratory Investigations:

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

### Additional Information:

On ceasing aropax reaction stopped after 10 days, but when patient restarted drug at smaller dose immediate recurrence of reaction occurred and persisted till ceased altogether. - 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

### Report Detail

**Case Number:** 107737 **Seq:** 1 **Gender:** F
**Reported:** 04/04/1996 **Weight:** 60.00
**Hospitalisation:** **Age:** 29Y
**Onset Date:** 16/12/1995 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 16/12/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107738 **Seq:** 1 **Gender:** F
**Reported:** 04/04/1996 **Weight:** 55.00
**Hospitalisation:** **Age:** 38
**Onset Date:** **DOB:** 05/05/1957
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia | | Sensation of bugs under skin. | Propranolol |

### Medicine Details:

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

**FLUPENTHIXOL DECANOATE (Suspected)** **Reason:** Schizophrenia
Injection 60.0 Milligram Weekly Intramuscular
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Senation of bugs under the skin commenced when on flupenthixol and worsened when aropax added.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 107739 **Seq:** 1 **Gender:** F
**Reported:** 04/04/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tongue disorder | | Muscle spasm of the tongue. | Diazepam. |

## Medicine Details:

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

## Laboratory Investigations:

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

## Additional Information:

Muscle spasm of the tongue which awakened the patient in the early hours of the morning.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 107741 **Seq:** 1 **Gender:** F
**Reported:** 04/04/1996 **Weight:** 53.00
**Hospitalisation:** **Age:** 31Y
**Onset Date:** 06/03/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Back pain<br>Extrapyramidal disorder<br>Gait disturbance<br>Hypertonia<br>Hypokinesia<br>Salivary hypersecretion<br>Sensory disturbance | | | Benztropine. |

## Medicine Details:

**CLONAZEPAM (Other drug)** **Reason:** Anxiety neurosis
500.0 Microgram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 07/02/1996 **Stopped:** 16/03/1996

## Laboratory Investigations:

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

## Additional Information:

Patient history: side effects with many antidepressants in past including tca, ssri's rima but not obviously estrapyramidal. symptoms improved with increased dose and then resolved within 8 days after treatment.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107767 **Seq:** 1 **Gender:** U
**Reported:** 09/04/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 28/03/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain<br>Drug withdrawal syndrome<br>Hyperhidrosis<br>Tinnitus<br>Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Reducing
**Batch:** **Started:** 01/04/1995 **Stopped:** 28/03/1996

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107803 **Seq:** 1 **Gender:** F
**Reported:** 11/04/1996 **Weight:** 109.00
**Hospitalisation:** **Age:** 55Y
**Onset Date:** 08/05/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Periorbital oedema | | | Required specific dermatological treatment |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 10/04/1995 **Stopped:** 08/05/1995

### Laboratory Investigations:

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

### Additional Information:

Patient was rechallenged on aropax in january 1996 and the same reaction occurred.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107816 **Seq:** 1 **Gender:** F
**Reported:** 11/04/1996 **Weight:** 50.00
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 03/04/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

**Batch:** **Started:** 02/04/1996 **Stopped:** 06/04/1996

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107902 **Seq:** 1 **Gender:** F
**Reported:** 15/04/1996 **Weight:** 56.00
**Hospitalisation:** **Age:** 34Y
**Onset Date:** 09/02/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia | Required Visit to Doctor | Paraethesia of hands, feet and mouth. | |
| Dizziness | Severe | | |
| Drug withdrawal syndrome | | | |
| Hyperacusis | Required Visit to Doctor | | |
| Nausea | Severe | | |
| Nervousness | Required Visit to Doctor | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/1995 **Stopped:** 28/02/1996

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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### Report Detail

**Case Number:** 107902 **Seq:** 1 **Gender:** F
**Reported:** 15/04/1996 **Weight:** 56.00
**Hospitalisation:** **Age:** 34Y
**Onset Date:** 09/02/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nightmare | Required Specialist Consultation | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/1995 **Stopped:** 28/02/1996

### Laboratory Investigations:

### Additional Information:

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107906 **Seq:** 1
**Reported:** 15/04/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 31/12/1995
**Outcome:** Not yet recovered

**Gender:** M
**Weight:**
**Age:** 49Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Confusional state<br>Consciousness fluctuating<br>Flushing<br>Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/12/1995 **Stopped:** 2D

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Histology<br>Radiololgy | | | | On biopsy it was a small cell carcinoma.<br>Ct chest showed a lung cancer and hilar mass. |

### Additional Information:

After his aropax use, there was a recurrence of his flushing, sweating and shaking episodes. - 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 107943 **Seq:** 1 **Gender:** F
**Reported:** 17/04/1996 **Weight:** 55.00
**Hospitalisation:** **Age:** 30Y
**Onset Date:** 09/02/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Syncope | | Collapse | |
| Chills | | Shivering attacks | |
| Flushing | | | |

### Medicine Details:

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

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 107946 **Seq:** 1 **Gender:** F
**Reported:** 18/04/1996 **Weight:**
**Hospitalisation:** **Age:** 78Y
**Onset Date:** 04/04/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence | | | Changed to moclobemide. |

## Medicine Details:

**BETAGAN (Other drug)** **Reason:**
Eye Drops 0.0 Ophthalmic
**Batch:** **Started:** **Stopped:** CONTIN

**OXAZEPAM (Other drug)** **Reason:** Anxiety neurosis
Oral application 15.0 Milligram As necessary Oral
**Batch:** **Started:** **Stopped:** CONTIN

**NIFEDIPINE (Other drug)** **Reason:** Essential benign hypertension
Oral application 30.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

**FRUSEMIDE (Other drug)** **Reason:**
Oral application 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

## Laboratory Investigations:

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

## Additional Information:

Patient had a previous reaction with sertraline.

## Report Detail

**Case Number:** 107946 **Seq:** 1 **Gender:** F
**Reported:** 18/04/1996 **Weight:**
**Hospitalisation:** **Age:** 78Y
**Onset Date:** 04/04/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **POTASSIUM CHLORIDE (Other drug)** | | | **Reason:** | | | |
| Oral application | 600.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | | CONTIN |
| **CALCIUM NOS (Other drug)** | | | **Reason:** | | | |
| Oral application | 0.0 | | Daily | | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | | CONTIN |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | Depression | | |
| Tablet | 20.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | 01/04/1996 | | **Stopped:** | 07/04/1996 | |

## Laboratory Investigations:

## Additional Information:

Patient had a previous reaction with sertraline.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108022 **Seq:** 1 **Gender:** F
**Reported:** 12/04/1996 **Weight:** 70.00
**Hospitalisation:** **Age:** 61Y
**Onset Date:** 28/03/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hot flush<br>Somnolence | | | |

### Medicine Details:

**CLINORIL (Other drug)** **Reason:** Other rheumatoid arthritis
Tablet 200.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

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

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

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 28/03/1996 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108262 **Seq:** 1
**Reported:** 03/05/1996
**Hospitalisation:**
**Onset Date:** 15/02/1996
**Outcome:** Recovered with sequelae

**Gender:** M
**Weight:** 80.00
**Age:** 40Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination<br>Diarrhoea | | Visual and auditory hallucinations. | Immodium, mersyndol and |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 14/02/1996 **Stopped:** 15/02/1996

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108389 **Seq:** 1 **Gender:** M
**Reported:** 10/05/1996 **Weight:** 75.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness | | | |
| Drug withdrawal syndrome | | | |
| Fatigue | | | |
| Headache | | | |
| Hypertonia | | | |
| Myalgia | | | |
| Nausea | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 12/01/1996 **Stopped:** 29/04/1996

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108403 **Seq:** 1 **Gender:** M
**Reported:** 13/05/1996 **Weight:**
**Hospitalisation:** **Age:** A5
**Onset Date:** 31/12/1994 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Deafness | | Delay in receiving messages | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108419 **Seq:** 1 **Gender:** F
**Reported:** 13/05/1996 **Weight:** 89.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** 09/02/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | | Coarse tremor, limbs head and neck | |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Phobic neurosis
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 09/02/1996 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108437 **Seq:** 1
**Reported:** 13/05/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 18/07/1995
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 81
**DOB:** 13/08/1913
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Coma<br>Confusional state<br>Hypokalaemia<br>Hyponatraemia | | | Rehydrated. |

## Medicine Details:

**COLOXYL WITH SENNA (Other drug)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:** CONTIN

**ROCALTROL (Other drug)** **Reason:** Osteoporosis
250.0 Microgram Daily
**Batch:** **Started:** **Stopped:** CONTIN

**PANADEINE (Other drug)** **Reason:**
8.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 18/07/1995

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Potassium | | 19/07/1995 | 3.3 | |
| | Potassium | | 20/07/1995 | 3.1 | |
| | Potassium | | 21/07/1995 | 3.5 | |
| | Potassium | | 24/07/1995 | 4.5 | |
| | Potassium | | 22/07/1995 | 4.4 | |
| | Sodium | | 18/07/1995 | 123 | |
| | Sodium | | 19/07/1995 | 128 | |

## Additional Information:

## Report Detail

**Case Number:** 108437 **Seq:** 1
**Reported:** 13/05/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 18/07/1995
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 81
**DOB:** 13/08/1913
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **SERENACE (Suspected)** | | | **Reason:** | |
| | 500.0 | Microgram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** | 18/07/1995 |
| **VOLTAREN (Suspected)** | | | **Reason:** | Osteoporosis |
| | 50.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | **Stopped:** | 18/07/1995 |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | 20/07/1995 | 130 | |
| | Sodium | | 21/07/1995 | 131 | |
| | Sodium | | 22/07/1995 | 136 | |
| | Sodium | | 24/07/1995 | 136 | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

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### Report Detail

**Case Number:** 108472 **Seq:** 1 **Gender:** M
**Reported:** 15/05/1996 **Weight:** 85.00
**Hospitalisation:** **Age:** 51Y
**Onset Date:** 02/04/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Parosmia<br>Dysgeusia | | Strong sweet smell | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 18/03/1996 **Stopped:** 16/04/1996

### Laboratory Investigations:

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

### Additional Information:

Previous fluoxetine without the smell/taste effect.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108483 **Seq:** 1 **Gender:** F
**Reported:** 15/05/1996 **Weight:** 50.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** 04/12/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state<br>Grand mal convulsion<br>Somnolence | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 10/11/1995 **Stopped:** 03/12/1995

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electroencephalog | | | | Eeg on 19/12/95 mildly abnormal |

### Additional Information:

Sydenham's chorea at 20 years of age.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108486 **Seq:** 1 **Gender:** F
**Reported:** 15/05/1996 **Weight:** 93.00
**Hospitalisation:** **Age:** 54Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Gravitational oedema | Required Specialist Consultation | | |

## Medicine Details:

**ZADINE (Other drug)** **Reason:** Hay fever
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

**OROXINE (Other drug)** **Reason:** Myxedema
Tablet 50.0 Microgram Daily Oral
**Batch:** **Started:** **Stopped:**

**TRISEQUENS (Other drug)** **Reason:** Othr disorders of menstruation
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 05/12/1995 **Stopped:**

## 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. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108486 **Seq:** 1 **Gender:** F
**Reported:** 15/05/1996 **Weight:** 93.00
**Hospitalisation:** **Age:** 54Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**PLENDIL (Suspected)** **Reason:** Essential benign hypertension
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1994 **Stopped:** 31/01/1995

## Laboratory Investigations:

## Additional Information:

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108487 **Seq:** 1 **Gender:** M
**Reported:** 15/05/1996 **Weight:** 87.00
**Hospitalisation:** **Age:** 48Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Gravitational oedema | Required Visit to Doctor | | Moduretic 5mg mane. |

### Medicine Details:

**BRINDLE SLIM (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 31/03/1996 **Stopped:**

**PLENDIL (Suspected)** **Reason:** Essential benign hypertension
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1994 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Reaction occurred when aropax was increased from 20mg to 30mg to 40mg daily over 6 weeks. patient has allergy to salicylates - breathing problems and oedema. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108488 **Seq:** 1 **Gender:** F
**Reported:** 15/05/1996 **Weight:** 65.00
**Hospitalisation:** **Age:** 30Y
**Onset Date:** 20/12/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Visual disturbance<br>Agitation<br>Dry mouth<br>Fatigue<br>Hyperhidrosis<br>Malaise<br>Weight increased | | Vision distorted (shaky) | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 13/12/1995 **Stopped:** 02/01/1996

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108489 **Seq:** 1
**Reported:** 15/05/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:**
**Age:** 72Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br>Orthostatic hypotension | | | <br>Moclobemide |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

**Batch:** **Started:** 02/02/1996 **Stopped:** 11/02/1996

### Laboratory Investigations:

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

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108490 **Seq:** 1
**Reported:** 15/05/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:**
**Age:** 72Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Keratitis<br><br>Hypophosphataemia | | Sjogren's syndrome. | Prednisolone, moclobemide, salt tab, artificial tears and saliva |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

**Batch:** **Started:** 02/02/1996 **Stopped:** 11/02/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Antinuclear factor<br>Electrolytes<br>Immunology | | | | Ana>640<br>Phosphate 0.45.<br>Anti la/ro+,ena+. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108491 **Seq:** 1 **Gender:** M
**Reported:** 15/05/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Erectile dysfunction<br>Libido decreased | | | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108493 **Seq:** 1 **Gender:** F
**Reported:** 15/05/1996 **Weight:**
**Hospitalisation:** **Age:** 30
**Onset Date:** **DOB:** 25/09/1965
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | | Chlorpromazine 200mg prn for 2-3 days |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
60.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 01Y

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108494 **Seq:** 1 **Gender:** F
**Reported:** 15/05/1996 **Weight:**
**Hospitalisation:** **Age:** 30
**Onset Date:** **DOB:** 25/09/1965
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | | Parkinsonian | |
| Torticollis | | Spasmodic torticollis | |
| Headache | | | Rest, panadol prn, soft collar, stat dose valium 5mg, stat dose indocid 100mg; bentropine (2 doses of 2mg given 12 hours apart) along with diazepam. |
| Hyperkinesia | | | |
| Pain | | | |

## Medicine Details:

**CHLORPROMAZINE HYDROCHLORIDE (Suspected)** **Reason:** Otr spec symp psychopathol nec
200.0 Milligram As necessary
**Batch:** **Started:** **Stopped:** 3D

**AROPAX (Suspected)** **Reason:**
60.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 12M

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108495 **Seq:** 1
**Reported:** 15/05/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered with sequelae

**Gender:** F
**Weight:**
**Age:** 30
**DOB:** 25/09/1965
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Confusional state<br>Constipation<br>Delirium<br>Disturbance in attention<br>Dry mouth<br>Urinary retention<br>Visual disturbance | | | Regular diazepam |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108523 **Seq:** 1 **Gender:** F
**Reported:** 16/05/1996 **Weight:**
**Hospitalisation:** **Age:** 36Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 28/06/1995 **Stopped:** 20/02/1996

### Laboratory Investigations:

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

### Additional Information:

Aropax reduced by 1/4 tab weekly. dizziness occurred at each reduction and continued for 3 weeks after cessation

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108578 **Seq:** 1 **Gender:** F
**Reported:** 20/05/1996 **Weight:**
**Hospitalisation:** **Age:** 73Y
**Onset Date:** 22/03/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Gait disturbance<br>Hallucination<br>Speech disorder<br>Syncope | | | |

## Medicine Details:

**SINEMET-M (Other drug)** **Reason:** Paralysis agitans
5.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:**

**COGENTIN (Other drug)** **Reason:** Paralysis agitans
2.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
10.0 Milligram Daily
**Batch:** **Started:** 03/03/1996 **Stopped:** 01/05/1996

## Laboratory Investigations:

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

## Additional Information:

Side effects to aropax appeared when increased to 20 mg better on 10 mg.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108635 **Seq:** 1
**Reported:** 23/05/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 21/03/1996
**Outcome:** Recovered

**Gender:** M
**Weight:**
**Age:** 71Y
**DOB:**
**Causality:** Causality certain

### Reaction Detail

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

### Medicine Details:

**MURELAX (Other drug)** **Reason:** Specific disorders of sleep
Tablet 15.0 Milligram As necessary Oral
**Batch:** **Started:** **Stopped:** CONTIN

**PREDNISOLONE (Other drug)** **Reason:** Other rheumatoid arthritis
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

**QUINOCTAL (Other drug)** **Reason:** Pain in limb
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:** CONTIN

**SALAZOPYRIN EN (Other drug)** **Reason:** Ulcerative colitis
Tablet 3.0 Gram Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

### Laboratory Investigations:

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

### Additional Information:

Retrial on aropax 1/2 tab once daily on two separate occasions subsequently also caused nausea.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108635 **Seq:** 1
**Reported:** 23/05/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 21/03/1996
**Outcome:** Recovered

**Gender:** M
**Weight:**
**Age:** 71Y
**DOB:**
**Causality:** Causality certain

## Reaction Detail

## Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **PANADEINE FORTE (Other drug)** | | | | **Reason:** | Other rheumatoid arthritis | |
| Tablet | 1.0 | Dose Unspecified | Daily | | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | | CONTIN |
| **AROPAX (Suspected)** | | | | **Reason:** | Depression | |
| Tablet | 20.0 | Milligram | Daily | | Oral | |
| **Batch:** | **Started:** | 20/03/1996 | | **Stopped:** | 24/03/1996 | |

## Laboratory Investigations:

## Additional Information:

Retrial on aropax 1/2 tab once daily on two separate occasions subsequently also caused nausea.

## Report Detail

**Case Number:** 108650 **Seq:** 1 **Gender:** F
**Reported:** 23/05/1996 **Weight:** 53.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 31/12/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**IMIGRAN (Other drug)** **Reason:** Migraine
0.0 As necessary
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1995 **Stopped:** CONTIN

## Laboratory Investigations:

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

## Additional Information:

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108713 **Seq:** 1 **Gender:** F
**Reported:** 27/05/1996 **Weight:** 64.00
**Hospitalisation:** **Age:** 24
**Onset Date:** **DOB:** 23/04/1972
**Outcome:** Unknown **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Hallucination<br>Paraesthesia<br>Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/09/1995 **Stopped:**

### Laboratory Investigations:

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

### Additional Information:

Patient experienced withdrawal symptoms each time they were withdrawn off aropax. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108716 **Seq:** 1 **Gender:** F
**Reported:** 27/05/1996 **Weight:**
**Hospitalisation:** **Age:** 41
**Onset Date:** 19/05/1996 **DOB:** 27/05/1954
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety<br>Chest pain<br>Nausea<br>Vomiting | | | Valium, temazepam |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

0.0

**Batch:** **Started:** 17/05/1996 **Stopped:** 20/05/1996

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108718 **Seq:** 1 **Gender:** F
**Reported:** 27/05/1996 **Weight:**
**Hospitalisation:** **Age:** 33Y
**Onset Date:** 31/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Eye pain<br>Visual disturbance | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/11/1994 **Stopped:** 28/03/1996

### Laboratory Investigations:

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

### Additional Information:

- 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108733 **Seq:** 1 **Gender:** F
**Reported:** 27/05/1996 **Weight:**
**Hospitalisation:** **Age:** 76Y
**Onset Date:** 31/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus<br>Rash pustular<br>Dermatitis psoriasiform | | Arms, back, abdomen and thighs<br>Infected eczema | |

## Medicine Details:

**DYAZIDE (Other drug)** **Reason:** Otr&unspec circulatory disease
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 17/11/1995 **Stopped:** 09/02/1996

## Laboratory Investigations:

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

## Additional Information:

Rash re-appeared within 2-3 weeks of rechallenge with aropax.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108759 **Seq:** 1 **Gender:** U
**Reported:** 28/05/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108760 **Seq:** 1 **Gender:** U
**Reported:** 28/05/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108761 **Seq:** 1 **Gender:** U
**Reported:** 28/05/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | | | |

### Medicine Details:

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108762 **Seq:** 1 **Gender:** U
**Reported:** 28/05/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle twitching | Severe | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108763 **Seq:** 1 **Gender:** F
**Reported:** 28/05/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108766 **Seq:** 1 **Gender:** F
**Reported:** 28/05/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108767 **Seq:** 1 **Gender:** U
**Reported:** 28/05/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Pruritus | | Burning sensation on chin | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 12M

## Laboratory Investigations:

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

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108768 **Seq:** 1 **Gender:** F
**Reported:** 28/05/1996 **Weight:**
**Hospitalisation:** **Age:** 79Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108769 **Seq:** 1 **Gender:** F
**Reported:** 28/05/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108770 **Seq:** 1 **Gender:** F
**Reported:** 28/05/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108771 **Seq:** 1 **Gender:** U
**Reported:** 28/05/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Headache | | Tingling on both sides of head | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108772 **Seq:** 1 **Gender:** U
**Reported:** 28/05/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

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

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108773 **Seq:** 1 **Gender:** U
**Reported:** 28/05/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

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

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

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

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108936 **Seq:** 1 **Gender:** F
**Reported:** 03/06/1996 **Weight:** 80.00
**Hospitalisation:** **Age:** 45
**Onset Date:** **DOB:** 03/03/1951
**Outcome:** Unknown **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Dizziness<br>Drug withdrawal syndrome<br>Tremor | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 40.0 Milligram Daily Oral

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

## Laboratory Investigations:

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

## Additional Information:

Patient tried to stop aropax 40mg twice - january and february'96 - adverse events occurred both times.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108939 **Seq:** 1 **Gender:** M
**Reported:** 03/06/1996 **Weight:** 85.00
**Hospitalisation:** **Age:** 38Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure<br>Migraine | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** 01/01/1996 **Stopped:** 28/04/1996

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108940 **Seq:** 1 **Gender:** F
**Reported:** 03/06/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Apathy | | Decreased motivation, flat days. | |
| Depression | | Extreme sadness and loss of self esteem | |
| Insomnia | | Lack of sleep | |
| Mouth ulceration | | Mouth and tongue sores/ulcers. | |
| Abdominal pain | | | |
| Constipation | | | |
| Drug ineffective | | | |
| Epistaxis | | | |
| Pain | | | |
| Purpura | | | |
| Urinary retention | | | |

## Medicine Details:

**EPILIM (Other drug)** **Reason:**
Tablet 1.0 Gram Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

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

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108940 **Seq:** 1 **Gender:** F
**Reported:** 03/06/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Weight increased | | | |

## Medicine Details:

**EPILIM (Other drug)** **Reason:**
Tablet 1.0 Gram Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 108944 **Seq:** 1 **Gender:** F
**Reported:** 03/06/1996 **Weight:** 50.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 16/02/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthralgia | | Painful coccyx. | Naprosyn |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 30/11/1995 **Stopped:** 03/02/1996

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 03/02/1996 **Stopped:** 28/02/1996

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 108952 **Seq:** 1 **Gender:** F
**Reported:** 03/06/1996 **Weight:**
**Hospitalisation:** **Age:** 39Y
**Onset Date:** 16/04/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Paraesthesia | | | |

## Medicine Details:

**EPILIM (Other drug)** **Reason:**
Oral application 800.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**PROLADONE (Other drug)** **Reason:**
Suppository 120.0 Milligram Daily Rectal
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 05/01/1996 **Stopped:** 15/04/1996

## Laboratory Investigations:

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

## Additional Information:

Narcotic dependency, chronic headaches.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109014 **Seq:** 1 **Gender:** F
**Reported:** 06/06/1996 **Weight:** 60.00
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 10/05/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Erythema multiforme | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 26/04/1996 **Stopped:** 11/05/1996

**IMOVANE (Suspected)** **Reason:** Convulsions
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 29/04/1996 **Stopped:** 11/05/1996

### Laboratory Investigations:

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

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 109016 **Seq:** 1 **Gender:** M
**Reported:** 06/06/1996 **Weight:**
**Hospitalisation:** **Age:** 41Y
**Onset Date:** 17/05/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain<br>Agitation<br>Insomnia | Severe | | |

## Medicine Details:

**LITHIUM CARBONATE (Suspected)** **Reason:** Unspecifid affective psychosis
4.0 Dose Unspecified Daily
**Batch:** **Started:** 01/12/1995 **Stopped:** 18/05/1996

**AROPAX (Suspected)** **Reason:** Unspecifid affective psychosis
1.0 Dose Unspecified Daily
**Batch:** **Started:** 01/12/1995 **Stopped:** 18/05/1996

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

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109043 **Seq:** 1 **Gender:** F
**Reported:** 11/06/1996 **Weight:**
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 31/05/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

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

### Medicine Details:

**ENALAPRIL MALEATE (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**MULTI-B FORTE (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**MICROGYNON 50 (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**PREDNISOLONE (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 109043 **Seq:** 1 **Gender:** F
**Reported:** 11/06/1996 **Weight:**
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 31/05/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **TEMAZEPAM (Other drug)** | | | **Reason:** | | |
| | 10.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 1.0 | Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** | 01/01/1996 | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

- 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109055 **Seq:** 1 **Gender:** F
**Reported:** 11/06/1996 **Weight:** 51.00
**Hospitalisation:** **Age:** 73Y
**Onset Date:** 14/05/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache<br>Nausea | | | |

### Medicine Details:

**LASIX (Other drug)** **Reason:**
40.0 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**OROXINE (Other drug)** **Reason:**
Tablet 50.0 Microgram Daily Oral
**Batch:** **Started:** **Stopped:**

**ADALAT (Other drug)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**ESTRADERM (Other drug)** **Reason:**
25.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 109055 **Seq:** 1
**Reported:** 11/06/1996
**Hospitalisation:**
**Onset Date:** 14/05/1996
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 51.00
**Age:** 73Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Debility&undue fatigue
20.0 Milligram Daily
**Batch:** **Started:** 14/05/1996 **Stopped:** 17/05/1996

## Laboratory Investigations:

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 109083 **Seq:** 1 **Gender:** F
**Reported:** 12/06/1996 **Weight:**
**Hospitalisation:** **Age:** 43Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state | | | |
| Depression | | | |
| Disturbance in attention | | | |
| Dizziness | | | |
| Drug withdrawal syndrome | | | |
| Hallucination | | | |
| Headache | | | |
| Nausea | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Recommenced aropax 20mg after 2 weeks off it and symptoms resolved.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109096 **Seq:** 1 **Gender:** F
**Reported:** 12/06/1996 **Weight:** 84.00
**Hospitalisation:** **Age:** 29Y
**Onset Date:** 30/05/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia<br>Dizziness<br>Drug withdrawal syndrome<br>Nausea | | Ache and odd sensation to right arm and | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/02/1996 **Stopped:** 28/05/1996

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 109115 **Seq:** 1 **Gender:** F
**Reported:** 13/06/1996 **Weight:** 66.00
**Hospitalisation:** **Age:** 68Y
**Onset Date:** 03/06/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain<br>Eructation | | | Gastrogel, changed to zoloft. |

## Medicine Details:

**PEPCIDINE (Other drug)** **Reason:** Abdominal pain
40.0 Milligram Daily
**Batch:** **Started:** 29/05/1996 **Stopped:** CONTIN

**DIAZEPAM (Other drug)** **Reason:** Specific disorders of sleep
15.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**TIMOLOL MALEATE (Other drug)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 31/05/1996 **Stopped:** 03/06/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109134 **Seq:** 1 **Gender:** M
**Reported:** 14/06/1996 **Weight:** 45.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 06/06/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug ineffective | | | |

### Medicine Details:

**MELLERIL (Other drug)** **Reason:**
Oral application 75.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/04/1996 **Stopped:** 05/06/1996

### 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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 109135 **Seq:** 1
**Reported:** 14/06/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 06/06/1996
**Outcome:** Recovered

**Gender:** F
**Weight:** 45.00
**Age:** 28Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperreflexia | | Increased reflexes, increased jaw reflexes | |
| Dystonia | | Stiffness in legs | |
| Amnesia | | | |
| Anxiety | | | |
| Hypertonia | | | |
| Serotonin syndrome | | | |
| Tachycardia | | | |
| Tremor | | | Cogentin 2mg imi, valium 5mg |

## Medicine Details:

**MELLERIL (Other drug)** **Reason:**
Oral application 75.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1996 **Stopped:**

**AURORIX (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 05/06/1996 **Stopped:** 07/06/1996

**AROPAX (Suspected)** **Reason:**
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/04/1996 **Stopped:** 05/06/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Stiffness (?dystonic) came on > 3hrs after 1st dose of aurorix and the same reaction occurred after 2nd dose. the dosage start date is not necessarily accurate but indicates that start 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 109154 **Seq:** 1 **Gender:** F
**Reported:** 14/06/1996 **Weight:** 65.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 28/05/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia<br>Coordination abnormal<br>Headache<br>Nausea<br>Somnolence<br>Visual disturbance | Severe | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 28/05/1996 **Stopped:** 30/05/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Rechallenged one week later - same course and result.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 109263 **Seq:** 1 **Gender:** M
**Reported:** 19/06/1996 **Weight:** 78.00
**Hospitalisation:** **Age:** 49Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Extrasystoles<br>Convulsion | | Ventricular ectopics | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1995 **Stopped:** 28/05/1996

**ENDEP (Suspected)** **Reason:** Specific disorders of sleep
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 01/06/1995 **Stopped:** 28/04/1996

**PROPRANOLOL HYDROCHLORIDE (Suspected)** **Reason:** Essential benign hypertension
Tablet 80.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1994 **Stopped:** CONTIN

**RIVOTRIL (Suspected)** **Reason:** Anxiety neurosis
Oral application 500.0 Microgram Daily Oral
**Batch:** **Started:** 01/01/1994 **Stopped:** CONTIN

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electrographics | | | | Holter monitor - veb(vt x once 5 beats only with no symptoms) |

## Additional Information:

Ceased aropax, changed to zoloft - myoclonus cured. veb persists but improved. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109265 **Seq:** 1 **Gender:** F
**Reported:** 19/06/1996 **Weight:**
**Hospitalisation:** **Age:** 44
**Onset Date:** 31/03/1996 **DOB:** 26/07/1951
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura | | Bruising over body | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 08/02/1996 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

## Report Detail

**Case Number:** 109266 **Seq:** 1 **Gender:** F
**Reported:** 19/06/1996 **Weight:** 57.00
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 11/03/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis<br>Agitation<br>Anxiety | | Sweating hands and feet | |

## Medicine Details:

**SEREPAX (Other drug)** **Reason:** Anxiety neurosis
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 11/03/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 11/03/1996 **Stopped:** 16/04/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109341 **Seq:** 1 **Gender:** F
**Reported:** 18/06/1996 **Weight:** 55.00
**Hospitalisation:** **Age:** 27Y
**Onset Date:** 31/03/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mania | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

0.0

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109413 **Seq:** 1 **Gender:** F
**Reported:** 21/06/1996 **Weight:** 60.00
**Hospitalisation:** **Age:** 47Y
**Onset Date:** 01/05/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nightmare<br>Nausea | | Frightening, vivid, easily remembered | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 22/03/1996 **Stopped:** 31/05/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109470 **Seq:** 1 **Gender:** F
**Reported:** 24/06/1996 **Weight:**
**Hospitalisation:** **Age:** 76Y
**Onset Date:** 16/11/1995 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination<br>Psychotic disorder | | | Stelazine, haloperidol |

### Medicine Details:

**ZANTAC (Suspected)** **Reason:** Gastritis&duodenitis
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 27/10/1995 **Stopped:** 16/11/1995

**NAPROXEN (Suspected)** **Reason:** Pain in joint
Tablet 1.0 Gram Daily Oral
**Batch:** **Started:** 27/10/1995 **Stopped:** 16/11/1995

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 22/08/1995 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Psychosis consisting of visiual hallucinations in a visually impaired patient.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 109491 **Seq:** 1 **Gender:** F
**Reported:** 25/06/1996 **Weight:** 68.00
**Hospitalisation:** **Age:** 51Y
**Onset Date:** 04/06/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Apathy<br>Depression<br>Disturbance in attention<br>Dizziness<br>Drug withdrawal syndrome<br>Nausea<br>Tinnitus | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1996 **Stopped:** 04/06/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Symptoms have settled down on recommencing aropax. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109638 **Seq:** 1 **Gender:** M
**Reported:** 01/07/1996 **Weight:** 85.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 24/05/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression<br>Drug withdrawal syndrome<br>Psychotic disorder | | | Recommencement of |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 10/05/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109697 **Seq:** 1 **Gender:** F
**Reported:** 04/07/1996 **Weight:** 59.00
**Hospitalisation:** **Age:** 86
**Onset Date:** 14/05/1996 **DOB:**
**Outcome:** Recovered 26/06/1996 **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Inappropriate antidiuretic hormon<br>Hyponatraemia | | Siadh pattern<br>Suspected SIADH | |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109768 **Seq:** 1 **Gender:** F
**Reported:** 04/07/1996 **Weight:**
**Hospitalisation:** **Age:** A2
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain | Severe | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109769 **Seq:** 1 **Gender:** F
**Reported:** 04/07/1996 **Weight:** 65.00
**Hospitalisation:** **Age:** 68Y
**Onset Date:** 06/05/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tinnitus<br>Drug ineffective<br>Drug withdrawal syndrome<br>Malaise<br>Nausea | | Noises in head, blowing and crackling | |

### Medicine Details:

**XANAX (Other drug)** **Reason:**
250.0 Microgram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 12/03/1996 **Stopped:** 10/04/1996

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 10/04/1996 **Stopped:** 06/05/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109826 **Seq:** 1 **Gender:** M
**Reported:** 08/07/1996 **Weight:** 60.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 25/06/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic function abnormal<br>Hypercholesterolaemia | | Abnormal lft | |

### Medicine Details:

**DUCENE (Other drug)** **Reason:** Anxiety neurosis
2.0 Dose Unspecified Daily
**Batch:** **Started:** 01/10/1995 **Stopped:**

**ZOCOR (Other drug)** **Reason:** Othr&unspec metabolic diseases
10.0 Milligram Daily
**Batch:** **Started:** 01/10/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/1994 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | | 25/06/1996 | 56 | |
| | Cholesterol | | | | Rise of cholesterol rom 4.7 to 9.8 mm/l |
| | GGT = SGGT = | | 25/06/1996 | 61 | |

### Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

## Report Detail

**Case Number:** 109839 **Seq:** 1 **Gender:** F
**Reported:** 08/07/1996 **Weight:**
**Hospitalisation:** **Age:** 45Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash | | | |

## Medicine Details:

**TOFRANIL (Other drug)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:**

**RIVOTRIL (Other drug)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 109896 **Seq:** 1 **Gender:** M
**Reported:** 11/07/1996 **Weight:**
**Hospitalisation:** **Age:** 61Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome<br>Hypotension<br>Weight decreased | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/11/1995 **Stopped:** 28/06/1996

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110041 **Seq:** 1 **Gender:** M
**Reported:** 18/07/1996 **Weight:**
**Hospitalisation:** **Age:** 41Y
**Onset Date:** 23/02/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertonia<br>Pain | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 23/02/1996 **Stopped:** 26/02/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110125 **Seq:** 1 **Gender:** M
**Reported:** 22/07/1996 **Weight:** 72.00
**Hospitalisation:** **Age:** 34Y
**Onset Date:** 06/07/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Drug withdrawal syndrome<br>Hallucination<br>Sleep walking | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/02/1996 **Stopped:** 05/07/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 110280 **Seq:** 1
**Reported:** 29/07/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 26/06/1996
**Outcome:** Recovered

**Gender:** F
**Weight:** 56.00
**Age:** 74Y
**DOB:**
**Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Malaise | | Had awful feeling | |
| Atrial fibrillation | | Rapid atrial fibrillation | |
| Paraesthesia | | Tingling down arms and legs | |
| Anxiety | | | |
| Diarrhoea | | | |
| Headache | | | |
| Nausea | | | Atrial fibrillation reverted to sinus rhythm by iv amiodarone |
| Tremor | | | |

## Medicine Details:

**FAMOTIDINE (Other drug)** **Reason:**
Oral application 40.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**VOLTAREN (Other drug)** **Reason:**
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:**
20.0 Milligram 2 times
**Batch:** **Started:** 26/06/1996 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

"3 hours after taking aropax 20mg, developed dry retching, had awful feeling shaking all over, diarrhoea. admitted to royal perth hospital. rapid atrial fibrillation reverted to sinus rhythm by iv amiodarone. on 2/7/96 took another aropax tablet - within 2 hours developed headache (described as tight numbing band), nausea and diarrhoea through the day. tingling down arms and legs. anxious. no atrial fibrillation."

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110283 **Seq:** 1 **Gender:** F
**Reported:** 26/07/1996 **Weight:** 49.00
**Hospitalisation:** **Age:** 37Y
**Onset Date:** 02/07/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic function abnormal | | | |

### Medicine Details:

**MOCLOBEMIDE (Other drug)** **Reason:**
Tablet 450.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1994 **Stopped:** 30/05/1996

**DIANE-35 ED (Other drug)** **Reason:** Contraception
Pill 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 01/01/1993 **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 25/06/1996 **Stopped:** 23/07/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | | 02/07/1996 | 591 | |
| | AST = SGOT | | 02/07/1996 | 303 | |

### Additional Information:

Past history of hepatitis c. patient has alchol 2 standards drinks per week. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110330 **Seq:** 1 **Gender:** F
**Reported:** 30/07/1996 **Weight:**
**Hospitalisation:** **Age:** 31Y
**Onset Date:** 02/10/1994 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain | | | |
| Dizziness | | | |
| Drug withdrawal syndrome | | | |
| Headache | | | |
| Hyperhidrosis | | | |
| Insomnia | | | |
| Nausea | | | |
| Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 24/03/1994 **Stopped:** 30/09/1994

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 110332 **Seq:** 1 **Gender:** M
**Reported:** 30/07/1996 **Weight:** 92.00
**Hospitalisation:** **Age:** 71
**Onset Date:** 31/12/1994 **DOB:** 18/05/1923
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abnormal dreams<br><br>Anxiety | | | Medication probable change to mianserin |

## Medicine Details:

**FOLIC ACID (Other drug)** **Reason:**
Oral application 0.0 Oral
**Batch:** **Started:** **Stopped:**

**IRON (Other drug)** **Reason:**
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

**DILOSYN (Other drug)** **Reason:** Other puritis conditions
2.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**PRAVACHOL (Other drug)** **Reason:** Othr&unspec metabolic diseases
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient has "restless legs syndrome complicating the picture. also has chronic renal failure/dialysis. - the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 110332 **Seq:** 1
**Reported:** 30/07/1996
**Hospitalisation:**
**Onset Date:** 31/12/1994
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 92.00
**Age:** 71
**DOB:** 18/05/1923
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **RIVOTRIL (Other drug)** | | | **Reason:** | Other disturbance of sensation |
| Oral application | 8.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 01/01/1993 | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression |
| Tablet | 20.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 01/11/1994 | | **Stopped:** | 28/07/1996 |

## Laboratory Investigations:

## Additional Information:

Patient has "restless legs syndrome complicating the picture. also has chronic renal failure/dialysis. - the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 110337 **Seq:** 1 **Gender:** M
**Reported:** 30/07/1996 **Weight:**
**Hospitalisation:** **Age:** 26Y
**Onset Date:** 11/05/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle twitching | | Facial tic, involuntary, originates lower face | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 26/04/1996 **Stopped:** 14/05/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Facial tic was involuntary, appeared to originate in the lower face and occurred every few minutes. the tic resolved a couple of days after ceasing medication.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110341 **Seq:** 1 **Gender:** M
**Reported:** 30/07/1996 **Weight:** 80.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Drug withdrawal syndrome<br>Headache | | Electric shocks, back of head, forehead, | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/02/1995 **Stopped:** 28/02/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Reaction occurred when patient ceased aropax. medication restarted and reaction resolved. aropax ceased again and reaction recurred. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110343 **Seq:** 1 **Gender:** M
**Reported:** 30/07/1996 **Weight:** 50.00
**Hospitalisation:** **Age:** 16Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Psychotic disorder | | Inappropriate behaviour - see additional | Medication dose regime changed but not specified |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/04/1995 **Stopped:** 28/06/1995

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient displayed unusual inappropriate behaviour. a lot of behaviour was disinhibited, especially sexual eg putting cat in microwave; dog in washing machine; overt sexual references in language. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110433 **Seq:** 1 **Gender:** F
**Reported:** 02/08/1996 **Weight:** 60.00
**Hospitalisation:** **Age:** 54Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea<br>Faecal incontinence | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 14/12/1995 **Stopped:** 28/02/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Symptoms settled within 48 hours of ceasing aropax. restarted aropax after 2-3 weeks and diarrhoea recurred within 24 hours. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110585 **Seq:** 1 **Gender:** M
**Reported:** 07/08/1996 **Weight:** 70.00
**Hospitalisation:** **Age:** 24Y
**Onset Date:** 07/07/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression | | See additional information | |

### Medicine Details:

**ALCOHOL (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1996 **Stopped:** 07/07/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient became aggressive, attacked people and was charged with assult. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110681 **Seq:** 1 **Gender:** F
**Reported:** 09/08/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Visual disturbance | | Altered spatial perception- affected driving | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Altered spatial perception which affected driving capacity. damaged car five times due to inability to adequately judge spatial dimensions.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110724 **Seq:** 1 **Gender:** F
**Reported:** 12/08/1996 **Weight:** 77.00
**Hospitalisation:** **Age:** 59Y
**Onset Date:** 23/01/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea | | | Lomotil |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** 04/08/1995 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110877 **Seq:** 1 **Gender:** F
**Reported:** 15/08/1996 **Weight:** 70.00
**Hospitalisation:** **Age:** 75Y
**Onset Date:** 03/08/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Malaise | | Felt terrible | |
| Gait disturbance | | Supported self to walk eg. walls/furniture | |
| Confusional state | | | |
| Coordination abnormal | | | |
| Pollakiuria | | | |

### Medicine Details:

**TENORMIN (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** 01/01/1980 **Stopped:**

**MODURETIC (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** 02/08/1996 **Stopped:** 04/08/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Mid-stream urine | | | | Microurine: 10 rbcs, <10 epidermal cells, leucocytes, no bacteria |

### Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110943 **Seq:** 1 **Gender:** U
**Reported:** 19/08/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 110945 **Seq:** 1 **Gender:** M
**Reported:** 19/08/1996 **Weight:** 78.00
**Hospitalisation:** **Age:** 50
**Onset Date:** **DOB:** 12/07/1946
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Atrial fibrillation | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 04/12/1995 **Stopped:** 26/06/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electrocardiograph | | | | Ecg - rapid af. |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110946 **Seq:** 1 **Gender:** F
**Reported:** 19/08/1996 **Weight:** 62.00
**Hospitalisation:** **Age:** 66Y
**Onset Date:** 03/07/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Malaise<br>Hyperhidrosis<br>Tremor | | Patient described gasping. | |

### Medicine Details:

**BACLOFEN (Other drug)** **Reason:** Morb&mort due otr ill-def caus
0.0
**Batch:** **Started:** 01/01/1995 **Stopped:**

**PREDNISOLONE (Other drug)** **Reason:** Morb&mort due otr ill-def caus
Oral application 12.5 Milligram Daily Oral
**Batch:** **Started:** 01/01/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 03/07/1996 **Stopped:** 03/07/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was rechallenged on aropax with same reaction occurring. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 110949 **Seq:** 1 **Gender:** F
**Reported:** 19/08/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthralgia<br>Face oedema<br>Pyrexia | | | |

## Medicine Details:

**FLUPENTHIXOL DECANOATE (Suspected)** **Reason:**
Injection 0.0 Intramuscular
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1995 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Haematology | | | | Fbc - wcc 6.3 (80% neutrophils), esr - 43. |

## Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 110980 **Seq:** 1 **Gender:** F
**Reported:** 20/08/1996 **Weight:** 58.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 14/08/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Deafness | | Difficulty in hearing | |
| Tinnitus | | Ears keep "popping" | |
| Ear pain | | Feeling of blocked ears | |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 14/08/1996 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient swapped over from fluoxetine to paroxetine without a washout period.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111042 **Seq:** 1 **Gender:** F
**Reported:** 20/08/1996 **Weight:**
**Hospitalisation:** **Age:** 78Y
**Onset Date:** 26/07/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state | | Acute confusion | |
| Thinking abnormal | | Obtundalon | |
| Inappropriate antidiuretic hormon | Life | | |
| Psychotic disorder | | | |

### Medicine Details:

**XANAX (Other drug)** **Reason:** Anxiety neurosis
0.0
**Batch:** **Started:** **Stopped:**

**PREDNISOLONE (Other drug)** **Reason:** Otr respiratory systm diseases
0.0
**Batch:** **Started:** **Stopped:**

**BECLOFORTE (Other drug)** **Reason:** Otr respiratory systm diseases
0.0
**Batch:** **Started:** **Stopped:**

**VENTOLIN (Other drug)** **Reason:** Otr respiratory systm diseases
0.0
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Serum osmolality | MMOLS/KG | 30/07/1996 | 272 | |
| | Sodium | 134 - 146 | 15/06/1996 | 138 | |
| | Sodium | 134 - 146 | 30/07/1996 | 116 | |
| | Urine osmolality | MMOLS/KG | 30/07/1996 | 610 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111042 **Seq:** 1 **Gender:** F
**Reported:** 20/08/1996 **Weight:**
**Hospitalisation:** **Age:** 78Y
**Onset Date:** 26/07/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
0.0
**Batch:** **Started:** 12/07/1996 **Stopped:** 26/07/1996

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111259 **Seq:** 1 **Gender:** F
**Reported:** 29/08/1996 **Weight:** 45.00
**Hospitalisation:** **Age:** 14Y
**Onset Date:** 10/08/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash<br>Pruritus | | Itchy rash on face and neck | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** 17/07/1996 **Stopped:** 13/08/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The reaction began to subside quickly after stopping paroxetine.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 111332 **Seq:** 1 **Gender:** F
**Reported:** 02/09/1996 **Weight:**
**Hospitalisation:** **Age:** 43Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia<br>Bruxism | | Jaw clenching | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

The reaction stopped when the drug was not taken. it restarted when the drug was recommenced.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111339 **Seq:** 1 **Gender:** M
**Reported:** 02/09/1996 **Weight:** 80.00
**Hospitalisation:** **Age:** 48Y
**Onset Date:** 30/07/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 20/07/1996 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111365 **Seq:** 1 **Gender:** F
**Reported:** 04/09/1996 **Weight:** 80.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** 29/09/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abnormal dreams<br>Flatulence<br>Nightmare<br>Weight increased | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 20/09/1995 **Stopped:** 30/04/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111383 **Seq:** 1 **Gender:** F
**Reported:** 04/09/1996 **Weight:** 62.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Bursitis | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/03/1996 **Stopped:** CONTIN

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111418 **Seq:** 1 **Gender:** M
**Reported:** 05/09/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia | | Paraesthesia-left upper quadrant face | Commenced tegretol |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 3W

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

## Report Detail

**Case Number:** 111424 **Seq:** 1 **Gender:** F
**Reported:** 05/09/1996 **Weight:**
**Hospitalisation:** **Age:** 78
**Onset Date:** 13/08/1996 **DOB:** 26/01/1918
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Bradycardia<br>Orthostatic hypotension | Severe | | |

## Medicine Details:

**ANGININE (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified As necessary Oral
**Batch:** **Started:** **Stopped:**

**NORVASC (Other drug)** **Reason:**
5.0 Milligram Daily
**Batch:** **Started:** 09/08/1996 **Stopped:**

**OROXINE (Other drug)** **Reason:**
Tablet 150.0 Microgram Daily Oral
**Batch:** **Started:** **Stopped:**

**PREDNISONE (Other drug)** **Reason:**
Tablet 1.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

## Report Detail

**Case Number:** 111424 **Seq:** 1 **Gender:** F
**Reported:** 05/09/1996 **Weight:**
**Hospitalisation:** **Age:** 78
**Onset Date:** 13/08/1996 **DOB:** 26/01/1918
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **FLORINEF (Other drug)** | | | **Reason:** | |
| Tablet | 100.0 | Microgram | Daily | Oral |
| **Batch:** | **Started:** | | | **Stopped:** |
| **WARFARIN SODIUM (Other drug)** | | | **Reason:** | |
| | 0.0 | | Alternate days | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **TRANSIDERM-NITRO (Suspected)** | | | **Reason:** | |
| | 0.0 | | | |
| **Batch:** | **Started:** | 07/08/1996 | | **Stopped:** |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | |
| | 20.0 | Milligram | Daily | |
| **Batch:** | **Started:** | 12/08/1996 | | **Stopped:** |

## Laboratory Investigations:

## Additional Information:

## Report Detail

**Case Number:** 111424 **Seq:** 1 **Gender:** F
**Reported:** 05/09/1996 **Weight:**
**Hospitalisation:** **Age:** 78
**Onset Date:** 13/08/1996 **DOB:** 26/01/1918
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**METOPROLOL TARTRATE (Suspected)** **Reason:**
50.0 Milligram Daily
**Batch:** **Started:** 08/08/1996 **Stopped:**

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 111425 **Seq:** 1 **Gender:** F
**Reported:** 05/09/1996 **Weight:** 106.00
**Hospitalisation:** **Age:** 54
**Onset Date:** **DOB:** 06/12/1941
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic function abnormal | Severe | | |

## Medicine Details:

**CALTRATE (Other drug)** **Reason:** Osteoporosis
Tablet 1.2 Gram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**DIAFORMIN (Other drug)** **Reason:** Diabetes mellitus
Tablet 1.0 Gram Daily Oral
**Batch:** **Started:** 01/01/1994 **Stopped:**

**INDAPAMIDE HEMIHYDRATE (Other drug)** **Reason:** Essential benign hypertension
Oral application 2.5 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 20/06/1996 **Stopped:** 08/07/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | 2 -40 U/L | 08/07/1996 | 251 | |
| | ALT = SGPT | 2 -40 U/L | 10/07/1996 | 129 | |
| | ALT = SGPT | 2 -40 U/L | 23/08/1996 | 29 (10-40) | |
| | ALT = SGPT | 2 -40 U/L | 12/07/1996 | 125 | |
| | AST = SGOT | 2- 35 U/L | 08/07/1996 | 25 | |
| | AST = SGOT | 2- 35 U/L | 10/07/1996 | 28 | |
| | AST = SGOT | 2- 35 U/L | 12/07/1996 | 31 | |

## Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 111425 **Seq:** 1 **Gender:** F
**Reported:** 05/09/1996 **Weight:** 106.00
**Hospitalisation:** **Age:** 54
**Onset Date:** **DOB:** 06/12/1941
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **CALTRATE (Other drug)** | | | | **Reason:** | Osteoporosis |
| Tablet | 1.2 | Gram | Daily | | Oral |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | |
| **DIAFORMIN (Other drug)** | | | | **Reason:** | Diabetes mellitus |
| Tablet | 1.0 | Gram | Daily | | Oral |
| **Batch:** | **Started:** | 01/01/1994 | | **Stopped:** | |
| **INDAPAMIDE HEMIHYDRATE (Other drug)** | | | | **Reason:** | Essential benign hypertension |
| Oral application | 2.5 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | |
| **AROPAX (Suspected)** | | | | **Reason:** | Depression |
| Tablet | 20.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 20/06/1996 | | **Stopped:** | 08/07/1996 |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | AST = SGOT | 2- 35 U/L | 23/08/1996 | 17 (10-40) | |
| | Bilirubin | 2-17 UMOL/L | 08/07/1996 | 14 | |
| | Bilirubin | 2-17 UMOL/L | 23/08/1996 | 8 (1-20) | |
| | Bilirubin | 2-17 UMOL/L | 12/07/1996 | 15 | |
| | Bilirubin | 2-17 UMOL/L | 10/07/1996 | 15 | |
| | GGT = SGGT = | 2-30 U/L | 08/07/1996 | 2167 | |
| | GGT = SGGT = | 2-30 U/L | 10/07/1996 | 1457 | |

## Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

## Report Detail

**Case Number:** 111425 **Seq:** 1 **Gender:** F
**Reported:** 05/09/1996 **Weight:** 106.00
**Hospitalisation:** **Age:** 54
**Onset Date:** **DOB:** 06/12/1941
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **CALTRATE (Other drug)** | | | **Reason:** | Osteoporosis | |
| Tablet | 1.2 | Gram | Daily | | Oral |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | |
| **DIAFORMIN (Other drug)** | | | **Reason:** | Diabetes mellitus | |
| Tablet | 1.0 | Gram | Daily | | Oral |
| **Batch:** | **Started:** | 01/01/1994 | | **Stopped:** | |
| **INDAPAMIDE HEMIHYDRATE (Other drug)** | | | **Reason:** | Essential benign hypertension | |
| Oral application | 2.5 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | L TERM | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 20.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 20/06/1996 | | **Stopped:** | 08/07/1996 |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | GGT = SGGT = ^ASTD | 2-30 U/L | 23/08/1996 | 186 (7-35) | |
| | GGT = SGGT = ^ASTD | 2-30 U/L | 12/07/1996 | 1783 | |
| | SAP = ALP | 20-120 U/L | 08/07/1996 | 354 | |
| | SAP = ALP | 20-120 U/L | 10/07/1996 | 285 | |
| | SAP = ALP | 20-120 U/L | 12/07/1996 | 344 | |
| | SAP = ALP | 20-120 U/L | 23/08/1996 | 171*20-130 | |

## Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 111426 **Seq:** 1 **Gender:** F
**Reported:** 05/09/1996 **Weight:**
**Hospitalisation:** **Age:** 90Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination<br>Diarrhoea | | Pt insisted dead relatives were visiting her | |

## Medicine Details:

**PARACETAMOL (Other drug)** **Reason:**
Oral application 3.0 Gram Daily Oral
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**PREDNISOLONE (Other drug)** **Reason:**
Tablet 2.5 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**ZANTAC (Other drug)** **Reason:**
Oral application 150.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1995 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 30/04/1996 **Stopped:** 01/05/1996

## 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. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 111450 **Seq:** 1 **Gender:** F
**Reported:** 06/09/1996 **Weight:**
**Hospitalisation:** **Age:** 52Y
**Onset Date:** 08/06/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash maculo-papular<br>Face oedema | | Rash on forehead, neck, cheeks. | |

## Medicine Details:

**PROVERA (Other drug)** **Reason:** Menopausal symptoms
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**ESTRADERM (Other drug)** **Reason:** Menopausal symptoms
Cream 1.0 Dose Unspecified Daily Topical
**Batch:** **Started:** L TERM **Stopped:**

**CLARATYNE (Other drug)** **Reason:** Hay fever
Oral application 10.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 31/05/1996 **Stopped:** 08/06/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Allergy to penicillin, bactrim, phenergan.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111485 **Seq:** 1 **Gender:** F
**Reported:** 09/09/1996 **Weight:** 85.00
**Hospitalisation:** **Age:** 34Y
**Onset Date:** 04/09/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea | | | |

### Medicine Details:

**LOGYNON ED (Other drug)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:**

**BECLOFORTE (Other drug)** **Reason:** Asthma
0.0
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** 20/08/1996 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient experiences nausea if takes aropax on empty stomach, feels ok if takes it with food.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111490 **Seq:** 1 **Gender:** M
**Reported:** 09/09/1996 **Weight:** 89.00
**Hospitalisation:** **Age:** 34Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient unable to sleep before 1-2am if takes aropax later than 10am patient is an alcoholic, largely abstinent.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 111500 **Seq:** 1 **Gender:** M
**Reported:** 09/09/1996 **Weight:** 67.00
**Hospitalisation:** **Age:** 70Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug level increased | | Elevated serum perhexiline concentrations | |

## Medicine Details:

**PEXID (Interaction)** **Reason:** Angina pectoris w/o hyperten
200.0 Milligram Daily
**Batch:** **Started:** 01/06/1995 **Stopped:** CONTIN

**AROPAX (Interaction)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 18/01/1996 **Stopped:** 27/02/1996

**AURORIX (Interaction)** **Reason:** Depression
600.0 Milligram Daily
**Batch:** **Started:** 01/05/1996 **Stopped:** CONTIN

**CARDIZEM (Other drug)** **Reason:** Angina pectoris w/o hyperten
180.0 Milligram Daily
**Batch:** **Started:** 01/05/1995 **Stopped:** CONTIN

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Serum drug level | | 11/07/1995 | 0.33 | Perhexiline serum |
| | Serum drug level | | 15/08/1995 | 0.31 | Perhexiline serum |
| | Serum drug level | | 07/09/1995 | 0.28 | Perhexiline serum |
| | Serum drug level | | 25/01/1996 | 0.88 | Perhexiline serum |
| | Serum drug level | | 13/02/1996 | 1.02 | Perhexiline serum |
| | Serum drug level | | 20/02/1996 | 1.54 | Perhexiline serum |
| | Serum drug level | | 05/03/1996 | 0.65 | Perhexiline serum |

## Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 111500 **Seq:** 1 **Gender:** M
**Reported:** 09/09/1996 **Weight:** 67.00
**Hospitalisation:** **Age:** 70Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **CARTIA (Other drug)** | | **Reason:** | Chron isch heart dis no hyper | |
| | 100.0 Milligram | Daily | | |
| **Batch:** | **Started:** 01/09/1995 | | **Stopped:** | CONTIN |
| **ENDONE (Other drug)** | | **Reason:** | Pain | |
| | 15.0 Milligram | Daily | | |
| **Batch:** | **Started:** 01/09/1995 | | **Stopped:** | CONTIN |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Serum drug level | | 19/03/1996 | 0.61 | Perhexiline serum |
| | Serum drug level | | 22/04/1996 | 0.43 | Perhexiline serum |
| | Serum drug level | | 20/06/1996 | 0.25 | Perhexiline serum |
| | Serum drug level | | 01/07/1996 | 0.59 | Perhexiline serum |

## Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111545 **Seq:** 1 **Gender:** F
**Reported:** 12/09/1996 **Weight:** 94.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 05/09/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Coordination abnormal | | Loss of balance - couldn't stand. | |
| Tremor | | Shaking uncontrolable. | |
| Visual disturbance | | Tunnel vision | Diazepam, maxolon |
| Dizziness | | | |
| Vomiting | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 20/05/1996 **Stopped:** 03/09/1996

**AURORIX (Suspected)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 05/09/1996 **Stopped:** 05/09/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111638 **Seq:** 1
**Reported:** 16/09/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 05/09/1996
**Outcome:** Recovered

**Gender:** F
**Weight:** 75.00
**Age:** 71Y
**DOB:**
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Flushing<br>Hypertension<br>Malaise<br>Nausea | | | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111654 **Seq:** 1 **Gender:** M
**Reported:** 17/09/1996 **Weight:** 65.00
**Hospitalisation:** **Age:** 17Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Orthostatic hypotension | | Dizziness, episodic, 3-4 times a day | |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 04/09/1996 **Stopped:** 11/09/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 111714 **Seq:** 1 **Gender:** M
**Reported:** 19/09/1996 **Weight:**
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 08/09/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Headache<br>Malaise<br>Tremor | | | |

## Medicine Details:

**NATRILIX (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** 05/08/1996 **Stopped:**

**ASPIRIN (Other drug)** **Reason:**
0.5 Dose Unspecified Daily
**Batch:** **Started:** 01/01/1990 **Stopped:**

**ADALAT OROS (Suspected)** **Reason:** Essential benign hypertension
30.0 Milligram Daily
**Batch:** **Started:** 06/09/1996 **Stopped:** 10/09/1996

**AROPAX (Suspected)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** 30/09/1994 **Stopped:**

## 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:** 111786 **Seq:** 1 **Gender:** F
**Reported:** 23/09/1996 **Weight:** 42.00
**Hospitalisation:** **Age:** 60
**Onset Date:** 09/04/1996 **DOB:** 11/12/1935
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | Myoclonic jerks. | Commenced on sertraline. |

## Medicine Details:

**MUSTINE HYDROCHLORIDE (Other drug)** **Reason:** Otr prim malig n lymphoid tisu
Injection 9.0 Milligram Monthly Intravenous
**Batch:** **Started:** **Stopped:**

**VINCRISTINE SULPHATE (Other drug)** **Reason:** Otr prim malig n lymphoid tisu
Injection 2.0 Milligram Monthly Intravenous
**Batch:** **Started:** **Stopped:**

**DEXAMETHASONE (Other drug)** **Reason:** Otr prim malig n lymphoid tisu
Injection 10.0 Milligram Monthly Intravenous
**Batch:** **Started:** **Stopped:**

**METHYLPREDNISOLONE (Other drug)** **Reason:** Otr prim malig n lymphoid tisu
Injection 1.0 Gram Monthly Intravenous
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient history: non-hodgkin lymphoma with depression.

### Report Detail

**Case Number:** 111786 **Seq:** 1 **Gender:** F
**Reported:** 23/09/1996 **Weight:** 42.00
**Hospitalisation:** **Age:** 60
**Onset Date:** 09/04/1996 **DOB:** 11/12/1935
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **TROPISETRON HYDROCHLORIDE (Other drug)** | | | **Reason:** | Otr prim malig n lymphoid tisu | |
| Injection | 10.0 | Milligram | Monthly | | Intravenous |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | Depression | |
| Tablet | 40.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 27/02/1996 | | **Stopped:** | 13/05/1996 |

### Laboratory Investigations:

### Additional Information:
Patient history: non-hodgkin lymphoma with depression.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111805 **Seq:** 1 **Gender:** M
**Reported:** 24/09/1996 **Weight:** 73.00
**Hospitalisation:** **Age:** 22Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Deep vein thrombosis<br>Dyspnoea<br>Pulmonary embolism<br>Respiratory disorder | | | |

### Medicine Details:

**MELLERIL (Suspected)** **Reason:** Unspecified psychosis
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 2M

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Other data<br>Protein | | | | Doppler studies confirmed a proximal dvt extending to the inferior vena cava and requiring a caval filter.<br>Further investigation on blood taken before anticoagulation revealed a protein deficiency (39% normal) which his brother and father also have to a lesser degree. |

### Additional Information:

Melleril was increased from 75mg to 300mg rather abruptly.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111829 **Seq:** 1 **Gender:** M
**Reported:** 25/09/1996 **Weight:**
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 18/09/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | Constant restlessness | |
| Agitation | | Panic attacks | |
| Anxiety | | | |
| Fatigue | Severe | | |
| Nausea | | | |
| Palpitations | | | |

### Medicine Details:

**MURELAX (Other drug)** **Reason:**
30.0 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 16/09/1996 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111876 **Seq:** 1 **Gender:** M
**Reported:** 27/09/1996 **Weight:**
**Hospitalisation:** **Age:** 28
**Onset Date:** **DOB:** 07/02/1968
**Outcome:** Recovered without treatment **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Testicular disorder | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 16/09/1996 **Stopped:** 17/09/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 111878 **Seq:** 1
**Reported:** 27/09/1996
**Hospitalisation:**
**Onset Date:** 29/08/1996
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 48.00
**Age:** 26Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Gingivitis | | Bleeding gums | |
| Confusional state | | | |
| Dizziness | | | |
| Dry mouth | | | |
| Nausea | | | Stemetil tab and suppos. rest. |
| Tremor | | | |
| Visual disturbance | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

0.0

**Batch:** **Started:** 01/04/1996 **Stopped:** 29/08/1996

## 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 111905 **Seq:** 1 **Gender:** F
**Reported:** 30/09/1996 **Weight:** 63.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 22/09/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Orthostatic hypotension<br>Bradycardia<br>Agitation<br>Asthenia<br>Drug withdrawal syndrome<br>Nausea<br>Vomiting | | Bp 120/80 and 100/80<br>Pulse 68 | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 04/04/1996 **Stopped:** 20/09/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The doctor observed a similar reaction in another patient, especially bradycardia, postural hypotension and agitation.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 112049 **Seq:** 1 **Gender:** F
**Reported:** 04/10/1996 **Weight:**
**Hospitalisation:** **Age:** 36Y
**Onset Date:** 22/03/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | Severe | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 03/07/1995 **Stopped:** 07/10/1995

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Reaction to aropax ceased on stopping, then returned immediately on rechallenge.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 112056 **Seq:** 1 **Gender:** M
**Reported:** 04/10/1996 **Weight:**
**Hospitalisation:** **Age:** 29Y
**Onset Date:** 30/08/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorexia<br>Ejaculation failure<br>Insomnia<br>Tremor | | | Normison. |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 28/08/1996 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112057 **Seq:** 1 **Gender:** F
**Reported:** 04/10/1996 **Weight:** 56.00
**Hospitalisation:** **Age:** 17Y
**Onset Date:** 06/08/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anaemia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 18/06/1996 **Stopped:** 13/08/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112058 **Seq:** 1 **Gender:** F
**Reported:** 04/10/1996 **Weight:** 84.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** 01/08/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Breast pain | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

**Batch:** **Started:** 15/07/1996 **Stopped:** 23/08/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112080 **Seq:** 1 **Gender:** F
**Reported:** 08/10/1996 **Weight:** 70.00
**Hospitalisation:** **Age:** 23Y
**Onset Date:** 19/07/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Hyperhidrosis<br>Nausea<br>Tremor | | | |

### Medicine Details:

**DIANE-35 ED (Other drug)** **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 19/07/1996 **Stopped:** 19/07/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112163 **Seq:** 1 **Gender:** F
**Reported:** 10/10/1996 **Weight:**
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 31/01/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia<br>Hyperhidrosis<br>Hyperthyroidism<br>Tremor<br>Weight decreased | | Orofacial dystonic movements | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1995 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112165 **Seq:** 1 **Gender:** F
**Reported:** 10/10/1996 **Weight:** 63.00
**Hospitalisation:** **Age:** 26Y
**Onset Date:** 29/09/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Galactorrhoea | | | Medication changed to |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 20/06/1996 **Stopped:** 30/09/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Prolactin | | 30/09/1996 | 621 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112192 **Seq:** 1 **Gender:** U
**Reported:** 10/10/1996 **Weight:** 55.00
**Hospitalisation:** **Age:** 24Y
**Onset Date:** 20/05/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Libido decreased | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 10/05/1996 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 112248 **Seq:** 1 **Gender:** F
**Reported:** 11/10/1996 **Weight:** 68.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 21/09/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Fatigue | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 12/06/1996 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

The patient ran out of aropax - three days after ceasing, she developed "electric shock" type sensations into arms, legs, tongue and jaw. symptoms settled promptly on resumption of paroxetine and patient felt well again. on questioning, the patient said she had similar symptoms one day when she ran out of aropax, one weekend six weeks previously.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 112344 **Seq:** 1 **Gender:** M
**Reported:** 17/10/1996 **Weight:** 90.00
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 27/08/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Erectile dysfunction<br><br>Libido decreased | | Erectile dysfunction | Melleril ceased then one week later paroxetine ceased & fluoxetine substituted |

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 18/08/1996 **Stopped:** 19/09/1996

**MELLERIL (Suspected)** **Reason:** Depression
25.0 Milligram Daily
**Batch:** **Started:** 18/08/1996 **Stopped:** 11/09/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 112422 **Seq:** 1 **Gender:** F
**Reported:** 21/10/1996 **Weight:**
**Hospitalisation:** **Age:** 26Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hernia congenital<br>Jaundice neonatal | | | Required hernia repair on |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Aropax taken during pregnancy by mother. child was born 3/6/96 by lower uterine caesarian section. the baby subsequently remained jaundiced for six weeks and required hernia repair on 25/7/96.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112466 **Seq:** 1 **Gender:** F
**Reported:** 23/10/1996 **Weight:** 77.00
**Hospitalisation:** **Age:** 20Y
**Onset Date:** 13/10/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Congenital hand malformation | | Symbiadydactyly (missing fingers r hand) | Baby being reviewed by plastics unit re |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/01/1995 **Stopped:** 28/01/1996 7M

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Infant born 13/10/96(single boy, birth weight 3390gm at term) with r symbiadydactyly. mother took aropax 20mg/day six months prior to pregnancy until 3-5 weeks into the pregnancy, when she realised she was pregnant. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112472 **Seq:** 1 **Gender:** M
**Reported:** 23/10/1996 **Weight:**
**Hospitalisation:** **Age:** AD
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle spasms<br>Headache<br>Nausea<br>Somnolence | | Spasm in leg | |

### Medicine Details:

**VALIUM (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 19/06/1996 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112613 **Seq:** 1 **Gender:** F
**Reported:** 28/10/1996 **Weight:** 65.00
**Hospitalisation:** **Age:** 61
**Onset Date:** **DOB:** 06/07/1935
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthritis | | Non-inflammatory arthritis | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 10/05/1996 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 112629 **Seq:** 1
**Reported:** 29/10/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:** 04/10/1996
**Outcome:** Recovered

**Gender:** F
**Weight:** 51.00
**Age:** 27Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Constipation<br><br>Abdominal pain | | Extreme constipation | Enemas, admission to hospital, colofac liquid per oral |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 4W

**XANAX (Suspected)** **Reason:** Anxiety neurosis
3.0 Milligram Daily
**Batch:** **Started:** 01/08/1995 **Stopped:** CONTIN

**ANAFRANIL (Suspected)** **Reason:** Anxiety neurosis
50.0 Milligram Daily
**Batch:** **Started:** 23/08/1996 **Stopped:** CONTIN

**PREPULSID FORTE (Suspected)** **Reason:**
40.0 Milligram Daily
**Batch:** **Started:** 30/05/1996 **Stopped:** CONTIN

## 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112756 **Seq:** 1 **Gender:** F
**Reported:** 04/11/1996 **Weight:** 65.00
**Hospitalisation:** **Age:** 54Y
**Onset Date:** 27/10/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome | | | |

### Medicine Details:

**CARDIZEM CD (Other drug)** **Reason:** Essential benign hypertension
180.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**EPILIM (Other drug)** **Reason:** Migraine
1.1 Gram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** 26/10/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112769 **Seq:** 1 **Gender:** M
**Reported:** 04/11/1996 **Weight:** 70.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 27/10/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome<br>Nausea<br>Vomiting | | | <br><br>Maxolon |

### Medicine Details:

**BENZTROPINE MESYLATE (Suspected)** **Reason:**
Tablet 500.0 Microgram Daily Oral
**Batch:** **Started:** **Stopped:** 25/10/1996

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 25/10/1996

**LITHIUM CARBONATE (Suspected)** **Reason:**
Tablet 750.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 25/10/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112787 **Seq:** 1 **Gender:** M
**Reported:** 04/11/1996 **Weight:** 68.00
**Hospitalisation:** **Age:** 74Y
**Onset Date:** 22/10/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence | | | |

### Medicine Details:

**CLOZARIL (Suspected)** **Reason:**
Tablet 250.0 Milligram 1 time Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 40.0 Milligram 1 time Oral
**Batch:** **Started:** **Stopped:**

**ALEPAM (Suspected)** **Reason:**
Tablet 5.0 Milligram 1 time Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient has had a previous adr to clozapine in may 95 - drowsiness, collapse unrousability.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 112869 **Seq:** 1 **Gender:** M
**Reported:** 05/11/1996 **Weight:**
**Hospitalisation:** **Age:** 48Y
**Onset Date:** 31/08/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Speech disorder | | Difficulty forming words | |
| Tongue oedema | | Swollen tongue | |
| Tremor | | Trembling | |
| Dysphagia | | | |
| Nausea | | | |

## Medicine Details:

**ALDECIN (Other drug)** **Reason:** Hay fever
Spray 0.0 Nasal
**Batch:** **Started:** 30/08/1996 **Stopped:**

**SUDAFED (Other drug)** **Reason:** Chronic nasopharyngitis
Oral application 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 30/08/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 0.5 Dose Unspecified 1 time Oral
**Batch:** **Started:** 31/08/1996 **Stopped:** 31/08/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Reaction occurred within a half hour of first dose.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112876 **Seq:** 1 **Gender:** M
**Reported:** 05/11/1996 **Weight:** 95.00
**Hospitalisation:** **Age:** 62
**Onset Date:** 31/03/1996 **DOB:** 19/04/1933
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sleep disorder | | Flings arms during sleep | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1993 **Stopped:**

**TOFRANIL (Suspected)** **Reason:**
Tablet 25.0 Milligram Daily Oral
**Batch:** **Started:** 01/03/1996 **Stopped:** 28/06/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 112877 **Seq:** 1 **Gender:** F
**Reported:** 05/11/1996 **Weight:** 59.00
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 01/09/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness | Required Visit to Doctor | | |
| Drug withdrawal syndrome | | | |
| Nausea | | | Maxolon |
| Photophobia | Required Specialist Consultation | | |
| Vomiting | Required Specialist Consultation | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/11/1995 **Stopped:** 29/08/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient had been on aropax previously and had stopped it abruptly because of pregnancy(8/95), and had the same symptoms. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 113014 **Seq:** 1
**Reported:** 12/11/1996
**Hospitalisation:**
**Onset Date:** 10/06/1996
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 86.00
**Age:** 54Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia<br>Drug withdrawal syndrome<br>Insomnia<br>Malaise<br>Tremor | | | |

## Medicine Details:

**ATENOLOL (Other drug)** **Reason:** Essential benign hypertension
50.0 Milligram Daily
**Batch:** **Started:** 01/01/1995 **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 08/05/1996 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient read warnings on a box about withdrawal so was able to minimize problem. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 113022 **Seq:** 1 **Gender:** M
**Reported:** 12/11/1996 **Weight:** 75.00
**Hospitalisation:** **Age:** 76Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash | Required Specialist Consultation | Rash on forearm, chest and upper legs. | |
| Pruritus | Required Specialist Consultation | | |

## Medicine Details:

**KEFLEX (Suspected)** **Reason:** Otr&nos infec&parasit diseases
2.0 Gram Daily
**Batch:** **Started:** 30/10/1996 **Stopped:** 07/11/1996

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**CARTIA (Suspected)** **Reason:**
100.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**ISOPTIN (Suspected)** **Reason:** Palpitation
240.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113057 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | Severe | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113061 **Seq:** 1 **Gender:** F
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:** 42Y
**Onset Date:** 02/03/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea<br>Paraesthesia<br>Headache | | Motion sickness<br>Tingling in lips, hands and feet | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 29/02/1996 1M

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient on aropax 20mg daily for one month. aropax ceased on 29/2/96 and reaction commenced on 2/3/96.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113063 **Seq:** 1 **Gender:** F
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:** 41Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertonia<br>Abdominal pain | | Muscle spasms in stomach, legs | Valium |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:** 5M

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 113067 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Insomnia | | | |

## Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113068 **Seq:** 1 **Gender:** F
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:** AD
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation neonatal | | Agitation | |
| Feeding disorder neonatal | | Difficulty breast feeding | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Oral application 0.0 Breast milk transfer
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Mother is taking aropax and is breast feeding. infant is agitated, unsettled and has difficulty breast feeding.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113069 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Anxiety neurosis

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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113070 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nightmare | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**METHADONE HYDROCHLORIDE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 113071 **Seq:** 1 **Gender:** F
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Libido decreased | | Sexual dysfunction | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 1M

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113072 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nightmare | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**METHADONE HYDROCHLORIDE (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113074 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hemiparesis<br>Hyperhidrosis<br>Nausea<br>Papilloedema<br>Vomiting | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**NAVANE (Suspected)** **Reason:**
10.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113075 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea | | | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113076 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113077 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | | Therapy changed to zoloft. |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113079 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Parosmia | | Experiences persistent "maple-syrup, | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 3W

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113080 **Seq:** 1 **Gender:** M
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug ineffective<br>Fatigue<br>Myalgia | | Increased depression | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

0.0

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient has chronic fatigue syndrome.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 113081 **Seq:** 1 **Gender:** F
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic function abnormal | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:** 4M

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT<br>GGT = SGGT =<br>SAP = ALP | | | | Alt = 27<br>Ggt = 160<br>Sap = 155 |

## Additional Information:

Patient has had previous exposure to hepatitis c.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113084 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertonia<br>Muscle twitching | | | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113087 **Seq:** 1 **Gender:** F
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic steatosis | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**PLENDIL (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113090 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113091 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypochromic anaemia<br>Thrombocytopenia | | Hb levels dropped from 13 to 9 in 7-10 | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113093 **Seq:** 1 **Gender:** M
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:** 30Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Grand mal convulsion | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1995 **Stopped:**

### 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 113095 **Seq:** 1 **Gender:** U
**Reported:** 12/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Malaise | | Feels terrible | |
| Tinnitus | | Ringing and buzzing in ears | |
| Dizziness | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**MOCLOBEMIDE (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113133 **Seq:** 1 **Gender:** F
**Reported:** 13/11/1996 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | | Night sweats | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

**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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 113135 **Seq:** 1 **Gender:** M
**Reported:** 13/11/1996 **Weight:**
**Hospitalisation:** **Age:** 44Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hot flush<br>Hypoaesthesia<br>Dizziness | | Felt heat racing from toes to head each<br>Numbness all over | Aropax discontinued and then restarted without a return of |

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **AROPAX (Suspected)** | | | **Reason:** Depression | |
| Tablet | 20.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 14/10/1996 | | **Stopped:** 18/10/1996 | |
| **ASPIRIN (Suspected)** | | | **Reason:** Ill-defined heart disease | |
| Oral application | 300.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | **Stopped:** | CONTIN |
| **ATENOLOL (Suspected)** | | | **Reason:** Essential benign hypertension | |
| Tablet | 50.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |
| **VASTIN (Suspected)** | | | **Reason:** Othr&unspec metabolic diseases | |
| Capsule | 40.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** | | **Stopped:** | |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 113135 **Seq:** 1 **Gender:** M
**Reported:** 13/11/1996 **Weight:**
**Hospitalisation:** **Age:** 44Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **ZANTAC (Suspected)** | | | **Reason:** | Disorders of gastric secretion | |
| Oral application | 300.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **ZESTRIL (Suspected)** | | | **Reason:** | Essential benign hypertension | |
| Tablet | 5.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113142 **Seq:** 1 **Gender:** M
**Reported:** 13/11/1996 **Weight:**
**Hospitalisation:** **Age:** 34Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Coordination abnormal | Severe | Loss of co-ordination | |
| Paraesthesia | Severe | Prickly sensation | |
| Drug withdrawal syndrome | | | Valium; discontinuation of aropax by slow reduction in dose |
| Nausea | Severe | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Obsessive compulsive neurosis
Tablet 60.0 Milligram Daily Oral
**Batch:** **Started:** 01/02/1995 **Stopped:**

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113207 **Seq:** 1 **Gender:** F
**Reported:** 18/11/1996 **Weight:** 67.00
**Hospitalisation:** **Age:** 34Y
**Onset Date:** 07/11/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Galactorrhoea | Required Specialist Consultation | | |

### Medicine Details:

**STELAZINE (Suspected)** **Reason:** Unspecified psychosis
10.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 8W

**TRIQUILAR ED (Suspected)** **Reason:** Contraception
1.0 Dose Unspecified Daily
**Batch:** **Started:** L TERM **Stopped:** 12/09/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient has previous history of galactorrhoea with melleril.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113219 **Seq:** 1 **Gender:** F
**Reported:** 18/11/1996 **Weight:** 55.00
**Hospitalisation:** **Age:** 36Y
**Onset Date:** 07/03/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Amenorrhoea<br>Constipation | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 07/03/1996 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113234 **Seq:** 1 **Gender:** F
**Reported:** 19/11/1996 **Weight:** 65.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 09/11/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyspnoea<br>Asthenia<br>Nausea | | Gasping for breath | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 08/11/1996 **Stopped:** 13/11/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113354 **Seq:** 1 **Gender:** F
**Reported:** 25/11/1996 **Weight:** 72.00
**Hospitalisation:** **Age:** 53Y
**Onset Date:** 18/10/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthritis<br>Systemic lupus erythematosus<br>Rash | | Joint swelling and tenderness all pip joints.<br>Lupus like syndome. | |

### Medicine Details:

**LOSEC (Suspected)** **Reason:** Other diseases of esophagus
40.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 11/11/1996

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113372 **Seq:** 1 **Gender:** M
**Reported:** 25/11/1996 **Weight:**
**Hospitalisation:** **Age:** 29Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash | | Skin irritation/eczema. | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113543 **Seq:** 1 **Gender:** F
**Reported:** 29/11/1996 **Weight:**
**Hospitalisation:** **Age:** 23Y
**Onset Date:** 25/11/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | | |

### Medicine Details:

**EPILIM (Other drug)** **Reason:** Other&unspecified epilepsy
0.0
**Batch:** **Started:** **Stopped:**

**TEGRETOL (Other drug)** **Reason:** Other&unspecified epilepsy
0.0
**Batch:** **Started:** **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
20.0 Milligram 1 time
**Batch:** **Started:** 25/11/1996 **Stopped:** 25/11/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient has approximately 3 seizures per year and has been seizure free for the last 4 months. reaction occurred within 2 hours of taking first dose.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 113546 **Seq:** 1 **Gender:** F
**Reported:** 29/11/1996 **Weight:** 0.00
**Hospitalisation:** **Age:** 74
**Onset Date:** **DOB:** 25/12/1921
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia<br>Headache<br>Myalgia<br>Nausea | | Suspected SIADH | Fluid restriction |

## Medicine Details:

**DOLOXENE (Other drug)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:**

**LIQUIFILM TEARS (Other drug)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:**

**ORUDIS GEL (Other drug)** **Reason:** Otr mus rheum,fibrosit&myalgia
Cream 2.0 Dose Unspecified Daily Topical
**Batch:** **Started:** L TERM **Stopped:**

**PEPCIDINE (Other drug)** **Reason:** Peptic ulcer nos w/o ment perf
20.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| 17/12/2002 | Sodium | 135-146 | 14/08/2003 | 132 | |

## Additional Information:

## Report Detail

**Case Number:** 113546 **Seq:** 1
**Reported:** 29/11/1996
**Hospitalisation:**
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 74
**DOB:** 25/12/1921
**Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **OGEN (Other drug)** | | | **Reason:** | | |
| | 1.2 | Milligram | Daily | | |
| **Batch:** | **Started:** | L TERM | | **Stopped:** | |
| **OROXINE (Other drug)** | | | **Reason:** | | |
| | 100.0 | Microgram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Pain | |
| Tablet | 10.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 15/11/1996 | | **Stopped:** | 17/11/1996 |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113652 **Seq:** 1 **Gender:** F
**Reported:** 03/12/1996 **Weight:** 51.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** 31/10/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea<br>Nausea | | Diarrhoea ++<br>Nausea ++ | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
10.0 Milligram Alternate days
**Batch:** **Started:** 10/10/1996 **Stopped:** 07/11/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 113656 **Seq:** 1 **Gender:** F
**Reported:** 03/12/1996 **Weight:** 96.00
**Hospitalisation:** **Age:** 53Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Perineal pain | | Pain in perineum | |
| Arthralgia | | Pain in shoulders and buttocks | |

## Medicine Details:

**DUCENE (Other drug)** **Reason:** Anxiety neurosis
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** 23/01/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 22/05/1996 **Stopped:** 21/08/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113658 **Seq:** 1 **Gender:** U
**Reported:** 03/12/1996 **Weight:**
**Hospitalisation:** **Age:** 18Y
**Onset Date:** 15/11/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aphasia | | Dysphasia for 2-5 minutes after seizure | |
| Syncope | | Loss of consciousness | |
| Convulsion | | Seizure-generalised or complex partial | Paroxetine ceased |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 09/11/1996 **Stopped:** 20/11/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113660 **Seq:** 1 **Gender:** M
**Reported:** 03/12/1996 **Weight:**
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 29/11/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain | | | |
| Anorexia | | | |
| Asthenia | | | |
| Dry mouth | | | |
| Eructation | | | |
| Hyperhidrosis | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 29/11/1996 **Stopped:** 30/11/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113690 **Seq:** 1 **Gender:** F
**Reported:** 05/12/1996 **Weight:** 68.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia<br>Anorexia<br>Fatigue<br>Yawning | | Difficulty achieving orgasm | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 11/06/1995 **Stopped:** 26/10/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113691 **Seq:** 1 **Gender:** F
**Reported:** 05/12/1996 **Weight:** 68.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 29/10/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rhinitis | Required Specialist Consultation | Blocked nose | |
| Abdominal pain | Severe | | |
| Diarrhoea | Required Specialist Consultation | | |
| Dizziness | Severe | | |
| Nausea | Severe | | |
| Vomiting | Severe | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 11/06/1995 **Stopped:** 26/10/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113693 **Seq:** 1 **Gender:** F
**Reported:** 05/12/1996 **Weight:**
**Hospitalisation:** **Age:** 43
**Onset Date:** **DOB:** 17/02/1953
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Drug withdrawal syndrome | | Electrical feelings in body when dose | The symptoms resolve with an increase in dose of aropax |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** 01/09/1994 **Stopped:**

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113751 **Seq:** 1 **Gender:** M
**Reported:** 09/12/1996 **Weight:** 89.00
**Hospitalisation:** **Age:** 30Y
**Onset Date:** 23/11/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/09/1996 **Stopped:** 23/11/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

"electric shocks" in right leg, right arm, trunk, mostly happening with foot fall while walking. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113828 **Seq:** 1 **Gender:** M
**Reported:** 11/12/1996 **Weight:** 75.00
**Hospitalisation:** **Age:** 66Y
**Onset Date:** 09/11/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Visual disturbance<br>Diarrhoea<br>Hyperhidrosis<br>Tremor | Severe | Poor vision | |

### Medicine Details:

**DUCENE (Other drug)** **Reason:**
5.0 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**BETALOC (Other drug)** **Reason:** Essential benign hypertension
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** 02/02/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram 1 time Oral
**Batch:** **Started:** 09/11/1996 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113856 **Seq:** 1 **Gender:** M
**Reported:** 12/12/1996 **Weight:** 76.00
**Hospitalisation:** **Age:** 48Y
**Onset Date:** 09/12/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia<br>Ejaculation failure | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 25/11/1996 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 113944 **Seq:** 1 **Gender:** F
**Reported:** 16/12/1996 **Weight:** 65.00
**Hospitalisation:** **Age:** 21Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mydriasis | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 13/11/1996 **Stopped:** 20/11/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114075 **Seq:** 1 **Gender:** F
**Reported:** 20/12/1996 **Weight:**
**Hospitalisation:** **Age:** 31
**Onset Date:** **DOB:** 21/12/1964
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura | | Bruising for a few weeks | Aropax reduced to 30mg/day |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/07/1996 **Stopped:**

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114109 **Seq:** 1 **Gender:** F
**Reported:** 23/12/1996 **Weight:**
**Hospitalisation:** **Age:** 82Y
**Onset Date:** 12/12/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypochloraemia<br>Hypoglycaemia<br>Hyponatraemia | | | Aropax ceased; normal saline 0.9% iv q8h, then q24h on 15/12/96; decreased dose of oral hypoglycaemics. |

## Medicine Details:

**DAONIL (Other drug)** **Reason:** Diabetes mellitus
10.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**DIABEX (Other drug)** **Reason:** Diabetes mellitus
1.0 Gram Daily
**Batch:** **Started:** L TERM **Stopped:** 14/12/1996

**CAPOTEN (Other drug)** **Reason:**
50.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**THYROXINE SODIUM (Other drug)** **Reason:** Myxedema
75.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Chloride | 96-109 | 13/12/1996 | 75 | |
| | Chloride | 96-109 | 14/12/1996 | 78 | |
| | Chloride | 96-109 | 17/12/1996 | 90 | |
| | Chloride | 96-109 | 15/12/1996 | 78 | |
| | Sodium | 135-145 | 13/12/1996 | 115 | |
| | Sodium | 135-145 | 14/12/1996 | 117 | |
| | Sodium | 135-145 | 15/12/1996 | 117 | |

## Additional Information:

Patient is allergic to sulphur, morphine and penicillin

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114109 **Seq:** 1
**Reported:** 23/12/1996
**Hospitalisation:**
**Onset Date:** 12/12/1996
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 82Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 05/12/1996 **Stopped:** 12/12/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | 135-145 | 17/12/1996 | 128 | |

### Additional Information:

Patient is allergic to sulphur, morphine and penicillin

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114139 **Seq:** 1 **Gender:** F
**Reported:** 24/12/1996 **Weight:** 60.00
**Hospitalisation:** **Age:** 49Y
**Onset Date:** 15/11/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea | Required Specialist Consultation | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/08/1996 **Stopped:** CONTIN

## 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114143 **Seq:** 1
**Reported:** 24/12/1996
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:**
**Age:** 66Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash<br>Thrombocytopenia | | | Hydrocortisone |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** 8M

**RHINOCORT (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** 8M

**BETALOC (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** 8M

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Platelets | | | | Platelets count 35,000. |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114170 **Seq:** 1 **Gender:** F
**Reported:** 30/12/1996 **Weight:** 68.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 16/12/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Erythema nodosum | | Classical erythema nodosum | Steroids |

### Medicine Details:

**MELLERIL (Other drug)** **Reason:** Depression
Oral application 50.0 Milligram Daily Oral
**Batch:** **Started:** 01/02/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/02/1996 **Stopped:** 19/12/1996

### 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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

## Report Detail

**Case Number:** 114203 **Seq:** 1 **Gender:** M
**Reported:** 30/12/1996 **Weight:**
**Hospitalisation:** **Age:** 86Y
**Onset Date:** 13/11/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Chest pain<br>Electrocardiogram abnormal<br>Extrasystoles<br>Hyperhidrosis<br>Hypotension | | | |

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **CYPROTERONE ACETATE (Other drug)** | | | **Reason:** Malignant neoplasm of prostate | |
| Oral application | 150.0 Milligram | Daily | Oral | |
| **Batch:** | **Started:** 01/08/1996 | | **Stopped:** | CONTIN |
| **FLUTAMIDE (Other drug)** | | | **Reason:** Malignant neoplasm of prostate | |
| Tablet | 750.0 Milligram | Daily | Oral | |
| **Batch:** | **Started:** 01/11/1996 | | **Stopped:** | CONTIN |
| **AROPAX (Suspected)** | | | **Reason:** Depression | |
| Tablet | 20.0 Milligram | Daily | Oral | |
| **Batch:** | **Started:** 21/10/1996 | | **Stopped:** 20/11/1996 | |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electrocardiograph | | | | Ecg during episode-occasional ventricular/supra ventricular |

## Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114233 **Seq:** 1 **Gender:** M
**Reported:** 30/12/1996 **Weight:** 56.00
**Hospitalisation:** **Age:** 69Y
**Onset Date:** 29/10/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea | Required Visit to Doctor | | Regular antiemetics and iv fluids; ng feeds recommenced; therapy changed to moclobemide 150mg orally bd. |
| Vomiting | Required Visit to Doctor | | |

## Medicine Details:

**OXAZEPAM (Other drug)** **Reason:**
7.5 Milligram As necessary
**Batch:** **Started:** **Stopped:**

**CIPROXIN (Other drug)** **Reason:**
Tablet 1.5 Gram Daily Oral
**Batch:** **Started:** 26/09/1996 **Stopped:**

**SOLONE (Other drug)** **Reason:**
5.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**NILSTAT (Other drug)** **Reason:**
Solution 4.0 Millilitre Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

### Report Detail

**Case Number:** 114233 **Seq:** 1 **Gender:** M
**Reported:** 30/12/1996 **Weight:** 56.00
**Hospitalisation:** **Age:** 69Y
**Onset Date:** 29/10/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **AMPHOTERICIN (Other drug)** | | | **Reason:** | | |
| Lozenge | 4.0 | Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | | |
| Tablet | 20.0 | Milligram | Daily | | Oral |
| **Batch:** | **Started:** | 25/10/1996 | | **Stopped:** | 30/10/1996 |
| **METROZINE (Suspected)** | | | **Reason:** | | |
| Tablet | 1.2 | Gram | Daily | | Oral |
| **Batch:** | **Started:** | 18/10/1996 | | **Stopped:** | 30/10/1996 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114265 **Seq:** 1 **Gender:** F
**Reported:** 02/01/1997 **Weight:** 45.00
**Hospitalisation:** **Age:** 83Y
**Onset Date:** 28/11/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Pruritus | | Complained of being eaten alive by ants. | <br>Phenergan |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 22/11/1996 **Stopped:** 27/12/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114291 **Seq:** 1 **Gender:** F
**Reported:** 06/01/1997 **Weight:** 102.00
**Hospitalisation:** **Age:** 61Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia<br>Drug withdrawal syndrome<br>Agitation<br>Dizziness | | Aches and pains<br>Felt high, agitated, restless and racing | |

### Medicine Details:

**ALDOMET (Other drug)** **Reason:** Essential benign hypertension
500.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 09/08/1996 **Stopped:** 01/11/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114304 **Seq:** 1 **Gender:** F
**Reported:** 06/01/1997 **Weight:** 57.00
**Hospitalisation:** **Age:** 31Y
**Onset Date:** 18/12/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome<br>Nausea<br>Nightmare | Severe | | |

### Medicine Details:

**RHINOCORT (Other drug)** **Reason:** Hay fever
Spray 2.0 Dose Unspecified Daily Nasal
**Batch:** **Started:** 22/11/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 09/05/1996 **Stopped:** 12/12/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114381 **Seq:** 1 **Gender:** M
**Reported:** 08/01/1997 **Weight:** 65.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 15/12/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus<br>Rash maculo-papular | | | Aropax ceased |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 05/10/1996 **Stopped:** 20/12/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Reaction commenced 6 weeks after starting aropax.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114497 **Seq:** 1 **Gender:** F
**Reported:** 13/01/1997 **Weight:** 60.00
**Hospitalisation:** **Age:** 52Y
**Onset Date:** 15/12/1996 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash erythematous | | Large circular red spots over body esp | |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Anxiety neurosis
20.0 Milligram Daily
**Batch:** **Started:** 09/12/1996 **Stopped:** 17/12/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient was rechallenged on paroxetine with same reaction occurring.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114548 **Seq:** 1 **Gender:** F
**Reported:** 15/01/1997 **Weight:** 79.00
**Hospitalisation:** **Age:** 68
**Onset Date:** **DOB:** 15/10/1928
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nightmare | | | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114560 **Seq:** 1 **Gender:** F
**Reported:** 16/01/1997 **Weight:** 52.00
**Hospitalisation:** **Age:** 63Y
**Onset Date:** 11/01/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea<br>Tachycardia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

**Batch:** **Started:** 11/01/1997 **Stopped:** 12/01/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114636 **Seq:** 1 **Gender:** M
**Reported:** 16/01/1997 **Weight:**
**Hospitalisation:** **Age:** 49Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic function abnormal | | | |

### Medicine Details:

**PANADEINE FORTE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**FLUCLOXACILLIN SODIUM (Suspected)** **Reason:** Otr&nos infec&parasit diseases
2.0 Gram Daily
**Batch:** **Started:** 17/11/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**FELDENE (Suspected)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | (4-40) | 06/04/1996 | 101 | Alt 200 |
| | ALT = SGPT | (4-40) | 24/11/1996 | 200 | Alt 200 |
| | ALT = SGPT | (4-40) | 26/11/1996 | 101 | Alt 200 |
| | ALT = SGPT | (4-40) | 25/11/1996 | 102 | Alt 200 |
| | ALT = SGPT | (4-40) | 13/01/1997 | 53 | Alt 200 |
| | AST = SGOT | (4-40) | 06/04/1996 | 53 | Ast 73 |
| | AST = SGOT | (4-40) | 13/01/1997 | 24 | Ast 73 |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114636 **Seq:** 1 **Gender:** M
**Reported:** 16/01/1997 **Weight:**
**Hospitalisation:** **Age:** 49Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**PANADEINE FORTE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**FLUCLOXACILLIN SODIUM (Suspected)** **Reason:** Otr&nos infec&parasit diseases
2.0 Gram Daily
**Batch:** **Started:** 17/11/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**FELDENE (Suspected)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | AST = SGOT | (4-40) | 26/11/1996 | 45 | Ast 73 |
| | AST = SGOT | (4-40) | 24/11/1996 | 73 | Ast 73 |
| | AST = SGOT | (4-40) | 25/11/1996 | 35 | Ast 73 |
| | Bilirubin | (<18) | 06/04/1996 | 12 | |
| | Bilirubin | (<18) | 24/11/1996 | 16 | |
| | Bilirubin | (<18) | 26/11/1996 | 14 | |
| | Bilirubin | (<18) | 13/01/1997 | 16 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114636 **Seq:** 1 **Gender:** M
**Reported:** 16/01/1997 **Weight:**
**Hospitalisation:** **Age:** 49Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**PANADEINE FORTE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**FLUCLOXACILLIN SODIUM (Suspected)** **Reason:** Otr&nos infec&parasit diseases
2.0 Gram Daily
**Batch:** **Started:** 17/11/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**FELDENE (Suspected)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Bilirubin | (<18) | 25/11/1996 | 14 | |
| | GGT = SGGT = | (4-45) | 06/04/1996 | 216 | Ggt 596 |
| | GGT = SGGT = | (4-45) | 24/11/1996 | 596 | Ggt 596 |
| | GGT = SGGT = | (4-45) | 25/11/1996 | 382 | Ggt 596 |
| | GGT = SGGT = | (4-45) | 26/11/1996 | 471 | Ggt 596 |
| | GGT = SGGT = | (4-45) | 13/01/1997 | 212 | Ggt 596 |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114636 **Seq:** 1 **Gender:** M
**Reported:** 16/01/1997 **Weight:**
**Hospitalisation:** **Age:** 49Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detai

### Medicine Details:

**PANADEINE FORTE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**FLUCLOXACILLIN SODIUM (Suspected)** **Reason:** Otr&nos infec&parasit diseases
2.0 Gram Daily
**Batch:** **Started:** 17/11/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**FELDENE (Suspected)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Liver biopsy | | | | 17/5/96 core biopsy specimen of liver shows only subtle deviation from normal of dubious clinical significance. thus, quantitatively minor fatty change is accompanied by very occasional foci of intralobular hepatocytolysis,possibly consequent upon fatty cyst rupture. otherwise hepatic morphology is unremarkable, with preservation of normal architecture and cytology, and |

### Additional Information:

## Report Detail

**Case Number:** 114636 **Seq:** 1 **Gender:** M
**Reported:** 16/01/1997 **Weight:**
**Hospitalisation:** **Age:** 49Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**PANADEINE FORTE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**FLUCLOXACILLIN SODIUM (Suspected)** **Reason:** Otr&nos infec&parasit diseases
2.0 Gram Daily
**Batch:** **Started:** 17/11/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**FELDENE (Suspected)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Liver biopsy | | | | Liver biospy contin: without inflammatory features. however in special stains there is mild increase both in dipas-positive material and haemosiderin within kupffer cells, consistent with previous hepatic injury, the natures of which is not evident, no liver cell siderosis is seen. |
| | SAP = ALP | (30-120) | 06/04/1996 | 96 | Alp 379 |
| | SAP = ALP | (30-120) | 24/11/1996 | 379 | Alp 379 |
| | SAP = ALP | (30-120) | 25/11/1996 | 248 | Alp 379 |

## Additional Information:

## Report Detail

**Case Number:** 114636 **Seq:** 1 **Gender:** M
**Reported:** 16/01/1997 **Weight:**
**Hospitalisation:** **Age:** 49Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

## Medicine Details:

**PANADEINE FORTE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**FLUCLOXACILLIN SODIUM (Suspected)** **Reason:** Otr&nos infec&parasit diseases
2.0 Gram Daily
**Batch:** **Started:** 17/11/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**FELDENE (Suspected)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | SAP = ALP | (30-120) | 26/11/1996 | 330 | Alp 379 |
| | SAP = ALP | (30-120) | 13/01/1997 | 84 | Alp 379 |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114639 **Seq:** 1 **Gender:** F
**Reported:** 20/01/1997 **Weight:** 57.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 11/01/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Hyperhidrosis<br>Insomnia<br>Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 09/01/1997 **Stopped:** 11/01/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114640 **Seq:** 1 **Gender:** M
**Reported:** 20/01/1997 **Weight:** 178.00
**Hospitalisation:** **Age:** 37Y
**Onset Date:** 09/01/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 02/01/1997 **Stopped:** 16/01/1997

**TAZAC (Suspected)** **Reason:** Other diseases of esophagus
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 01/06/1996 **Stopped:**

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114700 **Seq:** 1 **Gender:** F
**Reported:** 23/01/1997 **Weight:** 48.00
**Hospitalisation:** **Age:** 18Y
**Onset Date:** 10/11/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state<br>Hepatic failure<br><br>Jaundice | | | Vit k, supportive treatment and addition of omeprazole. |

## Medicine Details:

**ZANTAC (Suspected)** **Reason:** Prophylaxis
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 08/11/1996 **Stopped:** 11/11/1996

**FELDENE (Suspected)** **Reason:** Pain
Capsule 400.0 Milligram Daily Oral
**Batch:** **Started:** 06/11/1996 **Stopped:** 11/11/1996

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 20/09/1996 **Stopped:** 11/11/1996

**CALCIPARINE (Suspected)** **Reason:**
Injection 15.0 Thousand Internat Daily Subcutaneous
**Batch:** **Started:** 03/11/1996 **Stopped:** 11/11/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | | 10/11/1996 | 7810 | |
| | AST = SGOT | | 10/11/1996 | 6320 | |
| | Bilirubin | | 10/11/1996 | 128 | |
| | GGT = SGGT = | | 10/11/1996 | 184 | |
| | SAP = ALP | | 10/11/1996 | 254 | |

## Additional Information:

History of paracetamol and illicit substance abuse. 29/10/96 - paracetamol overdose - level 0.63 mmol/l. lfts normal 30/10/96.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114700 **Seq:** 1
**Reported:** 23/01/1997
**Hospitalisation:**
**Onset Date:** 10/11/1996
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 48.00
**Age:** 18Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**PANADOL (Suspected)** **Reason:** Pain
4.0 Gram Daily
**Batch:** **Started:** 05/11/1996 **Stopped:** 11/11/1996

## Laboratory Investigations:

## Additional Information:

History of paracetamol and illicit substance abuse. 29/10/96 - paracetamol overdose - level 0.63 mmol/l. lfts normal 30/10/96.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114707 **Seq:** 1 **Gender:** F
**Reported:** 23/01/1997 **Weight:**
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 28/11/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dry mouth<br>Rash | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 26/11/1996 **Stopped:**

**DIAZEPAM (Suspected)** **Reason:**
Oral application 5.0 Milligram Daily Oral
**Batch:** **Started:** 26/11/1996 **Stopped:**

**OGEN (Suspected)** **Reason:**
625.0 Microgram Daily
**Batch:** **Started:** 26/11/1996 **Stopped:**

**PIZOTIFEN MALATE (Suspected)** **Reason:**
Tablet 1.5 Milligram Daily Oral
**Batch:** **Started:** 26/11/1996 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

### Report Detail

**Case Number:** 114707 **Seq:** 1
**Reported:** 23/01/1997
**Hospitalisation:**
**Onset Date:** 28/11/1996
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 43Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**TEMAZEPAM (Suspected)** **Reason:**

Oral application 20.0 Milligram Daily Oral

**Batch:** **Started:** 26/11/1996 **Stopped:**

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114760 **Seq:** 1 **Gender:** F
**Reported:** 28/01/1997 **Weight:** 49.00
**Hospitalisation:** **Age:** 87Y
**Onset Date:** 13/01/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Oedema | Severe | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 28/12/1996 **Stopped:** 18/01/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

## Report Detail

**Case Number:** 114776 **Seq:** 1 **Gender:** M
**Reported:** 28/01/1997 **Weight:**
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 03/10/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor<br>Coordination abnormal | | Coarse hand tremor | |

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **COGENTIN (Suspected)** | | **Reason:** | | |
| Tablet | 2.0 Milligram | As necessary | Oral | |
| **Batch:** | **Started:** 23/09/1996 | | **Stopped:** | CONTIN |
| **TERIL (Suspected)** | | **Reason:** | | |
| Oral application | 600.0 Milligram | Daily | Oral | |
| **Batch:** | **Started:** 23/09/1996 | | **Stopped:** | CONTIN |
| **RISPERDAL (Suspected)** | | **Reason:** | Unspecified psychosis | |
| Tablet | 1.0 Milligram | Daily | Oral | |
| **Batch:** | **Started:** 23/09/1996 | | **Stopped:** | CONTIN |
| **LITHICARB (Suspected)** | | **Reason:** | | |
| Tablet | 1.7 Gram | Daily | Oral | |
| **Batch:** | **Started:** 23/09/1996 | | **Stopped:** | CONTIN |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Pharmacokinetics | | | | Carbamazepine level=32umol/l, lithium level=1.23umol/l both therapeutic levels |

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114776 **Seq:** 1 **Gender:** M
**Reported:** 28/01/1997 **Weight:**
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 03/10/1996 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 26/09/1996 **Stopped:** CONTIN

### Laboratory Investigations:

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114784 **Seq:** 1 **Gender:** M
**Reported:** 28/01/1997 **Weight:**
**Hospitalisation:** **Age:** 41Y
**Onset Date:** **DOB:**
**Outcome:** Death **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sudden death | | | |

## Medicine Details:

**DOLOXENE (Suspected)** **Reason:**
Capsule 0.0 Oral
**Batch:** **Started:** **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Serum drug level | | | | Plasma levels doloxene:8mcg/l, plasma levels paroxetine: |

## Additional Information:

Committee comment: include in annual fatality analysis

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114789 **Seq:** 1 **Gender:** F
**Reported:** 28/01/1997 **Weight:** 75.00
**Hospitalisation:** **Age:** 34
**Onset Date:** **DOB:** 01/08/1962
**Outcome:** Unknown **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Alopecia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

**Batch:** **Started:** 10/07/1995 **Stopped:** 25/10/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

When patient stopped aropax on 25/10/96 reaction ceased but when recommenced on the 10/11/96 reaction reoccurred.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114791 **Seq:** 1 **Gender:** F
**Reported:** 28/01/1997 **Weight:**
**Hospitalisation:** **Age:** 25
**Onset Date:** **DOB:** 12/06/1971
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anxiety<br>Drug withdrawal syndrome<br>Flushing<br>Somnolence<br>Tremor<br>Vertigo | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
10.0 Milligram Daily
**Batch:** **Started:** 19/12/1995 **Stopped:** 02/01/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114792 **Seq:** 1 **Gender:** F
**Reported:** 28/01/1997 **Weight:**
**Hospitalisation:** **Age:** 36Y
**Onset Date:** 28/09/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura<br>Menorrhagia<br>Eosinophilia | | Bruise on legs, arms and one breast.<br>Heavier periods | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

**Batch:** **Started:** 13/09/1996 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Eosinophils | 1.2 X 10'N<0.6 | 28/09/1996 | 13% | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114802 **Seq:** 1 **Gender:** F
**Reported:** 29/01/1997 **Weight:** 90.00
**Hospitalisation:** **Age:** 57Y
**Onset Date:** 18/01/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Anxiety<br>Drug withdrawal syndrome<br>Hyperhidrosis | | | Diazepam and reducing regime of aropax over 5 days. |

## Medicine Details:

**ALCOHOL (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**DAPA-TABS (Other drug)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** 01/01/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
60.0 Milligram Daily
**Batch:** **Started:** 01/10/1996 **Stopped:** 28/01/1997

## 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114814 **Seq:** 1 **Gender:** M
**Reported:** 28/01/1997 **Weight:**
**Hospitalisation:** **Age:** A3
**Onset Date:** 24/01/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | | Sweaty palms | |
| Oedema | | Swelling up of upper trunk and arms. | |
| Headache | | | |
| Nausea | | | |

### Medicine Details:

**ALEPAM (Other drug)** **Reason:**
Tablet 15.0 Milligram As necessary Oral
**Batch:** **Started:** 01/05/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 23/01/1997 **Stopped:** 24/01/1997

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114816 **Seq:** 1
**Reported:** 28/01/1997
**Hospitalisation:** Admitted to hospital
**Onset Date:** 10/08/1996
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** A3
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Extrapyramidal disorder<br>Oculogyration | | | Cogentin |

### Medicine Details:

**TEMAZE (Other drug)** **Reason:** Disturbance of sleep
Tablet 10.0 Milligram As necessary Oral
**Batch:** **Started:** 01/01/1996 **Stopped:**

**STEMETIL (Suspected)** **Reason:** Nausea and vomiting
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** 05/08/1996 **Stopped:** 05/08/1996

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/11/1995 **Stopped:**

### 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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114829 **Seq:** 1 **Gender:** M
**Reported:** 29/01/1997 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyspnoea | | | |

### Medicine Details:

**LAMIVUDINE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** CONTIN

**ZIDOVUDINE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** CONTIN

**ALPRAZOLAM (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** CONTIN

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:** CONTIN

### 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114829 **Seq:** 1 **Gender:** M
**Reported:** 29/01/1997 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

## Medicine Details:

**INDINAVIR SULFATE (Suspected)** **Reason:** Aids
Capsule 2.4 Gram Daily Oral
**Batch:** **Started:** 01/09/1996 **Stopped:** CONTIN

## Laboratory Investigations:

## Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114866 **Seq:** 1 **Gender:** M
**Reported:** 30/01/1997 **Weight:** 71.00
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyspnoea | | | |

### Medicine Details:

**ZANTAC (Other drug)** **Reason:** Otr disorders stomach function
300.0 Milligram Daily
**Batch:** **Started:** 01/01/1988 **Stopped:** 31/01/1996

**TAZAC (Other drug)** **Reason:** Otr disorders stomach function
300.0 Milligram Daily
**Batch:** **Started:** 01/05/1996 **Stopped:**

**BETOPTIC (Other drug)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** 01/10/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 15/09/1995 **Stopped:**

### 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. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114919 **Seq:** 1 **Gender:** M
**Reported:** 03/02/1997 **Weight:** 85.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 28/12/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyskinesia | | Involuntary movements of upper lip and | |

### Medicine Details:

**RISPERIDONE (Suspected)** **Reason:** Unspecified schizophrenia
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** 18/08/1996 **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 19/12/1996 **Stopped:** 16/01/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114920 **Seq:** 1 **Gender:** F
**Reported:** 03/02/1997 **Weight:** 47.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 16/01/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura | | Purpura upper and lower limb. | |

### Medicine Details:

**GRISOVIN (Suspected)** **Reason:** Dermatophytosis
Tablet 500.0 Milligram Daily Oral
**Batch:** **Started:** 10/01/1997 **Stopped:** 25/01/1997

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/09/1996 **Stopped:**

**MICROVAL (Suspected)** **Reason:** Contraception
1.0 Dose Unspecified Daily
**Batch:** **Started:** 01/12/1996 **Stopped:**

### 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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114974 **Seq:** 1 **Gender:** F
**Reported:** 05/02/1997 **Weight:**
**Hospitalisation:** **Age:** 68Y
**Onset Date:** 31/10/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hair colour changes | | | |

## Medicine Details:

**RENITEC (Suspected)** **Reason:**
5.0 Milligram Daily
**Batch:** **Started:** 01/01/1991 **Stopped:**

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 01/04/1996 **Stopped:**

**LASIX (Suspected)** **Reason:**
40.0 Milligram Daily
**Batch:** **Started:** 01/01/1983 **Stopped:**

**SANDOCAL 1000 (Suspected)** **Reason:**
100.0 Milligram Daily
**Batch:** **Started:** 01/01/1991 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114979 **Seq:** 1 **Gender:** F
**Reported:** 05/02/1997 **Weight:**
**Hospitalisation:** **Age:** 80Y
**Onset Date:** 20/01/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination | | | |

## Medicine Details:

**CAPTOPRIL (Other drug)** **Reason:**
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**COLCHICINE (Other drug)** **Reason:**
0.5 Milligram Daily
**Batch:** **Started:** **Stopped:**

**RANITIDINE (Other drug)** **Reason:**
15.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**DILTIAZEM HYDROCHLORIDE (Other drug)** **Reason:**
180.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

### Report Detail

**Case Number:** 114979 **Seq:** 1 **Gender:** F
**Reported:** 05/02/1997 **Weight:**
**Hospitalisation:** **Age:** 80Y
**Onset Date:** 20/01/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **CARDIPRIN 100 (Other drug)** | | | **Reason:** | | |
| | 100.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **PILOCARPINE (Other drug)** | | | **Reason:** | | |
| Eye Drops | 4.0 | Dose Unspecified | Daily | Ophthalmic | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | | |
| | 10.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | 18/01/1997 | | **Stopped:** | 21/01/1997 |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 114990 **Seq:** 1 **Gender:** M
**Reported:** 05/02/1997 **Weight:**
**Hospitalisation:** **Age:** 82Y
**Onset Date:** 01/01/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state<br>Dizziness<br>Hepatitis<br>Vomiting | | | |

### Medicine Details:

**LITHICARB (Other drug)** **Reason:** Depression
Tablet 125.0 Milligram Daily Oral
**Batch:** **Started:** 01/11/1996 **Stopped:** 06/01/1997

**TOLVON (Other drug)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/01/1995 **Stopped:**

**ZANTAC (Other drug)** **Reason:** Otr disorders stomach function
300.0 Milligram Daily
**Batch:** **Started:** 01/01/1995 **Stopped:**

**DIAZEPAM (Other drug)** **Reason:** Anxiety neurosis
5.0 Milligram Daily
**Batch:** **Started:** 01/01/1995 **Stopped:**

### 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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 114990 **Seq:** 1
**Reported:** 05/02/1997
**Hospitalisation:**
**Onset Date:** 01/01/1997
**Outcome:** Not yet recovered

**Gender:** M
**Weight:**
**Age:** 82Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **CAPOTEN (Other drug)** | | | **Reason:** | |
| | 12.5 Milligram | Daily | | |
| **Batch:** | **Started:** 01/01/1995 | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression |
| Tablet | 40.0 Milligram | Daily | | Oral |
| **Batch:** | **Started:** 01/11/1996 | | **Stopped:** | 06/01/1997 |

## Laboratory Investigations:

## Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115028 **Seq:** 1 **Gender:** F
**Reported:** 06/02/1997 **Weight:**
**Hospitalisation:** **Age:** 70Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | | | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115052 **Seq:** 1 **Gender:** U
**Reported:** 07/02/1997 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Weight increased | | | |

### Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115197 **Seq:** 1 **Gender:** F
**Reported:** 13/02/1997 **Weight:**
**Hospitalisation:** **Age:** 24Y
**Onset Date:** 03/02/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 16/01/1997 **Stopped:** 10/02/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115299 **Seq:** 1 **Gender:** F
**Reported:** 17/02/1997 **Weight:** 65.00
**Hospitalisation:** **Age:** 50
**Onset Date:** 31/01/1997 **DOB:** 08/11/1946
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura | | | |

### Medicine Details:

**DUCENE (Other drug)** **Reason:** Anxiety neurosis
5.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
20.0 Milligram Daily Oral
**Batch:** **Started:** 12/11/1996 **Stopped:** 12/02/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. The dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115381 **Seq:** 1 **Gender:** F
**Reported:** 18/02/1997 **Weight:** 52.00
**Hospitalisation:** **Age:** 72Y
**Onset Date:** 11/02/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Orthostatic hypotension<br>Syncope | Severe | Bp 90/40, 50/20 | |

### Medicine Details:

**PANADEINE FORTE (Interaction)** **Reason:** Pain
2.0 Dose Unspecified Total
**Batch:** **Started:** 11/02/1997 **Stopped:** 11/02/1997

**AROPAX (Interaction)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/12/1995 **Stopped:** 11/02/1997

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115409 **Seq:** 1 **Gender:** F
**Reported:** 19/02/1997 **Weight:** 80.00
**Hospitalisation:** **Age:** 33Y
**Onset Date:** 07/02/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Hyperkinesia<br>Insomnia<br>Nausea | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 07/02/1997 **Stopped:** 11/02/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115415 **Seq:** 1 **Gender:** M
**Reported:** 19/02/1997 **Weight:** 87.00
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 12/02/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
20.0 Milligram Daily
**Batch:** **Started:** 12/02/1997 **Stopped:** 17/02/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 115430 **Seq:** 1 **Gender:** M
**Reported:** 20/02/1997 **Weight:**
**Hospitalisation:** **Age:** 54Y
**Onset Date:** 04/01/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | | |

## Medicine Details:

**TRITACE (Other drug)** **Reason:** Essential benign hypertension
2.5 Milligram Daily
**Batch:** **Started:** 01/01/1995 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## 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.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 115442 **Seq:** 1 **Gender:** F
**Reported:** 20/02/1997 **Weight:**
**Hospitalisation:** **Age:** 32Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Mydriasis<br>Pallor<br>Palpitations<br>Tremor | | | |

## Medicine Details:

**ATIVAN (Other drug)** **Reason:**
Tablet 1.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115719 **Seq:** 1 **Gender:** F
**Reported:** 03/03/1997 **Weight:** 87.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 23/02/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tongue oedema<br>Hot flush | | Swollen tongue and throat | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** 21/02/1997 **Stopped:** 24/02/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115721 **Seq:** 1 **Gender:** F
**Reported:** 03/03/1997 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 31/10/1995 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Bruxism | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 0.0 Oral
**Batch:** **Started:** 01/10/1995 **Stopped:** 16/09/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115800 **Seq:** 1 **Gender:** M
**Reported:** 05/03/1997 **Weight:**
**Hospitalisation:** **Age:** 48Y
**Onset Date:** 25/02/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sensory disturbance<br>Agitation<br>Sleep disorder | | Felt like body screaming at itself. | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 25/02/1997 **Stopped:** 25/02/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 115802 **Seq:** 1 **Gender:** F
**Reported:** 05/03/1997 **Weight:**
**Hospitalisation:** **Age:** 17Y
**Onset Date:** 15/02/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depersonalisation<br>Disturbance in attention<br>Dizziness<br>Drug withdrawal syndrome<br>Headache | | | |

## Medicine Details:

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115853 **Seq:** 1 **Gender:** F
**Reported:** 12/03/1997 **Weight:** 50.00
**Hospitalisation:** **Age:** 69Y
**Onset Date:** 24/02/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Atrial fibrillation<br>Bundle branch block<br>Cardiac arrest | | | |

### Medicine Details:

**DIGOXIN (Other drug)** **Reason:** Otr&nos disord of heart rhythm
250.0 Microgram Daily
**Batch:** **Started:** **Stopped:**

**CHLOTRIDE (Other drug)** **Reason:** Congestive heart failure
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 14/01/1997 **Stopped:** 24/02/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electrocardiograph | | | | Ecg lbbb. echo mildly impaired lv, mild mr + tr. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115863 **Seq:** 1 **Gender:** F
**Reported:** 12/03/1997 **Weight:** 85.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** 31/12/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pyrexia<br>Anorgasmia<br>Diarrhoea<br>Hyperhidrosis | | Overheating | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/11/1996 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115882 **Seq:** 1 **Gender:** F
**Reported:** 12/03/1997 **Weight:** 55.00
**Hospitalisation:** **Age:** 41Y
**Onset Date:** 19/02/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperkinesia<br>Sleep disorder | | | |

### Medicine Details:

**XANAX (Other drug)** **Reason:** Anxiety neurosis
Tablet 0.7 Milligram Daily Oral
**Batch:** **Started:** 02/12/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
20.0 Milligram Daily
**Batch:** **Started:** 13/02/1997 **Stopped:** 10/03/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115902 **Seq:** 1 **Gender:** F
**Reported:** 12/03/1997 **Weight:**
**Hospitalisation:** **Age:** 32Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Apnoea<br>Dizziness<br>Hyperhidrosis<br>Nausea | | | |

### Medicine Details:

**EUHYPNOS (Other drug)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** 17/02/1997 **Stopped:**

**AROPAX (Suspected)** **Reason:**
20.0 Milligram 1 time
**Batch:** **Started:** 04/03/1997 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 115905 **Seq:** 1 **Gender:** M
**Reported:** 12/03/1997 **Weight:** 95.00
**Hospitalisation:** **Age:** 37Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic function abnormal | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
40.0 Milligram Daily
**Batch:** **Started:** 01/07/1996 **Stopped:** 28/10/1996

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116054 **Seq:** 1 **Gender:** F
**Reported:** 14/03/1997 **Weight:**
**Hospitalisation:** **Age:** 52Y
**Onset Date:** 11/02/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia | | Burning skin in arms and legs. | |
| Abdominal pain | | Epigastric discomfort | |
| Syncope | | Transient loss of conciousness | |
| Chest pain | | | |
| Dyspnoea | | | |

### Medicine Details:

**OXAZEPAM (Other drug)** **Reason:**
Oral application 0.0 Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 09/02/1997 **Stopped:** 11/02/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Has had anaphylactic reaction to bactrim some 10years ago- reported similar symptomatology.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116060 **Seq:** 1 **Gender:** F
**Reported:** 18/03/1997 **Weight:** 60.00
**Hospitalisation:** **Age:** 48Y
**Onset Date:** 15/02/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis<br>Nausea<br>Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 15/02/1997 **Stopped:** 15/02/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116100 **Seq:** 1 **Gender:** F
**Reported:** 18/03/1997 **Weight:** 75.00
**Hospitalisation:** **Age:** 30Y
**Onset Date:** 09/03/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea<br>Vomiting | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 09/03/1997 **Stopped:** 10/03/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Same reaction occured following day when morning dose taken.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 116177 **Seq:** 1 **Gender:** F
**Reported:** 20/03/1997 **Weight:**
**Hospitalisation:** **Age:** 51Y
**Onset Date:** 12/02/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Paraesthesia<br>Tremor | | | |

## Medicine Details:

**THIOLA (Other drug)** **Reason:**
Oral application 3.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 01/10/1996 **Stopped:** CONTIN

**FLUCONAZOLE (Other drug)** **Reason:** Moniliasis
50.0 Milligram Daily
**Batch:** **Started:** 01/07/1993 **Stopped:** CONTIN

**PREMARIN (Other drug)** **Reason:** Menopausal symptoms
625.0 Microgram Daily
**Batch:** **Started:** 01/01/1991 **Stopped:** CONTIN

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
10.0 Milligram Daily
**Batch:** **Started:** 07/02/1997 **Stopped:** 13/02/1997

## 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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116190 **Seq:** 1 **Gender:** M
**Reported:** 20/03/1997 **Weight:** 65.00
**Hospitalisation:** **Age:** 25Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia<br>Drug withdrawal syndrome<br>Malaise<br>Thinking abnormal | | Body aches | |

### Medicine Details:

**XANAX (Other drug)** **Reason:**
3.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**TEMAZEPAM (Other drug)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Reaction occurred 2 days after cessation of aropax, following 6 weeks of use. recommencing aropax terminated the reaction.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 116214 **Seq:** 1 **Gender:** F
**Reported:** 20/03/1997 **Weight:** 70.00
**Hospitalisation:** **Age:** A2
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Unintended pregnancy | | | |

## Medicine Details:

**BREVINOR (Interaction)** **Reason:** Contraception
0.0
**Batch:** **Started:** 01/02/1995 **Stopped:**

**AROPAX (Interaction)** **Reason:**
1.0 Dose Unspecified Daily
**Batch:** **Started:** 01/02/1997 **Stopped:**

## 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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116305 **Seq:** 1 **Gender:** M
**Reported:** 26/03/1997 **Weight:** 107.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 09/01/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Glaucoma | | | Pilocarpine, timolol. |

### Medicine Details:

**LITHIUM CARBONATE (Other drug)** **Reason:**
750.0 Milligram Daily
**Batch:** **Started:** 13/09/1996 **Stopped:** CONTIN

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 28/11/1996 **Stopped:** 17/01/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Other data | | | | 9/1/97 20/1/97 18/397 intraocular pressure (r) eye: 44 20 26 intraocular pressure (l) eye: 30 14 |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116379 **Seq:** 1 **Gender:** M
**Reported:** 01/04/1997 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Palpitations<br>Pharyngitis<br>Xerophthalmia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 116398 **Seq:** 1
**Reported:** 01/04/1997
**Hospitalisation:**
**Onset Date:** 31/12/1996
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 70.00
**Age:** 26Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dry mouth<br>Epistaxis | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 40.0 Milligram Daily Oral

**Batch:** **Started:** 01/12/1996 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

- 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116405 **Seq:** 1 **Gender:** F
**Reported:** 08/04/1997 **Weight:** 54.00
**Hospitalisation:** **Age:** 20Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 10/01/1997 **Stopped:** 01/04/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116406 **Seq:** 1 **Gender:** M
**Reported:** 02/04/1997 **Weight:** 70.00
**Hospitalisation:** **Age:** 27Y
**Onset Date:** 21/03/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Orthostatic hypotension<br>Syncope | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 12/03/1997 **Stopped:** 21/03/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116407 **Seq:** 1 **Gender:** F
**Reported:** 02/04/1997 **Weight:** 120.00
**Hospitalisation:** **Age:** 33Y
**Onset Date:** 06/03/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia | | Unable to achieve orgasm | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 04/03/1997 **Stopped:** 25/03/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 116411 **Seq:** 1 **Gender:** M
**Reported:** 02/04/1997 **Weight:** 70.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | Absence of ejaculation | |
| Libido decreased | | Loss of libido | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 21/01/1997 **Stopped:** CONTIN

**LEXOTAN (Suspected)** **Reason:**
18.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116419 **Seq:** 1 **Gender:** F
**Reported:** 03/04/1997 **Weight:** 53.00
**Hospitalisation:** **Age:** 16Y
**Onset Date:** 05/03/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Menorrhagia<br>Acne<br>Purpura | | Heavy periods | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 22/01/1997 **Stopped:** 19/03/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116424 **Seq:** 1 **Gender:** F
**Reported:** 03/04/1997 **Weight:** 65.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 20/02/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome<br>Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/08/1996 **Stopped:** 17/02/1997

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116494 **Seq:** 1 **Gender:** F
**Reported:** 07/04/1997 **Weight:** 65.00
**Hospitalisation:** **Age:** 55Y
**Onset Date:** 28/02/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia<br>Depression<br>Nausea | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 4D

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116583 **Seq:** 1 **Gender:** F
**Reported:** 09/04/1997 **Weight:** 54.00
**Hospitalisation:** **Age:** 20Y
**Onset Date:** 01/03/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome | Severe | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 10/01/1997 **Stopped:** 01/04/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116584 **Seq:** 1 **Gender:** F
**Reported:** 09/04/1997 **Weight:** 63.00
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 09/03/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 07/03/1997 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 116677 **Seq:** 1 **Gender:** F
**Reported:** 14/04/1997 **Weight:** 60.00
**Hospitalisation:** **Age:** 33Y
**Onset Date:** 05/04/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia | | Tightening of facial muscles and spasm. | |

## Medicine Details:

**LEVLEN ED (Other drug)** **Reason:** Contraception
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram 1 time Oral
**Batch:** **Started:** 05/04/1997 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Past history of allergy to indomethacin and aspirin - rash.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116689 **Seq:** 1 **Gender:** M
**Reported:** 10/04/1997 **Weight:**
**Hospitalisation:** **Age:** 73
**Onset Date:** **DOB:** 09/12/1923
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Serotonin syndrome | | | |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116701 **Seq:** 1 **Gender:** M
**Reported:** 14/04/1997 **Weight:** 90.00
**Hospitalisation:** **Age:** 20Y
**Onset Date:** 27/03/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle twitching | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 10/03/1997 **Stopped:**

**XANAX (Suspected)** **Reason:**
Tablet 3.0 Milligram Daily Oral
**Batch:** **Started:** 18/03/1997 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 116705 **Seq:** 1
**Reported:** 14/04/1997
**Hospitalisation:**
**Onset Date:** 02/04/1997
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 80.00
**Age:** 31Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea | | | |
| Drug withdrawal syndrome | | | |
| Headache | | | |
| Hyperhidrosis | | | |
| Insomnia | | | |
| Palpitations | | | |
| Tremor | | | |
| Vertigo | | | |
| Vomiting | | | |

## Medicine Details:

**PANADEINE (Other drug)** **Reason:** Migraine
0.0 As necessary
**Batch:** **Started:** **Stopped:**

**OGEN (Other drug)** **Reason:** Menopausal symptoms
2.5 Milligram Daily
**Batch:** **Started:** 01/06/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/09/1995 **Stopped:** 31/03/1997

## 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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

## Report Detail

**Case Number:** 116712 **Seq:** 1 **Gender:** F
**Reported:** 14/04/1997 **Weight:** 55.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 31/01/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state<br>Migraine | | | |

## Medicine Details:

**PHYSEPTONE (Other drug)** **Reason:** Pain
60.0 Milligram Daily
**Batch:** **Started:** 01/01/1994 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** 24/01/1997 **Stopped:** 09/04/1997

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 116848 **Seq:** 1 **Gender:** F
**Reported:** 17/04/1997 **Weight:**
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 10/04/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Face oedema | | | |

### Medicine Details:

**TRITACE (Interaction)** **Reason:** Essential benign hypertension
Capsule 2.5 Milligram Daily Oral
**Batch:** **Started:** 14/03/1997 **Stopped:**

**AROPAX (Interaction)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 08/04/1997 **Stopped:** 10/04/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117018 **Seq:** 1 **Gender:** F
**Reported:** 24/04/1997 **Weight:** 70.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 01/03/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia<br>Chills | | Sensation of knees giving away.<br>Shuddering | |

### Medicine Details:

**PROVELLE-28 (Other drug)** **Reason:** Menopausal symptoms
Pill 1.0 Dose Unspecified 1 time Oral
**Batch:** **Started:** 27/09/1996 **Stopped:**

**ZYRTEC (Other drug)** **Reason:** Otr ecz&der due otr&unsp cause
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 01/01/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117025 **Seq:** 1 **Gender:** F
**Reported:** 24/04/1997 **Weight:** 63.00
**Hospitalisation:** **Age:** 57Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tetany | | | |

### Medicine Details:

**SERC (Other drug)** **Reason:**
0.0
**Batch:** **Started:** L TERM **Stopped:**

**CALCITRIOL (Other drug)** **Reason:**
0.2 Microgram Daily
**Batch:** **Started:** L TERM **Stopped:**

**ISOPTIN (Other drug)** **Reason:**
80.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**MURELAX (Other drug)** **Reason:**
30.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 117025 **Seq:** 1 **Gender:** F
**Reported:** 24/04/1997 **Weight:** 63.00
**Hospitalisation:** **Age:** 57Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117170 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1997 **Weight:**
**Hospitalisation:** **Age:** 48Y
**Onset Date:** 20/03/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Prothrombin level decreased<br>Purpura | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 0.0 Daily Oral
**Batch:** **Started:** 05/03/1997 **Stopped:** 20/03/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117177 **Seq:** 1 **Gender:** M
**Reported:** 01/05/1997 **Weight:** 76.00
**Hospitalisation:** **Age:** 41Y
**Onset Date:** 24/04/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Accommodation disorder<br>Dystonia<br>Mydriasis | | Difficulty focussing<br>Stiff jaw. | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
30.0 Milligram Daily
**Batch:** **Started:** 18/04/1997 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

### Report Detail

**Case Number:** 117184 **Seq:** 1 **Gender:** M
**Reported:** 01/05/1997 **Weight:** 46.00
**Hospitalisation:** **Age:** 80Y
**Onset Date:** 11/04/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Muscle twitching | | | |

### Medicine Details:

**PANADEINE FORTE (Suspected)** **Reason:**
1.0 Gram As necessary
**Batch:** **Started:** 07/04/1997 **Stopped:** 11/04/1997

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 10/04/1997 **Stopped:** 11/04/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117186 **Seq:** 1 **Gender:** M
**Reported:** 01/05/1997 **Weight:** 61.00
**Hospitalisation:** **Age:** 76Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | Myoclonic jerks | |
| Amnesia | | Short term memory loss | |
| Anaemia vitamin B12 deficiency | | | |
| Dizziness | | | |
| Dry mouth | | | |
| Pain | | | |
| Pancytopenia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 60.0 Milligram Weekly Oral

**Batch:** **Started:** 01/01/1996 **Stopped:** 28/02/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient on aropax 20mg per day since november 1995. reduced to 3 df per week on january 1997. a large number of adverse drug reactions to xanax, ativan and aurorix. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 117187 **Seq:** 1 **Gender:** F
**Reported:** 01/05/1997 **Weight:**
**Hospitalisation:** **Age:** 65Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Visual disturbance | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 0.0 Oral
**Batch:** **Started:** 01/01/1997 **Stopped:**

**PULMICORT (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**VENTOLIN (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

## 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117197 **Seq:** 1 **Gender:** M
**Reported:** 02/05/1997 **Weight:** 71.00
**Hospitalisation:** **Age:** 31Y
**Onset Date:** 15/04/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthralgia<br>Throat tightness<br>Dry mouth<br>Dysphagia | | Massive pain in knees.<br>Throat closing up | |

### Medicine Details:

**DI-GESIC (Other drug)** **Reason:** Otr&unsp vertebrogen pain synd
4.0 Dose Unspecified Daily
**Batch:** **Started:** 01/01/1989 **Stopped:**

**VALIUM (Other drug)** **Reason:** Depression
5.0 Milligram Daily
**Batch:** **Started:** 15/04/1997 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram 1 time Oral
**Batch:** **Started:** 15/04/1997 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

History of allergy to penicillin. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117423 **Seq:** 1 **Gender:** M
**Reported:** 12/05/1997 **Weight:**
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 13/04/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 11/04/1997 **Stopped:** 20/04/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 117424 **Seq:** 1
**Reported:** 12/05/1997
**Hospitalisation:** Admitted to hospital
**Onset Date:** 01/05/1997
**Outcome:** Death

**Gender:** F
**Weight:** 55.00
**Age:** 86Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Syncope<br>Asthenia<br>Dizziness<br>Drug level increased<br>Hepatitis<br>Nausea<br>Sudden death | | Falls | |

## Medicine Details:

**PEXID (Interaction)** **Reason:** Angina pectoris w/o hyperten
200.0 Milligram Daily
**Batch:** **Started:** 01/11/1996 **Stopped:** 01/05/1997

**AROPAX (Interaction)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 25/03/1997 **Stopped:** 01/05/1997

**SOLPRIN (Other drug)** **Reason:** Angina pectoris w/o hyperten
150.0 Milligram Daily
**Batch:** **Started:** 01/11/1996 **Stopped:** CONTIN

**AMIODARONE HYDROCHLORIDE (Other drug)** **Reason:** Otr&nos disord of heart rhythm
200.0 Milligram Daily
**Batch:** **Started:** 01/11/1996 **Stopped:** CONTIN

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | (0-30) | 01/05/1997 | 95 | |
| | AST = SGOT | (0-30) | 01/05/1997 | 118 | |
| | Bilirubin | ( 0-20) | 01/05/1997 | 34 | |
| | GGT = SGGT = | (0-60) | 01/05/1997 | 74 | |
| | SAP = ALP | (0-60) | 01/05/1997 | 159 | |
| | Serum drug level | | | | Levels of perhexiline were high (>2ng/ml) on admission. |

## Additional Information:

Committee comment: include in annual fatality analysis the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

## Report Detail

**Case Number:** 117424 **Seq:** 1
**Reported:** 12/05/1997
**Hospitalisation:** Admitted to hospital
**Onset Date:** 01/05/1997
**Outcome:** Death

**Gender:** F
**Weight:** 55.00
**Age:** 86Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **DIGOXIN (Other drug)** | | **Reason:** | Otr&nos disord of heart rhythm | |
| | 62.5 Microgram | Daily | | |
| **Batch:** | **Started:** 01/11/1996 | | **Stopped:** | CONTIN |
| **CAPTOPRIL (Other drug)** | | **Reason:** | Congestive heart failure | |
| | 50.0 Milligram | Daily | | |
| **Batch:** | **Started:** | | **Stopped:** | CONTIN |
| **THYROXINE SODIUM (Other drug)** | | **Reason:** | Myxedema | |
| | 150.0 Microgram | Daily | | |
| **Batch:** | **Started:** | | **Stopped:** | CONTIN |
| **FRUSEMIDE (Other drug)** | | **Reason:** | Congestive heart failure | |
| | 40.0 Milligram | Daily | | |
| **Batch:** | **Started:** | | **Stopped:** | CONTIN |

## Laboratory Investigations:

## Additional Information:

Committee comment: include in annual fatality analysis the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117513 **Seq:** 1 **Gender:** F
**Reported:** 12/05/1997 **Weight:**
**Hospitalisation:** **Age:** 69Y
**Onset Date:** 25/12/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Conjunctivitis | | Itchy red eyes. | |
| Rash erythematous | | Rash on face, patches in oxilla/cubital | Alpha keri lotion, calamine lotion, promethazine po, methopt, prednisolone, betamethasone top |
| Pruritus | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 17/12/1996 **Stopped:** 30/12/1996

**PARACETAMOL (Suspected)** **Reason:**
6.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**PANADEINE (Suspected)** **Reason:**
6.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:** 27/12/1996

**TEMAZEPAM (Suspected)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** 19/12/1996 **Stopped:** 27/12/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 117513 **Seq:** 1
**Reported:** 12/05/1997
**Hospitalisation:**
**Onset Date:** 25/12/1996
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 69Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **COLOXYL (Suspected)** | | | **Reason:** | |
| | 3.0 | Dose Unspecified | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **LACTULOSE (Suspected)** | | | **Reason:** | |
| | 40.0 | Millilitre | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117529 **Seq:** 1 **Gender:** F
**Reported:** 13/05/1997 **Weight:** 70.00
**Hospitalisation:** **Age:** 73Y
**Onset Date:** 05/05/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Headache | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

**Batch:** **Started:** 05/05/1997 **Stopped:** 07/05/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117553 **Seq:** 1 **Gender:** M
**Reported:** 14/05/1997 **Weight:**
**Hospitalisation:** **Age:** 56Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence | | Sleepy by day | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/11/1995 **Stopped:** 28/05/1996

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117554 **Seq:** 1 **Gender:** F
**Reported:** 14/05/1997 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 31/12/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fatigue | Required Visit to Doctor | | |
| Yawning | Required Visit to Doctor | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/1996 **Stopped:** 28/12/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117556 **Seq:** 1 **Gender:** M
**Reported:** 14/05/1997 **Weight:** 60.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 31/03/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Erectile dysfunction<br>Libido decreased | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
10.0 Milligram Daily
**Batch:** **Started:** 01/01/1996 **Stopped:** 28/11/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117682 **Seq:** 1 **Gender:** M
**Reported:** 19/05/1997 **Weight:** 112.00
**Hospitalisation:** **Age:** 59Y
**Onset Date:** 31/08/1996 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Deafness<br>Tinnitus | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1996 **Stopped:** 28/10/1996

**XANAX (Suspected)** **Reason:** Anxiety neurosis
1.5 Milligram Daily
**Batch:** **Started:** 01/01/1996 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117683 **Seq:** 1 **Gender:** F
**Reported:** 19/05/1997 **Weight:**
**Hospitalisation:** **Age:** 54Y
**Onset Date:** 11/01/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | | | |

### Medicine Details:

**FERRO-GRADUMET (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**PREDNISOLONE (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**ECOTRIN (Other drug)** **Reason:**
2.6 Gram Daily
**Batch:** **Started:** **Stopped:**

**FELDENE (Other drug)** **Reason:**
Oral application 30.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

## Report Detail

**Case Number:** 117683 **Seq:** 1 **Gender:** F
**Reported:** 19/05/1997 **Weight:**
**Hospitalisation:** **Age:** 54Y
**Onset Date:** 11/01/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **PREMARIN (Other drug)** | | | **Reason:** | | |
| | 300.0 | Microgram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **PROVERA (Other drug)** | | | **Reason:** | | |
| | 2.5 | Milligram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **ROCALTROL (Other drug)** | | | **Reason:** | | |
| | 50.0 | Microgram | Daily | | |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **ZANTAC (Other drug)** | | | **Reason:** | | |
| Tablet | 300.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117683 **Seq:** 1 **Gender:** F
**Reported:** 19/05/1997 **Weight:**
**Hospitalisation:** **Age:** 54Y
**Onset Date:** 11/01/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 27/12/1996 **Stopped:** 11/01/1997

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117771 **Seq:** 1 **Gender:** F
**Reported:** 23/05/1997 **Weight:**
**Hospitalisation:** **Age:** 58Y
**Onset Date:** 15/05/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Headache | Severe | | |

### Medicine Details:

**PREMARIN (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 15/05/1997 **Stopped:** 19/05/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117785 **Seq:** 1 **Gender:** M
**Reported:** 23/05/1997 **Weight:** 94.00
**Hospitalisation:** **Age:** 49Y
**Onset Date:** 11/02/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia | | Right hemi facial spasm. | |

### Medicine Details:

**OROXINE (Other drug)** **Reason:** Myxedema
Tablet 100.0 Microgram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**NORVASC (Suspected)** **Reason:** Essential benign hypertension
Tablet 2.5 Milligram Daily Oral
**Batch:** **Started:** 11/02/1997 **Stopped:** 14/05/1997

**AROPAX (Suspected)** **Reason:**
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** 11/02/1997 **Stopped:** 25/02/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117789 **Seq:** 1 **Gender:** F
**Reported:** 23/05/1997 **Weight:**
**Hospitalisation:** **Age:** 42Y
**Onset Date:** 07/05/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia<br>Disturbance in attention<br>Hypertonia<br>Tremor | | Aching stiffness at back of head/ neck/ | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/02/1997 **Stopped:** 09/05/1997

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117794 **Seq:** 1 **Gender:** M
**Reported:** 23/05/1997 **Weight:**
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 14/03/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension<br>Headache | | 200/110 | Dapatab and coversyl. |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 21/01/1997 **Stopped:** 24/04/1997

**LEXOTAN (Suspected)** **Reason:**
6.0 Milligram Daily
**Batch:** **Started:** 01/01/1971 **Stopped:**

### 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.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 117815 **Seq:** 1 **Gender:** F
**Reported:** 26/05/1997 **Weight:**
**Hospitalisation:** **Age:** 81Y
**Onset Date:** 09/05/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | | |

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
0.0
**Batch:** **Started:** 18/04/1997 **Stopped:**

**MOCLOBEMIDE (Suspected)** **Reason:**
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 22/04/1997 **Stopped:**

**LISINOPRIL (Suspected)** **Reason:**
Oral application 5.0 Milligram Daily Oral
**Batch:** **Started:** 28/04/1997 **Stopped:**

**AMLODIPINE (Suspected)** **Reason:**
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 13/02/1997 **Stopped:** 22/05/1997

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

On paroxetine previously and developed hyponatraemia the dosage start date is not necessarily accurate but indicates that start 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 117815 **Seq:** 1
**Reported:** 26/05/1997
**Hospitalisation:**
**Onset Date:** 09/05/1997
**Outcome:** Not yet recovered

**Gender:** F
**Weight:**
**Age:** 81Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **COLCHICINE (Suspected)** | | **Reason:** | | |
| Tablet | 1.0 Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** 13/02/1997 | | **Stopped:** | |
| **FERRO-GRADUMET (Suspected)** | | **Reason:** | | |
| Tablet | 1.0 Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** 01/04/1997 | | **Stopped:** | |
| **ASCORBIC ACID (Suspected)** | | **Reason:** | | |
| Tablet | 1.0 Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** 01/04/1997 | | **Stopped:** | |

## Laboratory Investigations:

## Additional Information:

On paroxetine previously and developed hyponatraemia the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117872 **Seq:** 1
**Reported:** 26/05/1997
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** M
**Weight:**
**Age:** 58
**DOB:** 16/04/1939
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Jaundice | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/1996 **Stopped:** 28/11/1996

**SERTRALINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
**Batch:** **Started:** 10/09/1996 **Stopped:** 19/10/1996

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | | 19/10/1996 | 82 | |
| | Bilirubin | | 19/10/1996 | 169 | |
| | GGT = SGGT = | | 19/10/1996 | 697 | |
| | SAP = ALP | | 19/10/1996 | 579 | |

### Additional Information:

Alcohol abuse the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117936 **Seq:** 1 **Gender:** F
**Reported:** 29/05/1997 **Weight:** 66.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 20/04/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Anxiety | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 13/04/1997 **Stopped:** 26/04/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117999 **Seq:** 1 **Gender:** U
**Reported:** 02/06/1997 **Weight:** 55.00
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 22/05/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash | | | Given phenergan injection once a day for 2 days |

### Medicine Details:

**DUCENE (Other drug)** **Reason:** Nervousness
2.5 Milligram As necessary
**Batch:** **Started:** 01/02/1997 **Stopped:**

**QUESTRAN (Other drug)** **Reason:**
4.0 Gram Daily
**Batch:** **Started:** 01/01/1989 **Stopped:**

**XANAX (Other drug)** **Reason:** Nervousness
3.0 Milligram Daily
**Batch:** **Started:** 01/01/1996 **Stopped:**

**FOLIC ACID (Other drug)** **Reason:**
5.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Had taken rulide before 3/4/97 (no reaction then) the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 117999 **Seq:** 1 **Gender:** U
**Reported:** 02/06/1997 **Weight:** 55.00
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 22/05/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | |
|---|---|---|---|
| **IMODIUM (Other drug)** | | **Reason:** | |
| | 6.0 Milligram | Daily | |
| **Batch:** | **Started:** 01/01/1989 | | **Stopped:** |
| **PREDNISOLONE (Other drug)** | | **Reason:** | Chronc enteritis&ulcer colitis |
| | 2.5 Milligram | Daily | |
| **Batch:** | **Started:** 01/01/1989 | | **Stopped:** |
| **IMURAN (Other drug)** | | **Reason:** | Chronc enteritis&ulcer colitis |
| | 25.0 Milligram | Daily | |
| **Batch:** | **Started:** 01/01/1989 | | **Stopped:** |
| **RULIDE (Suspected)** | | **Reason:** | Acute pharyngitis |
| | 300.0 Milligram | Daily | |
| **Batch:** | **Started:** 20/05/1997 | | **Stopped:** 22/05/1997 |

## Laboratory Investigations:

## Additional Information:

Had taken rulide before 3/4/97 (no reaction then) the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 117999 **Seq:** 1 **Gender:** U
**Reported:** 02/06/1997 **Weight:** 55.00
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 22/05/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **EPHEDRINE (Suspected)** | | **Reason:** | | |
| Nasal Drops | 2.0 Dose Unspecified | Daily | | Nasal |
| **Batch:** | **Started:** 20/05/1997 | | **Stopped:** | 22/05/1997 |
| **CAPADEX (Suspected)** | | **Reason:** | | |
| | 3.0 Dose Unspecified | Daily | | |
| **Batch:** | **Started:** 20/05/1997 | | **Stopped:** | |
| **AROPAX (Suspected)** | | **Reason:** | Anxiety neurosis | |
| | 1.0 Dose Unspecified | Daily | | |
| **Batch:** | **Started:** 18/05/1997 | | **Stopped:** | 22/05/1997 |

### Laboratory Investigations:

### Additional Information:

Had taken rulide before 3/4/97 (no reaction then) the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118031 **Seq:** 1 **Gender:** F
**Reported:** 04/06/1997 **Weight:** 95.00
**Hospitalisation:** **Age:** 26Y
**Onset Date:** 22/04/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence<br>Agitation<br>Disturbance in attention<br>Insomnia<br>Tremor<br>Vomiting | | Decreased alertness | |

### Medicine Details:

**MOCLOBEMIDE (Other drug)** **Reason:** Depression
300.0 Milligram Daily
**Batch:** **Started:** 01/02/1997 **Stopped:** CONTIN

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 22/04/1997 **Stopped:** 27/04/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118044 **Seq:** 1 **Gender:** M
**Reported:** 04/06/1997 **Weight:** 65.00
**Hospitalisation:** **Age:** 56Y
**Onset Date:** 30/05/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Glossitis<br>Abdominal pain<br>Diarrhoea<br>Headache<br>Insomnia<br>Tremor | | Sore tongue and palate | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 19/05/1997 **Stopped:** 31/05/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

No allergies. aropax withdrawn.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118089 **Seq:** 1 **Gender:** F
**Reported:** 05/06/1997 **Weight:**
**Hospitalisation:** **Age:** 73
**Onset Date:** **DOB:** 29/08/1923
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | | Carbamazepine & paroxetine |

### Medicine Details:

**TEGRETOL (Suspected)** **Reason:**
Oral Liquid 200.0 Milligram Daily Oral
**Batch:** **Started:** 19/04/1997 **Stopped:** 05/05/1997

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** 29/04/1997 **Stopped:** 05/05/1997

**MORPHINE NOS (Suspected)** **Reason:**
Oral Liquid 30.0 Milligram Daily Oral
**Batch:** **Started:** 27/04/1997 **Stopped:**

**VERAPAMIL HYDROCHLORIDE (Suspected)** **Reason:**
240.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 118089 **Seq:** 1 **Gender:** F
**Reported:** 05/06/1997 **Weight:**
**Hospitalisation:** **Age:** 73
**Onset Date:** **DOB:** 29/08/1923
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **ENALAPRIL MALEATE (Suspected)** | | | **Reason:** | |
| | 10.0 Milligram | Daily | | |
| **Batch:** | **Started:** 02/05/1997 | | **Stopped:** | 04/05/1997 |
| **MIANSERIN HYDROCHLORIDE (Suspected)** | | | **Reason:** | |
| | 60.0 Milligram | Daily | | |
| **Batch:** | **Started:** | | **Stopped:** | 14/04/1997 |

## Laboratory Investigations:

## Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118170 **Seq:** 1 **Gender:** M
**Reported:** 10/06/1997 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle twitching | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118172 **Seq:** 1 **Gender:** F
**Reported:** 10/06/1997 **Weight:** 80.00
**Hospitalisation:** **Age:** 43
**Onset Date:** **DOB:** 13/10/1953
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic function abnormal | | | |

### Medicine Details:

**DIAZEPAM (Other drug)** **Reason:**
5.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**PERICYAZINE (Other drug)** **Reason:**
5.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/10/1995 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | (0-60) | 13/01/1997 | 161 | |
| | ALT = SGPT | (0-60) | 20/01/1997 | 129 | |
| | ALT = SGPT | (0-60) | 18/02/1997 | 71 | |
| | AST = SGOT | (0-50) | 13/01/1997 | 94 | |
| | AST = SGOT | (0-50) | 20/01/1997 | 73 | |
| | AST = SGOT | (0-50) | 18/02/1997 | 55 | |
| | Bilirubin | (0-21) | 13/01/1997 | 8 | |

### Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 118172 **Seq:** 1
**Reported:** 10/06/1997
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 80.00
**Age:** 43
**DOB:** 13/10/1953
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **DIAZEPAM (Other drug)** | | | **Reason:** | |
| | 5.0 Milligram | Daily | | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | |
| **PERICYAZINE (Other drug)** | | | **Reason:** | |
| | 5.0 Milligram | Daily | | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression |
| | 20.0 Milligram | Daily | | |
| **Batch:** | **Started:** | 01/10/1995 | **Stopped:** | |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Bilirubin | (0-21) | 20/01/1997 | 5 | |
| | Bilirubin | (0-21) | 18/02/1997 | 10 | |
| | GGT = SGGT = | (0-40) | 13/01/1997 | 44 | |
| | GGT = SGGT = | (0-40) | 20/01/1997 | 49 | |
| | GGT = SGGT = | (0-40) | 18/02/1997 | 31 | |
| | SAP = ALP | (0-120) | 13/01/1997 | 99 | |
| | SAP = ALP | (0-120) | 20/01/1997 | 94 | |

## Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118172 **Seq:** 1
**Reported:** 10/06/1997
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 80.00
**Age:** 43
**DOB:** 13/10/1953
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **DIAZEPAM (Other drug)** | | | **Reason:** | |
| | 5.0 Milligram | Daily | | |
| **Batch:** | **Started:** | L TERM | **Stopped:** | |
| **PERICYAZINE (Other drug)** | | | **Reason:** | |
| | 5.0 Milligram | Daily | | |
| **Batch:** | **Started:** | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | Depression |
| | 20.0 Milligram | Daily | | |
| **Batch:** | **Started:** | 01/10/1995 | **Stopped:** | |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | SAP = ALP | (0-120) | 18/02/1997 | 102 | |

### Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118174 **Seq:** 1 **Gender:** M
**Reported:** 10/06/1997 **Weight:** 178.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** 22/03/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Yawning | | Gross involuntary yawning | |

### Medicine Details:

**TEMAZEPAM (Other drug)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 11/03/1997 **Stopped:** 22/03/1997

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 22/03/1997 **Stopped:** 29/04/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118183 **Seq:** 1 **Gender:** F
**Reported:** 10/06/1997 **Weight:** 58.00
**Hospitalisation:** **Age:** 22
**Onset Date:** **DOB:** 16/10/1974
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary retention | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Immediate onset of inability to pass urine. dosage stopped and recovered. restarted on 10mg/day --> difficulty passing urine, but no retention. symptoms settled after 5 days on 10mg. rechallenged with 20 mg --> no further retention.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118184 **Seq:** 1 **Gender:** M
**Reported:** 10/06/1997 **Weight:** 85.00
**Hospitalisation:** **Age:** 66Y
**Onset Date:** 05/05/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Haematuria<br>Urinary tract infection | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Mid-stream urine | | | | Midstream urine-e.coli 108 |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118229 **Seq:** 1 **Gender:** M
**Reported:** 13/06/1997 **Weight:** 68.00
**Hospitalisation:** **Age:** 41Y
**Onset Date:** 22/05/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | Nocturnal myoclonus | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
40.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118306 **Seq:** 1
**Reported:** 16/06/1997
**Hospitalisation:** Admitted to hospital
**Onset Date:** 24/05/1997
**Outcome:** Recovered

**Gender:** F
**Weight:** 48.00
**Age:** 50Y
**DOB:**
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea<br>Rectal haemorrhage | | Blood diarrhoea | Dehydration. |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 24/05/1997 **Stopped:** 24/05/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118351 **Seq:** 1 **Gender:** M
**Reported:** 18/06/1997 **Weight:**
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 31/05/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Vaginal haemorrhage<br>Anaemia | | Concurrent vaginal bleeding<br>Drop in haemoglobin. | |

### Medicine Details:

**ENALAPRIL MALEATE (Other drug)** **Reason:** Essential benign hypertension
5.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**TEMAZEPAM (Other drug)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**ASPIRIN (Other drug)** **Reason:**
100.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**SPIRONOLACTONE (Other drug)** **Reason:** Essential benign hypertension
150.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Haemoglobin | | | | Hb dropped to 8.4 |

### Additional Information:

Anaemia improving when paroxetine ceased. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 118351 **Seq:** 1 **Gender:** M
**Reported:** 18/06/1997 **Weight:**
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 31/05/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | |
|---|---|---|---|
| **GEMFIBROZIL (Other drug)** | | **Reason:** | Othr&unspec metabolic diseases |
| | 1.2 Gram Daily | | |
| **Batch:** | **Started:** L TERM | **Stopped:** | |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | **Reason:** | Depression |
| | 0.0 | | |
| **Batch:** | **Started:** 04/04/1997 | **Stopped:** | 01/06/1997 |

## Laboratory Investigations:

## Additional Information:

Anaemia improving when paroxetine ceased. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118476 **Seq:** 1 **Gender:** F
**Reported:** 23/06/1997 **Weight:** 70.00
**Hospitalisation:** **Age:** 48Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | Severe | | |
| Hyperkinesia | | | |
| Hyperventilation | Severe | | |
| Tremor | Severe | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Total Oral
**Batch:** **Started:** 12/06/1997 **Stopped:** 14/06/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118487 **Seq:** 1 **Gender:** M
**Reported:** 23/06/1997 **Weight:**
**Hospitalisation:** **Age:** 34Y
**Onset Date:** 10/04/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 07/04/1997 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118488 **Seq:** 1 **Gender:** F
**Reported:** 23/06/1997 **Weight:** 80.00
**Hospitalisation:** **Age:**
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Epistaxis | | Blood nose with clots 3 episodes in 3 days | |

### Medicine Details:

**SODIUM VALPROATE (Other drug)** **Reason:** Convulsions
Tablet 1.5 Gram Daily Oral
**Batch:** **Started:** 01/08/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1997 **Stopped:**

### 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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118525 **Seq:** 1
**Reported:** 24/06/1997
**Hospitalisation:**
**Onset Date:** 04/04/1997
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 75.00
**Age:** 29
**DOB:** 27/09/1967
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 14/03/1997 **Stopped:** 12/06/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118569 **Seq:** 1 **Gender:** F
**Reported:** 26/06/1997 **Weight:** 70.00
**Hospitalisation:** **Age:** 57Y
**Onset Date:** 20/06/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diarrhoea<br>Dyspepsia<br>Nausea | | | |

### Medicine Details:

**TEGRETOL (Other drug)** **Reason:**
Tablet 1.4 Gram Daily Oral
**Batch:** **Started:** 01/02/1996 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 20/06/1997 **Stopped:** 22/06/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Same reaction occurrs within 2 hours of taking each aropax tablet. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118581 **Seq:** 1 **Gender:** M
**Reported:** 26/06/1997 **Weight:** 65.00
**Hospitalisation:** **Age:** 55Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure<br>Weight increased | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/1996 **Stopped:** 28/03/1997

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118586 **Seq:** 1 **Gender:** M
**Reported:** 26/06/1997 **Weight:** 90.00
**Hospitalisation:** **Age:** 50Y
**Onset Date:** 14/05/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Salivary gland enlargement | | Bilateral swelling/submandibular salivary | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 08/05/1997 **Stopped:** 22/05/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118587 **Seq:** 1 **Gender:** F
**Reported:** 26/06/1997 **Weight:**
**Hospitalisation:** **Age:** 62Y
**Onset Date:** 02/06/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Alopecia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 05/12/1996 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118692 **Seq:** 1
**Reported:** 30/06/1997
**Hospitalisation:** Admitted to hospital
**Onset Date:** 18/06/1997
**Outcome:** Recovered

**Gender:** F
**Weight:** 60.00
**Age:** 65Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Depression<br>Hyponatraemia<br>Inappropriate antidiuretic hormon | | Resembles relapse of psychotic depressior | Fluid restriction. |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 11/06/1997 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Calcium | | 18/06/1997 | 2.52 | |
| | Chloride | | 18/06/1997 | 194 | |
| | Creatinine | | 18/06/1997 | 0.05 | |
| | Potassium | | 18/06/1997 | 3.9 | |
| | Serum osmolality | | 18/06/1997 | 268 | |
| | Sodium | | 18/06/1997 | 130 | |
| | Urea | | 18/06/1997 | 3.5 | |

### Additional Information:

This presentation resembles a relapse of her psychiotic depression.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118692 **Seq:** 1
**Reported:** 30/06/1997
**Hospitalisation:** Admitted to hospital
**Onset Date:** 18/06/1997
**Outcome:** Recovered

**Gender:** F
**Weight:** 60.00
**Age:** 65Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 11/06/1997 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Urine Sodium | | 18/06/1997 | 67 | |
| | Urine osmolality | | 18/06/1997 | 55 | |
| | bicarbonate | | 18/06/1997 | 27 | |

### Additional Information:

This presentation resembles a relapse of her psychiotic depression.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118773 **Seq:** 1
**Reported:** 02/07/1997
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 75.00
**Age:** 29
**DOB:** 27/09/1967
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 14/03/1997 **Stopped:** 12/06/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Other data | | | | 30/10/96-bp 130/80, 27/2/97- bp 140/90, 14/3/97- started aropax 21/3/97 bp 130/95, 4/4/97 bp-130/100, 29/5/97-bp140/100 12/6/97-140/100-ceased aropax. 19/6/97-bp130/100. |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118778 **Seq:** 1 **Gender:** F
**Reported:** 02/07/1997 **Weight:** 57.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pain | | Bad ache inside | |
| Malaise | | Feeling sick | |
| Hypertonia | | Fingers curled up hard to open. | |
| Rash | | Rash on belly an groin. | |
| Dizziness | | | |
| Syncope | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Nervousness

0.0

**Batch:** **Started:** **Stopped:** 3D

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient has had vulval cancer and lymph glands removed.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 118793 **Seq:** 1
**Reported:** 03/07/1997
**Hospitalisation:** Admitted to hospital
**Onset Date:** 14/03/1997
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 68.00
**Age:** 53Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diabetes mellitus | Severe | | Increased insulin requirements. |

## Medicine Details:

**MIXTARD (NORDISK) (Suspected)** **Reason:** Diabetes mellitus
0.0
**Batch:** **Started:** 01/02/1995 **Stopped:**

**SAQUINAVIR MESYLATE (Suspected)** **Reason:** Hiv infection
Capsule 1.8 Gram Daily Oral
**Batch:** **Started:** 01/12/1996 **Stopped:**

**STAVUDINE (Suspected)** **Reason:** Hiv infection
Capsule 80.0 Milligram Daily Oral
**Batch:** **Started:** 01/12/1996 **Stopped:**

**3TC (Suspected)** **Reason:** Hiv infection
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 01/08/1995 **Stopped:**

## 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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 118793 **Seq:** 1
**Reported:** 03/07/1997
**Hospitalisation:** Admitted to hospital
**Onset Date:** 14/03/1997
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 68.00
**Age:** 53Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **PEPCIDINE (Suspected)** | | | **Reason:** | Ulcer of stomach w/o ment perf |
| Tablet | 80.0 Milligram | | Daily | Oral |
| **Batch:** | **Started:** 01/08/1995 | | | **Stopped:** |
| **AROPAX (Suspected)** | | | **Reason:** | Depression |
| Tablet | 20.0 Milligram | | Daily | Oral |
| **Batch:** | **Started:** 01/01/1996 | | | **Stopped:** |
| **INDERAL (Suspected)** | | | **Reason:** | Hered&famil nerv systm dis nos |
| Tablet | 40.0 Milligram | | Daily | Oral |
| **Batch:** | **Started:** 01/01/1995 | | | **Stopped:** |
| **IMODIUM (Suspected)** | | | **Reason:** | Diarrhea |
| Capsule | 4.0 Milligram | | Daily | Oral |
| **Batch:** | **Started:** 01/01/1995 | | | **Stopped:** |

## Laboratory Investigations:

## Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118793 **Seq:** 1
**Reported:** 03/07/1997
**Hospitalisation:** Admitted to hospital
**Onset Date:** 14/03/1997
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 68.00
**Age:** 53Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**BACTRIM DS (Suspected)** **Reason:** Prophylaxis

Tablet 0.5 Dose Unspecified Daily Oral

**Batch:** **Started:** 01/06/1995 **Stopped:**

### Laboratory Investigations:

### Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118796 **Seq:** 1 **Gender:** M
**Reported:** 03/07/1997 **Weight:** 82.00
**Hospitalisation:** **Age:** 66Y
**Onset Date:** 19/05/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Haematuria | | | |

### Medicine Details:

**MOGADON (Other drug)** **Reason:** Specific disorders of sleep
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1994 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 14/05/1997 **Stopped:** 20/05/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Reaction to aropax reoccurred when reintroduced. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118881 **Seq:** 1 **Gender:** F
**Reported:** 07/07/1997 **Weight:**
**Hospitalisation:** **Age:** 48
**Onset Date:** **DOB:** 16/09/1948
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertonia | | Mild to moderate muscle spasm, | Reduced dose of aropax from 40mg daily to 20mg daily |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Muscle spasm still occurs with lower dose, but to a lesser degree.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118954 **Seq:** 1 **Gender:** F
**Reported:** 08/07/1997 **Weight:**
**Hospitalisation:** **Age:** 31Y
**Onset Date:** 17/06/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Alopecia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 02/06/1997 **Stopped:** 20/06/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

### Report Detail

**Case Number:** 118955 **Seq:** 1 **Gender:** F
**Reported:** 08/07/1997 **Weight:** 55.00
**Hospitalisation:** **Age:** 25Y
**Onset Date:** 20/04/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 18/04/1997 **Stopped:**

**ALPRAZOLAM (Suspected)** **Reason:**
Oral application 5.0 Milligram Daily Oral
**Batch:** **Started:** 01/03/1997 **Stopped:**

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 118956 **Seq:** 1 **Gender:** F
**Reported:** 08/07/1997 **Weight:** 70.00
**Hospitalisation:** **Age:** 52
**Onset Date:** 31/08/1995 **DOB:** 23/03/1943
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthralgia | | Pain in knees and fingers. | |
| Convulsion | Severe | | |
| Hyperhidrosis | | | |
| Muscle twitching | Severe | | |
| Nausea | | | |
| Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 16/05/1995 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient started on 1 tab daily. increased to 2 tabs daily, when side effects became more pronounced, dose reduced back to 1 tab daily. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119104 **Seq:** 1 **Gender:** F
**Reported:** 15/07/1997 **Weight:** 65.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** 07/07/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urticaria | | | Aropax ceased and loratadine |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 04/07/1997 **Stopped:** 09/07/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 119105 **Seq:** 1 **Gender:** F
**Reported:** 15/07/1997 **Weight:** 55.00
**Hospitalisation:** **Age:** 57Y
**Onset Date:** 03/06/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | | Excessive sweating | |
| Diarrhoea | | | |
| Drug withdrawal syndrome | | | Dose reduced by 10mg every 3-4 days from 50mg to zero. diazepam given for wihdrawal |
| Nausea | | | |
| Tremor | | | |
| Vomiting | | | |

## Medicine Details:

**ROHYPNOL (Other drug)** **Reason:** Disturbance of sleep
Tablet 2.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1996 **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 50.0 Milligram Reducing Oral
**Batch:** **Started:** 01/03/1996 **Stopped:** 10/06/1997

**THYROXINE SODIUM (Suspected)** **Reason:** Myxedema
Tablet 175.0 Microgram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**LASIX (Suspected)** **Reason:**
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

## 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. the dosage start date is not necessarily accurate but indicates that start 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 119105 **Seq:** 1
**Reported:** 15/07/1997
**Hospitalisation:**
**Onset Date:** 03/06/1997
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 55.00
**Age:** 57Y
**DOB:**
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**ZANTAC (Suspected)** **Reason:** Ulcer of stomach w/o ment perf

Tablet 300.0 Milligram Daily Oral

**Batch:** **Started:** 01/02/1996 **Stopped:**

## Laboratory Investigations:

## Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119292 **Seq:** 1 **Gender:** F
**Reported:** 21/07/1997 **Weight:**
**Hospitalisation:** **Age:** 71Y
**Onset Date:** 15/07/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rash maculo-papular | | | Calamine lotion, antihistamine |

### Medicine Details:

**THIORIDAZINE HYDROCHLORIDE (Other drug)** **Reason:** Otr spec symp psychopathol nec
10.0 Milligram As necessary
**Batch:** **Started:** 01/07/1997 **Stopped:**

**RISPERIDONE (Other drug)** **Reason:** Unspecified psychosis
2.0 Milligram Daily
**Batch:** **Started:** 04/07/1997 **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
10.0 Milligram 1 time
**Batch:** **Started:** 14/07/1997 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119355 **Seq:** 1 **Gender:** M
**Reported:** 23/07/1997 **Weight:**
**Hospitalisation:** **Age:** 19Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Face oedema | | Puffy face | |

### Medicine Details:

**ALCOHOL (Interaction)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**AROPAX (Interaction)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 02/07/1997 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119357 **Seq:** 1 **Gender:** F
**Reported:** 23/07/1997 **Weight:**
**Hospitalisation:** **Age:** 62
**Onset Date:** **DOB:** 21/02/1935
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Back pain<br>Gait disturbance<br>Myalgia | | | Aropax ceased. |

### Medicine Details:

**ORUDIS (Other drug)** **Reason:**
Capsule 100.0 Milligram As necessary Oral
**Batch:** **Started:** **Stopped:**

**OGEN (Other drug)** **Reason:** Menopausal symptoms
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/1996 **Stopped:** 28/06/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Other data | | | | Cat scan for back - disc degeneration |

### Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 119360 **Seq:** 1 **Gender:** F
**Reported:** 23/07/1997 **Weight:**
**Hospitalisation:** **Age:** 57
**Onset Date:** **DOB:** 05/06/1940
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Haemolytic anaemia | | Haemolytic anaemia lasting 14 -21 days. | Aropax-20 ceased. |

## Medicine Details:

**ASPIRIN (Other drug)** **Reason:**
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1996 **Stopped:**

**ENALAPRIL MALEATE (Other drug)** **Reason:** Essential benign hypertension
Tablet 5.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**GEMFIBROZIL (Other drug)** **Reason:**
Tablet 1.2 Gram Daily Oral
**Batch:** **Started:** **Stopped:**

**TEMAZEPAM (Other drug)** **Reason:** Disturbance of sleep
Capsule 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Haematology | | 09/05/1997 | 0.78 | Haptoglobin |
| | Haemoglobin | | 09/05/1997 | 84GL | |
| | Reticulocytes | | 09/05/1997 | 8.7 | Retic |

## Additional Information:

Patient also had gynaecology bleeding. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 119360 **Seq:** 1 **Gender:** F
**Reported:** 23/07/1997 **Weight:**
**Hospitalisation:** **Age:** 57
**Onset Date:** **DOB:** 05/06/1940
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 05/04/1997 **Stopped:** 20/05/1997

## Laboratory Investigations:

## Additional Information:

Patient also had gynaecology bleeding. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119364 **Seq:** 1 **Gender:** M
**Reported:** 23/07/1997 **Weight:**
**Hospitalisation:** **Age:** 30Y
**Onset Date:** 18/07/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination | | Auditory hallucination | |

### Medicine Details:

**FLUANXOL (Other drug)** **Reason:**
Injection 0.0 Intramuscular
**Batch:** **Started:** **Stopped:**

**AVIL (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified As necessary Oral
**Batch:** **Started:** **Stopped:**

**ANTENEX (Other drug)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 16/07/1997 **Stopped:** 18/07/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient experienced similar reaction with zoloft.

## Report Detail

**Case Number:** 119528 **Seq:** 1 **Gender:** F
**Reported:** 30/07/1997 **Weight:** 58.00
**Hospitalisation:** **Age:** 70Y
**Onset Date:** 02/07/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Syncope | | Fainted | |
| Palpitations | | Heart raced for 2 days (fluttering) | |
| Dizziness | | | |
| Nausea | | | |

## Medicine Details:

**TENORMIN (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

**PREDNISOLONE (Other drug)** **Reason:**
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**ROCALTROL (Other drug)** **Reason:**
Capsule 2.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

**FOSAMAX (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Allergy to erythromycin.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 119528 **Seq:** 1 **Gender:** F
**Reported:** 30/07/1997 **Weight:** 58.00
**Hospitalisation:** **Age:** 70Y
**Onset Date:** 02/07/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **PEPCIDINE (Other drug)** | | | **Reason:** | | |
| Tablet | 2.0 | Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** | | | **Stopped:** | |
| **AROPAX (Suspected)** | | | **Reason:** | | |
| Tablet | 1.0 | Dose Unspecified | Daily | | Oral |
| **Batch:** | **Started:** | 02/07/1997 | | **Stopped:** | 02/07/1997 |

## Laboratory Investigations:

## Additional Information:

Allergy to erythromycin.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119544 **Seq:** 1 **Gender:** F
**Reported:** 30/07/1997 **Weight:** 55.00
**Hospitalisation:** **Age:** 27Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 10/05/1997 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119550 **Seq:** 1 **Gender:** F
**Reported:** 30/07/1997 **Weight:**
**Hospitalisation:** **Age:** 46
**Onset Date:** **DOB:** 26/07/1951
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia | | Muscle weakness - legs. | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
**Batch:** **Started:** 22/03/1997 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient had been on 20mg daily from 5/6/96. increased to 30 mg on 22/3/97.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 119551 **Seq:** 1 **Gender:** M
**Reported:** 30/07/1997 **Weight:** 0.00
**Hospitalisation:** **Age:** 40
**Onset Date:** 31/12/1996 **DOB:** 04/09/1956
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Alcoholism<br>Alopecia | | Alcohol craving | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
60.0 Milligram Daily Oral
**Batch:** **Started:** 01/09/1995 **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

The date of onset is not accurate but indicates that onset occurred sometime during the year. The dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119554 **Seq:** 1 **Gender:** F
**Reported:** 30/07/1997 **Weight:** 60.00
**Hospitalisation:** **Age:** 27
**Onset Date:** 28/04/1997 **DOB:** 31/12/1969
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Breast enlargement<br>Galactorrhoea<br>Hyperprolactinaemia | | | |

### Medicine Details:

**MICROGYNON 30 ED (Other drug)** **Reason:**
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1997 **Stopped:** 17/06/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Other data<br>Prolactin | <br>(<20) | <br>28/04/1997 | <br>57 | Pregnancy test-negative.<br>Lh/fsh - normal |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119571 **Seq:** 1 **Gender:** F
**Reported:** 31/07/1997 **Weight:**
**Hospitalisation:** **Age:** 66Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | | Night sweats | |
| Nightmare | | Vivid unpleasant dreams | |
| Diarrhoea | | | Aropax ceased |
| Nausea | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 27/03/1997 **Stopped:** 10/07/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient 90% recovered.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119584 **Seq:** 1 **Gender:** M
**Reported:** 01/08/1997 **Weight:** 63.00
**Hospitalisation:** **Age:** 62Y
**Onset Date:** 20/06/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysarthria<br>Dysphagia<br>Dysphonia<br>Throat tightness | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 13/06/1997 **Stopped:** CONTIN

**ENALAPRIL MALEATE (Suspected)** **Reason:**
2.5 Milligram Daily
**Batch:** **Started:** **Stopped:**

**AMOXYCILLIN SODIUM (Suspected)** **Reason:**
1.5 Gram Daily
**Batch:** **Started:** 16/06/1997 **Stopped:** 23/06/1997

**TEMAZEPAM (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 20/06/1997 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119584 **Seq:** 1
**Reported:** 01/08/1997
**Hospitalisation:**
**Onset Date:** 20/06/1997
**Outcome:** Not yet recovered

**Gender:** M
**Weight:** 63.00
**Age:** 62Y
**DOB:**
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**CHLORPROMAZINE HYDROCHLORIDE (Suspected)** **Reason:**
50.0 Milligram Daily
**Batch:** **Started:** 18/06/1997 **Stopped:** 19/06/1997

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119627 **Seq:** 1 **Gender:** M
**Reported:** 01/08/1997 **Weight:**
**Hospitalisation:** **Age:** 55Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | Ejaculatory problems. | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 119639 **Seq:** 1 **Gender:** M
**Reported:** 04/08/1997 **Weight:**
**Hospitalisation:** **Age:** 71
**Onset Date:** 25/07/1997 **DOB:** 18/09/1925
**Outcome:** Death, maybe drug **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Coma | | Deeply stuporosed | Central & arterial lines inserted. sodium bicarbonate 8.4% 150ml, calcium gluconate 10mmol, frusemide 330mg, atrovent 0.6mg,vitamin k 10mg i.m., glucose 50% 40ml. dopamine & adrenaline |
| Cyanosis | | Stertorous respirations | |
| Cardiac failure | | | |
| Hepatic function abnormal | | | |
| Hypotension | | | |
| Hypothermia | | | |
| Lactic acidosis | | | |

## Medicine Details:

**WARFARIN SODIUM (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**METFORMIN HYDROCHLORIDE (Suspected)** **Reason:**
1.0 Gram Daily
**Batch:** **Started:** **Stopped:**

**GLIPIZIDE (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**SIMVASTATIN (Suspected)** **Reason:**
10.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Electrocardiograph | | | | Ecg showed bifascicular block with first degree heart block but the t waves were not excessively peaked. |
| | Electrolytes | | | | U&es showed sodium 139, potassium 6.9, chloride 97, bicarbonate 5, and creatinine 252. corrected calcium was 2.62 |
| | Haematology | | | | Initial abg's showed ph 6.80, pco2 17, po2 122, hco3 27, be -28 and saturation 94%. lactate level was 28 (<2.1) |

## Additional Information:

Patient died 4 hours after admission on 27/07/1997 committee comment: include in annual fatality analysis

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 119639 **Seq:** 1 **Gender:** M
**Reported:** 04/08/1997 **Weight:**
**Hospitalisation:** **Age:** 71
**Onset Date:** 25/07/1997 **DOB:** 18/09/1925
**Outcome:** Death, maybe drug **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Renal failure acute | | | |

## Medicine Details:

**RANITIDINE (Suspected)** **Reason:**
300.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**COVERSYL (Suspected)** **Reason:**
4.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**IMDUR (Suspected)** **Reason:**
60.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

## Additional Information:

Patient died 4 hours after admission on 27/07/1997 committee comment: include in annual fatality analysis

## Report Detail

**Case Number:** 119639 **Seq:** 1
**Reported:** 04/08/1997
**Hospitalisation:**
**Onset Date:** 25/07/1997
**Outcome:** Death, maybe drug

**Gender:** M
**Weight:**
**Age:** 71
**DOB:** 18/09/1925
**Causality:** Causality possible

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **FRUSEMIDE (Suspected)** | | | **Reason:** | |
| | 40.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **QUININE BISULPHATE (Suspected)** | | | **Reason:** | |
| | 300.0 | Milligram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |
| **GEMFIBROZIL (Suspected)** | | | **Reason:** | |
| | 1.2 | Gram | Daily | |
| **Batch:** | **Started:** | | | **Stopped:** |

## Laboratory Investigations:

## Additional Information:

Patient died 4 hours after admission on 27/07/1997 committee comment: include in annual fatality analysis

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119698 **Seq:** 1 **Gender:** F
**Reported:** 05/08/1997 **Weight:** 60.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 22/07/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tinnitus<br>Diarrhoea<br>Dizziness<br>Drug withdrawal syndrome<br>Nausea | | Buzzing inside head & whole body | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** **Stopped:** 18/07/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Symptoms settled on resuming aropax

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119778 **Seq:** 1 **Gender:** F
**Reported:** 08/08/1997 **Weight:** 55.00
**Hospitalisation:** **Age:** 39Y
**Onset Date:** 24/07/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Tremor<br>Sleep disorder | | Trembling episode | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 07/07/1997 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Trembling episode after increasing dose to 40mg. symptoms settled on reducing dose to 20mg daily.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119800 **Seq:** 1 **Gender:** M
**Reported:** 11/08/1997 **Weight:** 82.00
**Hospitalisation:** **Age:** 40
**Onset Date:** **DOB:** 02/11/1956
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Yawning | | Big yawns | |
| Bruxism | | Clamping of teeth | |
| Malaise | | Felt weak & miserable | |
| Asthenia | | Weakness in the legs | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/06/1997 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient reduced dose to half and felt better. when patient went to full dose for a couple of days the big yawns started again the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119801 **Seq:** 1
**Reported:** 11/08/1997
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 65.00
**Age:** 52
**DOB:** 25/10/1944
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura | | Bruising on lower legs vary from 1cm to | |

### Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **PROGYNOVA (Other drug)** | | | **Reason:** | Menopausal symptoms | |
| Tablet | 2.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | 01/01/1994 | | **Stopped:** | CONTIN |
| **PROVERA (Other drug)** | | | **Reason:** | Menopausal symptoms | |
| Tablet | 5.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | 01/01/1994 | | **Stopped:** | CONTIN |
| **PULMICORT (Other drug)** | | | **Reason:** | Asthma | |
| Inhalation | 4.0 | Dose Unspecified | Daily | Inhalation | |
| **Batch:** | **Started:** | 01/01/1995 | | **Stopped:** | CONTIN |
| **XANAX (Other drug)** | | | **Reason:** | | |
| Tablet | 1.5 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | 01/12/1995 | | **Stopped:** | CONTIN |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Haematology | | | | Fbe, coagulation screen & antiplatelet antbodies all nad |

### Additional Information:

As medication helps and problems of adverse effect is slight.... therapy continued unchanged the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119801 **Seq:** 1
**Reported:** 11/08/1997
**Hospitalisation:**
**Onset Date:**
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 65.00
**Age:** 52
**DOB:** 25/10/1944
**Causality:** Causality possible

### Reaction Detail

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 03/03/1997 **Stopped:** CONTIN

### Laboratory Investigations:

### Additional Information:

As medication helps and problems of adverse effect is slight.... therapy continued unchanged the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 119803 **Seq:** 1 **Gender:** F
**Reported:** 11/08/1997 **Weight:** 60.00
**Hospitalisation:** **Age:** 48Y
**Onset Date:** 10/03/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dysgeusia | | Bitter taste | |
| Convulsion | | Complex partial seizure aura of paranomic | |
| Speech disorder | | Difficulty articulating speech | |
| Torticollis | | Head turned to left stared fixedly for 3.5 | |
| Tremor | | Tremor of tongue | |
| Parosmia | | Typical smell | |
| Dysarthria | | | |

## Medicine Details:

**PHENYTOIN SODIUM (Other drug)** **Reason:**
Oral application 130.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1970 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 02/09/1996 **Stopped:** 28/03/1997

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 119807 **Seq:** 1 **Gender:** M
**Reported:** 11/08/1997 **Weight:**
**Hospitalisation:** **Age:** 73Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ascites<br>Oedema peripheral<br><br>Pleural effusion | | | Commenced on frusemide 40-80mg daily, lisinopril 10mg daily |

## Medicine Details:

**ASPIRIN (Other drug)** **Reason:**
Tablet 150.0 Milligram Daily Oral
**Batch:** **Started:** L TERM **Stopped:**

**GLICLAZIDE (Other drug)** **Reason:**
Tablet 80.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 0.0 Oral
**Batch:** **Started:** 01/02/1997 **Stopped:** 28/05/1997

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Other data | | | | Heart echo indicated most likely cause was a silent myocardial |

## Additional Information:

Duration of adverse reaction several weeks the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119816 **Seq:** 1 **Gender:** M
**Reported:** 12/08/1997 **Weight:**
**Hospitalisation:** **Age:** 12Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | Worsening myoclonic jerks | Aropax ceased |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
10.0 Milligram Daily
**Batch:** **Started:** S TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Worsening myoclonic jerks becoming generalised, frequent and more painful

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 119831 **Seq:** 1 **Gender:** F
**Reported:** 11/08/1997 **Weight:** 59.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 06/08/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain | | | |
| Dizziness | | | |
| Fatigue | | | |
| Headache | | | |
| Nausea | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 06/08/1997 **Stopped:** 07/08/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Reaction occurred 2 hours after taking aropax 20mg.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120011 **Seq:** 1 **Gender:** F
**Reported:** 18/08/1997 **Weight:** 50.00
**Hospitalisation:** **Age:** 62Y
**Onset Date:** 13/08/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Gait disturbance | | Shuffling gait | |
| Tremor | | Tremor prominent in lower limbs at rest. | |
| Extrapyramidal disorder | | | Cogentin 1mg i.v. |

### Medicine Details:

**HYPNODORM (Other drug)** **Reason:**
0.5 Milligram Daily
**Batch:** **Started:** 21/07/1997 **Stopped:**

**NORVASC (Other drug)** **Reason:** Essential benign hypertension
5.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**OROXINE (Other drug)** **Reason:** Myxedema
100.0 Microgram Daily
**Batch:** **Started:** L TERM **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 25/07/1997 **Stopped:** 13/08/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120048 **Seq:** 1 **Gender:** F
**Reported:** 19/08/1997 **Weight:** 55.00
**Hospitalisation:** **Age:** 31Y
**Onset Date:** 01/08/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Photosensitivity reaction | Severe | | |

### Medicine Details:

**PSORALEN NOS (Interaction)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**AROPAX (Interaction)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/07/1997 **Stopped:** 15/07/1997

**AROPAX (Interaction)** **Reason:** Depression
10.0 Milligram Daily
**Batch:** **Started:** 15/07/1997 **Stopped:** 05/08/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Other data | | | | 6 joules of uva |

### Additional Information:

Psoralen has been used repeatedley in the past with no problems. on this occassion with the aropax the patient had an acute reaction.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120065 **Seq:** 1 **Gender:** F
**Reported:** 19/08/1997 **Weight:** 65.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 08/06/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abdominal pain<br>Agitation<br>Insomnia | Severe | Severe gastrointestinal epigastric burning | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 07/06/1997 **Stopped:** 12/06/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120097 **Seq:** 1 **Gender:** F
**Reported:** 20/08/1997 **Weight:**
**Hospitalisation:** **Age:** 36Y
**Onset Date:** 08/08/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Dizziness<br>Drug withdrawal syndrome<br>Nausea | | Pins & needles in hands | |

### Medicine Details:

**PROPRANOLOL HYDROCHLORIDE (Other drug)** **Reason:** Migraine
1.0 Dose Unspecified Daily
**Batch:** **Started:** 01/01/1996 **Stopped:** 08/08/1997

**F.G.F. (Other drug)** **Reason:** Iron deficiency anemias
1.0 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
1.0 Dose Unspecified Daily
**Batch:** **Started:** 01/01/1995 **Stopped:** 08/08/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Same reaction after sudden cessation last year the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120114 **Seq:** 1 **Gender:** F
**Reported:** 18/08/1997 **Weight:** 55.00
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 10/04/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dystonia | | | |

### Medicine Details:

| | | | |
|---|---|---|---|
| **PREMARIN (Other drug)** | | **Reason:** | Menopausal symptoms |
| | 625.0 Milligram | Daily | |
| **Batch:** | **Started:** 01/01/1995 | | **Stopped:** |
| **PROVERA (Other drug)** | | **Reason:** | Menopausal symptoms |
| | 2.5 Milligram | Daily | |
| **Batch:** | **Started:** 01/01/1995 | | **Stopped:** |
| **AROPAX (Suspected)** | | **Reason:** | Depression |
| | 20.0 Milligram | 1 time | |
| **Batch:** | **Started:** 10/04/1997 | | **Stopped:** |

### 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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120316 **Seq:** 1 **Gender:** F
**Reported:** 27/08/1997 **Weight:** 50.00
**Hospitalisation:** **Age:** 46Y
**Onset Date:** 26/06/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle twitching | | Muscle fasciculation / contractions | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 23/06/1997 **Stopped:** 30/06/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120340 **Seq:** 1 **Gender:** F
**Reported:** 26/08/1997 **Weight:** 50.00
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 17/07/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hallucination<br>Delirium<br>Delusion<br>Paranoia | | Visual and auditory hallucinations | Ceased aropax and phenergan |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
40.0 Milligram Daily
**Batch:** **Started:** 15/07/1997 **Stopped:** 17/07/1997

**PHENERGAN (Suspected)** **Reason:** Specific disorders of sleep
50.0 Milligram Daily
**Batch:** **Started:** 15/07/1997 **Stopped:** 17/07/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Periodic alcohol use and slightly elevated lft's and macrocytosis.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 120357 **Seq:** 1 **Gender:** M
**Reported:** 28/08/1997 **Weight:** 80.00
**Hospitalisation:** **Age:** 69Y
**Onset Date:** 17/08/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Confusional state<br>Hyponatraemia<br>Somnolence | | | |

## Medicine Details:

**THYROXINE SODIUM (Other drug)** **Reason:** Myxedema
275.0 Microgram Daily
**Batch:** **Started:** 01/01/1985 **Stopped:** CONTIN

**FLUPENTHIXOL DECANOATE (Other drug)** **Reason:** Otr spec symp psychopathol nec
Injection 30.0 Milligram Alternate weeks Intramuscular
**Batch:** **Started:** **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Otr spec symp psychopathol nec
100.0 Milligram Daily
**Batch:** **Started:** 10/08/1997 **Stopped:** 22/08/1997

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | 17/08/1997 | 109 | |

## Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120391 **Seq:** 1
**Reported:** 28/08/1997
**Hospitalisation:** Hospitalisation prolonged
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:** 0.00
**Age:** 99U
**DOB:**
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypotonia | | Marked hypotonia from birth to 4 weeks | |
| Feeding disorder neonatal | | Very bad feeding | Nasogastric tube for 4 weeks |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
0.0 Daily Oral
**Batch:** **Started:** 01/12/1996 **Stopped:** 28/01/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Reviewed 11/08/1997 & no abnormalities present. Maternal use of Aropax during pregnancy. The dosage start and stop dates ares not necessarily accurate but indicates that start and stop occurred sometime during the month.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 120447 **Seq:** 1 **Gender:** F
**Reported:** 01/09/1997 **Weight:** 55.00
**Hospitalisation:** **Age:** 22Y
**Onset Date:** 31/07/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia<br>Face oedema | | Paraesthesia chin on waking resolved by<br>Swollen chin | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 16/07/1997 **Stopped:** 31/07/1997

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 120532 **Seq:** 1 **Gender:** F
**Reported:** 04/09/1997 **Weight:** 66.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | | Night sweats, soaking, requiring linen | |

## Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 04/08/1995 **Stopped:** 18/06/1996

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

All blood parameters normal. physical examination unremarkable, resolution of night sweats on drug cessation.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120569 **Seq:** 1 **Gender:** M
**Reported:** 05/09/1997 **Weight:** 65.00
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 16/08/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Crying<br>Drug withdrawal syndrome<br>Nightmare | | Crying fits | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**

0.0

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Symptoms occurred after stopping aropax. patient has a history of sch1zophr- enia.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120586 **Seq:** 1 **Gender:** F
**Reported:** 08/09/1997 **Weight:**
**Hospitalisation:** **Age:** 22Y
**Onset Date:** 15/06/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion<br>Syncope | | Atypical sieizure at home.<br>Blacked out | |

### Medicine Details:

**STELAZINE (Other drug)** **Reason:** Unspecified psychosis
Oral application 6.0 Milligram Daily Oral
**Batch:** **Started:** 07/11/1995 **Stopped:**

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1997 **Stopped:** 15/07/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120587 **Seq:** 1 **Gender:** F
**Reported:** 08/09/1997 **Weight:** 50.00
**Hospitalisation:** **Age:** 57Y
**Onset Date:** 25/07/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Rhinitis<br>Yawning | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 12/07/1997 **Stopped:** 06/08/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient used grapefruit juice with drug after 1 week.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120602 **Seq:** 1 **Gender:** M
**Reported:** 09/09/1997 **Weight:**
**Hospitalisation:** **Age:** 50Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Ejaculation failure | | Inability to ejaculate | Periactin |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Previously when depressed, impotent. aropax has good effect on ability to have an erection - but unable to ejaculate. periactin added - slight improvement able to ejaculate sometimes after 1 hour intercourse.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120636 **Seq:** 1
**Reported:** 08/09/1997
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Recovered

**Gender:** F
**Weight:**
**Age:** 27Y
**DOB:**
**Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Oedema | Severe | Severe fluid retenion | Ceased aropax |

### Medicine Details:

**CISAPRIDE (Other drug)** **Reason:**
15.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120922 **Seq:** 1 **Gender:** U
**Reported:** 18/09/1997 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 03/03/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cough | | | |
| Fatigue | | | |
| Hepatitis | | | |
| Myalgia | | | |
| Nausea | | | |
| Pyrexia | | | |
| Vomiting | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 16/11/1996 **Stopped:** 01/05/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | ALT = SGPT | | 03/03/1997 | 276 | |
| | GGT = SGGT = | | 03/03/1997 | 239 | |
| | Immunology | | | | Tests for hepatitis a,b,c - normal. cmr, ebn all negative. |
| | SAP = ALP | | 03/03/1997 | 180 | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120955 **Seq:** 1 **Gender:** F
**Reported:** 19/09/1997 **Weight:**
**Hospitalisation:** **Age:** 37Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura | | Developed multiple bruises | |
| Rash | | Eczematoma rash on trunk & proxinical | |
| Pruritus | | Itchy urticated | Dose reduced by psychiatrist |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

0.0

**Batch:** **Started:** 01/04/1997 **Stopped:**

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120966 **Seq:** 1 **Gender:** M
**Reported:** 19/09/1997 **Weight:** 75.00
**Hospitalisation:** **Age:** 42Y
**Onset Date:** 11/09/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnolence<br>Anorexia<br>Asthenia<br>Dry mouth<br>Insomnia<br>Nausea<br>Nervousness | | Sleepy | Ceased aropax |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 11/09/1997 **Stopped:** 16/09/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 120977 **Seq:** 1 **Gender:** M
**Reported:** 22/09/1997 **Weight:** 83.00
**Hospitalisation:** **Age:** 65Y
**Onset Date:** 08/09/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hot flush<br>Hyperhidrosis<br>Insomnia<br>Nausea<br>Pruritus | | | |

### Medicine Details:

**OXAZEPAM (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**THEOPHYLLINE (Other drug)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 06/09/1997 **Stopped:** 15/09/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 121159 **Seq:** 1
**Reported:** 26/09/1997
**Hospitalisation:** Admitted to hospital
**Onset Date:**
**Outcome:** Unknown

**Gender:** F
**Weight:**
**Age:** 21
**DOB:** 22/11/1975
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | Severe | | |
| Drug withdrawal syndrome | | | Mylanta, chlorpromazine & |
| Nausea | Required Visit to Doctor | | |
| Paraesthesia | Severe | | |
| Tremor | Required Visit to Doctor | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:** 28/08/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Reactions occurred 2-3 days after aropax ceased. however, agitation was present whilst on aropax.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 121179 **Seq:** 1 **Gender:** F
**Reported:** 29/09/1997 **Weight:**
**Hospitalisation:** **Age:** 84Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypertension | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 121209 **Seq:** 1 **Gender:** M
**Reported:** 30/09/1997 **Weight:**
**Hospitalisation:** **Age:** 51Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia | | Unable to ejaculate | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 29/07/1997 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 121237 **Seq:** 1 **Gender:** F
**Reported:** 30/09/1997 **Weight:**
**Hospitalisation:** **Age:** 29
**Onset Date:** **DOB:** 03/03/1968
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Paraesthesia | Required Visit to Doctor | Tingling limbs | |
| Dizziness | | | Patient restarted aropax and symptoms resolved almost immediately so tried a gradual withdrawal |
| Drug withdrawal syndrome | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 17/12/1996 **Stopped:** 23/02/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 121238 **Seq:** 1 **Gender:** F
**Reported:** 30/09/1997 **Weight:**
**Hospitalisation:** **Age:** 29
**Onset Date:** **DOB:** 03/03/1968
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Medication error | | Inappropriate exposure | Pregnancy terminated. |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 17/12/1996 **Stopped:** 23/02/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 121267 **Seq:** 1 **Gender:** M
**Reported:** 01/10/1997 **Weight:** 88.00
**Hospitalisation:** **Age:** 33Y
**Onset Date:** 04/09/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura | | Large ecchymoses on right tigh, very minor | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/10/1996 **Stopped:** 12/09/1997

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 121275 **Seq:** 1 **Gender:** M
**Reported:** 01/10/1997 **Weight:** 109.00
**Hospitalisation:** **Age:** 51Y
**Onset Date:** 31/08/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Photophobia | Severe | | Therapy changed to |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
60.0 Milligram Daily
**Batch:** **Started:** 16/12/1996 **Stopped:** 28/08/1997

**DIAZEPAM (Suspected)** **Reason:**
4.0 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 that onset occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 121299 **Seq:** 1 **Gender:** F
**Reported:** 03/10/1997 **Weight:** 52.00
**Hospitalisation:** **Age:** 26Y
**Onset Date:** 14/09/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fatigue<br>Dizziness<br>Nausea<br>Vomiting<br>Yawning | | Very tired | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 0.0 Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 121497 **Seq:** 1 **Gender:** M
**Reported:** 10/10/1997 **Weight:**
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 31/12/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fatigue<br>Nausea<br>Tinnitus | | | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
0.0
**Batch:** **Started:** **Stopped:**

**MINIPRESS (Suspected)** **Reason:**
Tablet 2.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Patient is also withdrawing from clonazepam, as part of a benzodiazepine addiction. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

## Report Detail

**Case Number:** 121963 **Seq:** 1 **Gender:** F
**Reported:** 28/10/1997 **Weight:** 50.00
**Hospitalisation:** **Age:** 45Y
**Onset Date:** 18/10/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

## Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Photophobia<br>Depersonalisation<br>Dizziness | | Flashes of light. | |

## Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
1.2 Dose Unspecified Daily
**Batch:** **Started:** **Stopped:** 17/10/1997

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

## Additional Information:

Same symptoms occured on each of 3 attempts to stop aropax.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122012 **Seq:** 1 **Gender:** F
**Reported:** 30/10/1997 **Weight:**
**Hospitalisation:** **Age:** 25Y
**Onset Date:** 31/05/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hypoaesthesia<br>Hyperaesthesia<br>Neuralgia<br>Paraesthesia | | Numbness and tightness in left lower leg.<br>Sensitivity to touch. | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
10.0 Milligram Daily
**Batch:** **Started:** 01/12/1996 **Stopped:** 28/08/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122174 **Seq:** 1 **Gender:** M
**Reported:** 06/11/1997 **Weight:** 80.00
**Hospitalisation:** **Age:** 49
**Onset Date:** **DOB:** 31/03/1948
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorgasmia | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 04/09/1997 **Stopped:** 01/10/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122209 **Seq:** 1 **Gender:** F
**Reported:** 06/11/1997 **Weight:** 70.00
**Hospitalisation:** **Age:** 40Y
**Onset Date:** 25/10/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus<br>Rash | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 24/10/1997 **Stopped:** 26/10/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122291 **Seq:** 1 **Gender:** F
**Reported:** 11/11/1997 **Weight:** 97.00
**Hospitalisation:** **Age:** 43Y
**Onset Date:** 25/10/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hot flush<br>Nausea<br>Tremor | Severe | | |

### Medicine Details:

**MICROGYNON 30 (Other drug)** **Reason:** Contraception
Tablet 0.0 Daily Oral
**Batch:** **Started:** 01/01/1993 **Stopped:**

**AROPAX (Suspected)** **Reason:**
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 25/10/1997 **Stopped:** 25/10/1997

### 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122321 **Seq:** 1 **Gender:** F
**Reported:** 13/11/1997 **Weight:**
**Hospitalisation:** **Age:** 38Y
**Onset Date:** 19/09/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatitis | | | Medication stopped |

### Medicine Details:

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/04/1997 **Stopped:** 19/09/1997

**DIAZEPAM (Suspected)** **Reason:** Anxiety neurosis
Tablet 15.0 Milligram Daily Oral
**Batch:** **Started:** 20/06/1997 **Stopped:** 19/09/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122346 **Seq:** 1 **Gender:** F
**Reported:** 14/11/1997 **Weight:** 65.00
**Hospitalisation:** **Age:** 26Y
**Onset Date:** 11/08/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Neuropathy peripheral<br>Hypoaesthesia | | Multiple peripheral neuropathy<br>Peripheral numbness | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 01/06/1997 **Stopped:** 28/10/1997

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122379 **Seq:** 1 **Gender:** F
**Reported:** 18/11/1997 **Weight:** 70.00
**Hospitalisation:** **Age:** 20Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Intra-uterine death | | Foetal death in utero | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Other data | | | | Autopsy suggests cause was severe placental insufficiency. date of death approximately 28 weeks gestation |

### Additional Information:

Mother had severe depression but was otherwise well. doesnt smoke, no other risk factors for placentil insufficiency. no prior exposure to aropax. no other medication.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122571 **Seq:** 1 **Gender:** U
**Reported:** 20/11/1997 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 05/11/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | Na+ = 127 | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 04/11/1997 **Stopped:** 05/11/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122588 **Seq:** 1 **Gender:** F
**Reported:** 19/11/1997 **Weight:** 44.00
**Hospitalisation:** **Age:** 49Y
**Onset Date:** 26/10/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Disturbance in attention<br>Paralysis<br>Anxiety<br>Thinking abnormal | | Couldn't eat, sit still concentrate, think.<br>R hand/arm went into muscle contraction | |

### Medicine Details:

**ROHYPNOL (Other drug)** **Reason:**
1.0 Milligram Daily
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
20.0 Milligram Daily
**Batch:** **Started:** 24/10/1997 **Stopped:** 02/11/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122710 **Seq:** 1 **Gender:** M
**Reported:** 24/11/1997 **Weight:** 78.00
**Hospitalisation:** **Age:** 24Y
**Onset Date:** 23/10/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Osteoarthritis<br>Arthralgia | | Stiff, painful joints in hands | |

### Medicine Details:

**OROXINE (Other drug)** **Reason:** Myxedema
Tablet 200.0 Microgram Daily Oral
**Batch:** **Started:** 01/04/1994 **Stopped:** CONTIN

**NORMISON (Other drug)** **Reason:** Specific disorders of sleep
Oral application 20.0 Milligram Alternate days Oral
**Batch:** **Started:** **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 16/10/1997 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

The patient is allergic to penicillin and keflin the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122732 **Seq:** 1 **Gender:** F
**Reported:** 25/11/1997 **Weight:** 66.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** 20/03/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyskinesia | | R foot twitching & shaking at night while | |

### Medicine Details:

**OXAZEPAM (Other drug)** **Reason:** Anxiety neurosis
45.0 Milligram Daily
**Batch:** **Started:** 01/01/1992 **Stopped:**

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 01/02/1997 **Stopped:** 28/05/1997

### 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122749 **Seq:** 1 **Gender:** M
**Reported:** 26/11/1997 **Weight:**
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 31/07/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hepatic function abnormal | | Worsening of lft's | Medication changed to serzone |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 02/07/1997 **Stopped:** 20/10/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122767 **Seq:** 1 **Gender:** F
**Reported:** 27/11/1997 **Weight:** 100.00
**Hospitalisation:** **Age:** 32Y
**Onset Date:** 31/07/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Arthralgia | | Pain in proximal interphalangeal joint both | Dose of aropax reduced to |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 18/06/1997 **Stopped:**

**ZANTAC (Suspected)** **Reason:**
2.0 Dose Unspecified Daily
**Batch:** **Started:** 01/06/1996 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- 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.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122768 **Seq:** 1 **Gender:** F
**Reported:** 27/11/1997 **Weight:**
**Hospitalisation:** **Age:** 36Y
**Onset Date:** **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation | | Evening restlessness in lower limbs, on | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**TAMOXIFEN CITRATE (Suspected)** **Reason:** Malignant neoplasm of breast
0.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122770 **Seq:** 1
**Reported:** 18/11/1997
**Hospitalisation:** Admitted to hospital
**Onset Date:** 15/05/1997
**Outcome:** Unknown

**Gender:** F
**Weight:** 80.00
**Age:** 55
**DOB:** 31/01/1942
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Angina pectoris | | | Heparinised and given a gtn patch, had a stress test and |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
20.0 Milligram Daily
**Batch:** **Started:** 01/05/1997 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122771 **Seq:** 1 **Gender:** M
**Reported:** 27/11/1997 **Weight:** 95.00
**Hospitalisation:** **Age:** 55Y
**Onset Date:** 20/05/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation<br>Erectile dysfunction<br>Insomnia | | | Therapy changed to prozac and then to zoloft. |

### Medicine Details:

**VALIUM (Suspected)** **Reason:** Anxiety neurosis
5.0 Milligram As necessary
**Batch:** **Started:** 01/05/1997 **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 01/05/1997 **Stopped:** 28/08/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient is a chronic alcoholic. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122773 **Seq:** 1 **Gender:** F
**Reported:** 27/11/1997 **Weight:** 90.00
**Hospitalisation:** **Age:** 35Y
**Onset Date:** 18/10/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Extrapyramidal disorder | | Muscle spasm in jaw, teeth chattering, stiff | |

### Medicine Details:

**BRICANYL (Other drug)** **Reason:**
0.0 As necessary
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 17/10/1997 **Stopped:** 22/10/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122964 **Seq:** 1 **Gender:** U
**Reported:** 02/12/1997 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 18/07/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Anorexia<br>Dizziness<br>Nausea<br>Palpitations<br>Tremor | | | |

### Medicine Details:

**MICROVAL (Other drug)** **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** **Stopped:** CONTIN

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 18/07/1997 **Stopped:** 26/07/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 122991 **Seq:** 1 **Gender:** F
**Reported:** 03/12/1997 **Weight:** 68.00
**Hospitalisation:** **Age:** 36Y
**Onset Date:** 05/11/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura | | Bruising to thigh and forearm | |

### Medicine Details:

**MULTIVITAMINS (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**TRIPHASIL (Suspected)** **Reason:**
0.0
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 40.0 Milligram Daily Oral
**Batch:** **Started:** 04/08/1997 **Stopped:** CONTIN

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123016 **Seq:** 1 **Gender:** M
**Reported:** 03/12/1997 **Weight:**
**Hospitalisation:** **Age:** 26Y
**Onset Date:** 20/06/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Urinary incontinence | | | Desmopressin |

### Medicine Details:

**CLOZARIL (Suspected)** **Reason:** Unspecified schizophrenia
300.0 Milligram Daily
**Batch:** **Started:** 01/01/1997 **Stopped:**

**LITHIUM CARBONATE (Suspected)** **Reason:**
750.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:**
40.0 Milligram Daily
**Batch:** **Started:** L TERM **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient also drinks 10 x 375ml cans of coke a day. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123054 **Seq:** 1 **Gender:** M
**Reported:** 04/12/1997 **Weight:** 68.00
**Hospitalisation:** **Age:** 54Y
**Onset Date:** 28/10/1997 **DOB:**
**Outcome:** Unknown **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea | | Marked nausea over 24 hours | |

### Medicine Details:

**XANAX (Other drug)** **Reason:** Anxiety neurosis
Tablet 0.5 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

**AROPAX (Suspected)** **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 25/10/1997 **Stopped:** 29/10/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123195 **Seq:** 1 **Gender:** F
**Reported:** 09/12/1997 **Weight:**
**Hospitalisation:** **Age:** 82Y
**Onset Date:** 29/09/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia Inappropriate antidiuretic hormon | | | |

### Medicine Details:

**RENITEC (Other drug)** **Reason:** Essential benign hypertension
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 01/01/1996 **Stopped:** CONTIN

**HALOPERIDOL (Other drug)** **Reason:** Otr spec symp psychopathol nec
4.0 Milligram Daily
**Batch:** **Started:** 01/09/1997 **Stopped:** CONTIN

**VERAPAMIL HYDROCHLORIDE (Other drug)** **Reason:** Essential benign hypertension
160.0 Milligram Daily
**Batch:** **Started:** 01/01/1996 **Stopped:** CONTIN

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason:** Depression
10.0 Milligram Daily
**Batch:** **Started:** 27/09/1997 **Stopped:** 30/09/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Creatinine | | 29/09/1997 | 0.060 | |
| | Creatinine | | 01/10/1997 | 0.055 | |
| | Creatinine | | 03/10/1997 | 0.046 | |
| | Creatinine | | 10/10/1997 | 0.056 | |
| | Creatinine | | 02/10/1997 | 0.055 | |
| | Creatinine | | 21/10/1997 | 0.063 | |
| | Sodium | | 29/09/1997 | 128 | |

### Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123195 **Seq:** 1 **Gender:** F
**Reported:** 09/12/1997 **Weight:**
**Hospitalisation:** **Age:** 82Y
**Onset Date:** 29/09/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **RENITEC (Other drug)** | | **Reason:** Essential benign hypertension | | |
| Tablet | 10.0 Milligram | Daily | Oral | |
| **Batch:** | **Started:** 01/01/1996 | | **Stopped:** | CONTIN |
| **HALOPERIDOL (Other drug)** | | **Reason:** Otr spec symp psychopathol nec | | |
| | 4.0 Milligram | Daily | | |
| **Batch:** | **Started:** 01/09/1997 | | **Stopped:** | CONTIN |
| **VERAPAMIL HYDROCHLORIDE (Other drug)** | | **Reason:** Essential benign hypertension | | |
| | 160.0 Milligram | Daily | | |
| **Batch:** | **Started:** 01/01/1996 | | **Stopped:** | CONTIN |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | **Reason:** Depression | | |
| | 10.0 Milligram | Daily | | |
| **Batch:** | **Started:** 27/09/1997 | | **Stopped:** | 30/09/1997 |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Sodium | | 01/10/1997 | 120 | |
| | Sodium | | 02/10/1997 | 130 | |
| | Sodium | | 03/10/1997 | 127 | |
| | Sodium | | 10/10/1997 | 133 | |
| | Sodium | | 21/10/1997 | 137 | |
| | Urea | | 29/09/1997 | 3.4 | |
| | Urea | | 01/10/1997 | 3.6 | |

### Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

## Report Detail

**Case Number:** 123195 **Seq:** 1 **Gender:** F
**Reported:** 09/12/1997 **Weight:**
**Hospitalisation:** **Age:** 82Y
**Onset Date:** 29/09/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | |
|---|---|---|---|---|
| **RENITEC (Other drug)** | | **Reason:** | Essential benign hypertension | |
| Tablet | 10.0 Milligram | Daily | Oral | |
| **Batch:** | **Started:** 01/01/1996 | | **Stopped:** | CONTIN |
| **HALOPERIDOL (Other drug)** | | **Reason:** | Otr spec symp psychopathol nec | |
| | 4.0 Milligram | Daily | | |
| **Batch:** | **Started:** 01/09/1997 | | **Stopped:** | CONTIN |
| **VERAPAMIL HYDROCHLORIDE (Other drug)** | | **Reason:** | Essential benign hypertension | |
| | 160.0 Milligram | Daily | | |
| **Batch:** | **Started:** 01/01/1996 | | **Stopped:** | CONTIN |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | **Reason:** | Depression | |
| | 10.0 Milligram | Daily | | |
| **Batch:** | **Started:** 27/09/1997 | | **Stopped:** | 30/09/1997 |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Urea | | 02/10/1997 | 4.1 | |
| | Urea | | 03/10/1997 | 2.9 | |
| | Urea | | 10/10/1997 | 3.9 | |
| | Urea | | 21/10/1997 | 4.6 | |
| | Urine Sodium | | 29/09/1997 | - | |
| | Urine Sodium | | 21/10/1997 | - | |
| | Urine Sodium | | 11/10/1997 | 16 | |

## Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123195 **Seq:** 1 **Gender:** F
**Reported:** 09/12/1997 **Weight:**
**Hospitalisation:** **Age:** 82Y
**Onset Date:** 29/09/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

### Medicine Details:

| | | | | |
|---|---|---|---|---|
| **RENITEC (Other drug)** | | **Reason:** | Essential benign hypertension | |
| Tablet | 10.0 Milligram | Daily | Oral | |
| **Batch:** | **Started:** 01/01/1996 | | **Stopped:** | CONTIN |
| **HALOPERIDOL (Other drug)** | | **Reason:** | Otr spec symp psychopathol nec | |
| | 4.0 Milligram | Daily | | |
| **Batch:** | **Started:** 01/09/1997 | | **Stopped:** | CONTIN |
| **VERAPAMIL HYDROCHLORIDE (Other drug)** | | **Reason:** | Essential benign hypertension | |
| | 160.0 Milligram | Daily | | |
| **Batch:** | **Started:** 01/01/1996 | | **Stopped:** | CONTIN |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | **Reason:** | Depression | |
| | 10.0 Milligram | Daily | | |
| **Batch:** | **Started:** 27/09/1997 | | **Stopped:** | 30/09/1997 |

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Urine Sodium | | 03/10/1997 | 43 | |
| | Urine Sodium | | 01/10/1997 | - | |
| | Urine Sodium | | 02/10/1997 | - | |
| | Urine osmolality | | 29/09/1997 | - | |
| | Urine osmolality | | 01/10/1997 | - | |
| | Urine osmolality | | 02/10/1997 | - | |
| | Urine osmolality | | 03/10/1997 | 347 | |

### Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

## Report Detail

**Case Number:** 123195 **Seq:** 1 **Gender:** F
**Reported:** 09/12/1997 **Weight:**
**Hospitalisation:** **Age:** 82Y
**Onset Date:** 29/09/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

## Reaction Detail

## Medicine Details:

| | | | | | |
|---|---|---|---|---|---|
| **RENITEC (Other drug)** | | | **Reason:** | Essential benign hypertension | |
| Tablet | 10.0 | Milligram | Daily | Oral | |
| **Batch:** | **Started:** | 01/01/1996 | | **Stopped:** | CONTIN |
| **HALOPERIDOL (Other drug)** | | | **Reason:** | Otr spec symp psychopathol nec | |
| | 4.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | 01/09/1997 | | **Stopped:** | CONTIN |
| **VERAPAMIL HYDROCHLORIDE (Other drug)** | | | **Reason:** | Essential benign hypertension | |
| | 160.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | 01/01/1996 | | **Stopped:** | CONTIN |
| **PAROXETINE HYDROCHLORIDE (Suspected)** | | | **Reason:** | Depression | |
| | 10.0 | Milligram | Daily | | |
| **Batch:** | **Started:** | 27/09/1997 | | **Stopped:** | 30/09/1997 |

## Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Urine osmolality | | 11/10/1997 | 235 | |

## Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123222 **Seq:** 1 **Gender:** U
**Reported:** 09/12/1997 **Weight:**
**Hospitalisation:** **Age:** 70Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dermatitis bullous | | Blood blisters in the mouth and/on roof of | Patient burst blisters for reduction of pain. |

### Medicine Details:

**HYDROCORTISONE (Other drug)** **Reason:** Rash
Ointment 0.0 Topical
**Batch:** **Started:** **Stopped:**

**STEMETIL (Other drug)** **Reason:** Rash
Tablet 5.0 Milligram As necessary Oral
**Batch:** **Started:** **Stopped:**

**LINCTUS CODEINE (Other drug)** **Reason:** Cough
Oral application 30.0 Millilitre Daily Oral
**Batch:** **Started:** **Stopped:**

**DUCENE (Other drug)** **Reason:** Nervousness
Tablet 10.0 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 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123222 **Seq:** 1 **Gender:** U
**Reported:** 09/12/1997 **Weight:**
**Hospitalisation:** **Age:** 70Y
**Onset Date:** **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

### Medicine Details:

| | | | | | | |
|---|---|---|---|---|---|---|
| **DYMADON (Other drug)** | | | **Reason:** Pain | | | |
| Tablet | 8.0 | Dose Unspecified | Daily | | Oral | |
| **Batch:** | **Started:** | | | **Stopped:** | | |
| **NAPROSYN (Other drug)** | | | **Reason:** Pain in joint | | | |
| Suppository | 1.0 | Dose Unspecified | Daily | | Rectal | |
| **Batch:** | **Started:** | | | **Stopped:** | | |
| **AROPAX (Suspected)** | | | **Reason:** | | | |
| Tablet | 1.0 | Dose Unspecified | Daily | | Oral | |
| **Batch:** | **Started:** | 01/04/1997 | | **Stopped:** | | CONTIN |

### Laboratory Investigations:

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123268 **Seq:** 1 **Gender:** M
**Reported:** 11/12/1997 **Weight:**
**Hospitalisation:** **Age:** 54Y
**Onset Date:** 20/11/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pruritus | | Pruritus around mouth, eyes, forehead, | Zantac and aropax ceased. commenced zyrtec. |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 03/11/1997 **Stopped:** 17/11/1997

**ZANTAC (Suspected)** **Reason:** Otr disorders stomach function
Tablet 300.0 Milligram Daily Oral
**Batch:** **Started:** 03/11/1997 **Stopped:** 24/11/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123394 **Seq:** 1 **Gender:** F
**Reported:** 15/12/1997 **Weight:** 63.00
**Hospitalisation:** **Age:** 28Y
**Onset Date:** 20/10/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dizziness<br>Drug withdrawal syndrome | | | Stemetil 5mg tds |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 04/05/1997 **Stopped:** 03/12/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123481 **Seq:** 1 **Gender:** M
**Reported:** 17/12/1997 **Weight:** 54.00
**Hospitalisation:** **Age:** 27Y
**Onset Date:** **DOB:**
**Outcome:** Unknown **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nausea | Severe | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
20.0 Milligram Daily
**Batch:** **Started:** 01/12/1997 **Stopped:** 03/12/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123573 **Seq:** 1 **Gender:** F
**Reported:** 22/12/1997 **Weight:** 60.00
**Hospitalisation:** **Age:** 44Y
**Onset Date:** 30/11/1997 **DOB:**
**Outcome:** Not yet recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle twitching | | Facial muscle fasciculation | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
**Batch:** **Started:** 06/11/1997 **Stopped:** 16/12/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | Biochemistry | | | | Normal calcium/albumin |
| | Other data | | | | Negative cherstek's |

### Additional Information:

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123651 **Seq:** 1
**Reported:** 24/12/1997
**Hospitalisation:**
**Onset Date:** 31/10/1997
**Outcome:** Not yet recovered

**Gender:** F
**Weight:** 60.00
**Age:** 21
**DOB:** 06/12/1975
**Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Acne | | Acne or variation of acne | Aropax was gradually withdrawn over one week |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

**Batch:** **Started:** 01/05/1997 **Stopped:** 28/11/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- 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. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123661 **Seq:** 1 **Gender:** F
**Reported:** 30/12/1997 **Weight:** 75.00
**Hospitalisation:** **Age:** 7Y
**Onset Date:** 18/12/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality certain

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Muscle spasms | | | |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
**Batch:** **Started:** 18/12/1997 **Stopped:** 20/12/1997

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

Patient has had similar reactions to other anti depressants patient experienced leg cramps each time when took aropax at night.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123684 **Seq:** 1 **Gender:** M
**Reported:** 30/12/1997 **Weight:**
**Hospitalisation:** **Age:**
**Onset Date:** 31/08/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality possible

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Convulsion | | Myoclonic jerks in all four limbs | Clonazepam and sodium |

### Medicine Details:

**AROPAX (Suspected)** **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

# THERAPEUTIC GOODS ADMINISTRATION
## Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 1997 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

### Report Detail

**Case Number:** 123685 **Seq:** 1 **Gender:** F
**Reported:** 30/12/1997 **Weight:** 50.00
**Hospitalisation:** **Age:** 13Y
**Onset Date:** 02/10/1997 **DOB:**
**Outcome:** Recovered **Causality:** Causality probable

### Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Purpura | | | Aropax discontinued |

### Medicine Details:

**AROPAX (Suspected)** **Reason:**
Tablet 20.0 Milligram Daily Oral
**Batch:** **Started:** 25/08/1997 **Stopped:**

### Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|---|
| | | | | | |

### Additional Information: