THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 105587 **Seq:** 1 **Gender:** F
Reported: 02/01/1996 **Weight:**
Hospitalisation: **Age:** 25Y
Onset Date: 20/12/1995 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 13/12/1995 **Stopped:** 24/12/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 105609 **Seq:** 1 **Gender:** M
Reported: 02/01/1996 **Weight:**
Hospitalisation: **Age:** 19Y
Onset Date: 16/12/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema	Severe		

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 14/12/1995 **Stopped:** 18/12/1995

RISPERDAL (Suspected) **Reason:** Unspecified psychosis
Oral application 1.0 Milligram Daily Oral
Batch: **Started:** 14/12/1995 **Stopped:** 18/12/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 105705 **Seq:** 1 **Gender:** F
Reported: 03/01/1996 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Unintended pregnancy			

Medicine Details:

LEVLEN ED (Interaction) **Reason:** Contraception
0.0
Batch: **Started:** **Stopped:**

PROZAC (Interaction) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 06M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 105790 **Seq:** 1 **Gender:** M
Reported: 10/01/1996 **Weight:**
Hospitalisation: **Age:** 13Y
Onset Date: 11/08/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Extrapyramidal reaction	Cogentin

Medicine Details:

MAXOLON (Suspected) **Reason:** Gastroenteritis and colitis
Tablet 6.0 Dose Unspecified Total Oral
Batch: **Started:** 09/08/1995 **Stopped:** 11/08/1995

PROZAC (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 18/05/1995 **Stopped:** 11/08/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 105797 **Seq:** 1
Reported: 10/01/1996
Hospitalisation: Admitted to hospital
Onset Date: 08/12/1995
Outcome: Recovered

Gender: F
Weight: 65.00
Age: 73Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Orthostatic hypotension			

Medicine Details:

THYROXINE SODIUM (Other drug) **Reason:** Myxedema
50.0 Microgram Daily
Batch: **Started:** 01/01/1994 **Stopped:** CONTIN

PROZAC (Suspected) **Reason:** Depression
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** 04/09/1995 **Stopped:** 08/12/1995

PROTHIADEN (Suspected) **Reason:** Depression
Oral application 150.0 Milligram Daily Oral
Batch: **Started:** 04/09/1995 **Stopped:** 08/12/1995

EPILIM (Suspected) **Reason:** Depression
1.0 Gram Daily
Batch: **Started:** 06/12/1995 **Stopped:** 08/12/1995

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.

Report Detail

Case Number: 105848 **Seq:** 1 **Gender:** M
Reported: 12/01/1996 **Weight:** 0.00
Hospitalisation: **Age:** 58
Onset Date: 15/01/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Suspected SIADH	

Medicine Details:

METRONIDAZOLE (Other drug) **Reason:**
Suppository 1.0 Gram Daily Rectal
Batch: **Started:** **Stopped:**

LOSEC (Other drug) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

DEMECLOCYCLINE HYDROCHLORIDE (Other drug) **Reason:**
Capsule 600.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PREDNISOLONE (Other drug) **Reason:**
Tablet 5.0 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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 105848 **Seq:** 1
Reported: 12/01/1996
Hospitalisation:
Onset Date: 15/01/1996
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 58
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Additional Information:

The date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Report Detail

Case Number: 106062 **Seq:** 1 **Gender:** F
Reported: 25/01/1996 **Weight:**
Hospitalisation: **Age:** 43Y
Onset Date: 21/01/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia			Pramin

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 19/01/1996 **Stopped:** 21/01/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 106236 **Seq:** 1
Reported: 05/02/1996
Hospitalisation:
Onset Date: 31/01/1996
Outcome: Not yet recovered

Gender: F
Weight: 57.00
Age: 55Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia		Hip pain	

Medicine Details:

MENOREST (Suspected) **Reason:** Menopausal symptoms

Cream 50.0 Microgram Daily Topical

Batch: **Started:** 22/01/1996 **Stopped:**

PROZAC (Suspected) **Reason:** Depression

Oral application 20.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 106322 **Seq:** 1 **Gender:** F
Reported: 07/02/1996 **Weight:** 51.00
Hospitalisation: **Age:** 62Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Headache Insomnia Palpitations	Required Visit to Doctor		

Medicine Details:

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

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 106348 **Seq:** 1 **Gender:** F
Reported: 07/02/1996 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Nausea Rash Tremor			

Medicine Details:

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

PROZAC (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 3M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 106417 **Seq:** 1 **Gender:** M
Reported: 12/02/1996 **Weight:** 92.00
Hospitalisation: **Age:** 48Y
Onset Date: 22/01/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular Chest pain Dyspnoea Fatigue Malaise Somnolence		On neck and arm	

Medicine Details:

HYPNODORM (Other drug)				**Reason:**	Disturbance of sleep
Tablet	4.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
COLOXYL (Other drug)				**Reason:**	Constipation
Oral application	2.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
ANTENEX (Other drug)				**Reason:**	Alcoholic addiction
Tablet	10.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
ANTABUSE (Other drug)				**Reason:**	Alcoholic addiction
Tablet	500.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previously had reaction to zoloft and aropax --> rash and git pains

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 106417 **Seq:** 1 **Gender:** M
Reported: 12/02/1996 **Weight:** 92.00
Hospitalisation: **Age:** 48Y
Onset Date: 22/01/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 18/01/1996 **Stopped:** 23/01/1996

Laboratory Investigations:

Additional Information:

Previously had reaction to zoloft and aropax --> rash and git pains

Report Detail

Case Number: 106419 **Seq:** 1 **Gender:** U
Reported: 12/02/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: 12/01/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Anorexia			

Medicine Details:

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

PROZAC (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 11/01/1996 **Stopped:** 15/01/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 106440 **Seq:** 1 **Gender:** F
Reported: 14/02/1996 **Weight:**
Hospitalisation: **Age:** 24Y
Onset Date: 01/02/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Back pain Blood creatine phosphokinase in Chest pain Vomiting			

Medicine Details:

SANDOMIGRAN (Other drug) **Reason:** Migraine
6.0 Dose Unspecified Daily
Batch: **Started:** 01/07/1993 **Stopped:**

NORMISON (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:**

PETHIDINE HYDROCHLORIDE (Suspected) **Reason:**
Injection 100.0 Milligram 1 time Intramuscular
Batch: **Started:** 01/02/1996 **Stopped:**

PROZAC (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 26/01/1996 **Stopped:** 01/02/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine Creatine Creatine		01/02/1996 02/02/1996 04/02/1996	3000 1800 450	

Additional Information:

Cpk elevation maybe related to an injection of pethidine. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 107028 **Seq:** 1 **Gender:** M
Reported: 14/03/1996 **Weight:** 77.00
Hospitalisation: **Age:** 60Y
Onset Date: 07/03/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination			

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 19/02/1996 **Stopped:** 11/03/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Severe reaction to efudix.

Report Detail

Case Number: 107040 **Seq:** 1 **Gender:** M
Reported: 13/03/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: 28/07/1995 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Depression Insomnia Suicide attempt			

Medicine Details:

PROZAC (Suspected) **Reason:**
0.0
Batch: **Started:** 13/07/1994 **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 107076 **Seq:** 1 **Gender:** F
Reported: 15/03/1996 **Weight:** 60.00
Hospitalisation: **Age:** 42Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Hepatic function abnormal			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/02/1995 **Stopped:** 28/02/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =	<65			Ggt level less than or equal to 140

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: 107250 **Seq:** 1 **Gender:** F
Reported: 15/03/1996 **Weight:** 80.00
Hospitalisation: **Age:** 41Y
Onset Date: 11/02/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Diarrhoea Hyperhidrosis			

Medicine Details:

THYROXINE SODIUM (Other drug) **Reason:** Myxedema
50.0 Microgram Daily
Batch: **Started:** 01/09/1995 **Stopped:** CONTIN

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 08/02/1996 **Stopped:** 29/02/1996

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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 107262 **Seq:** 1 **Gender:** F
Reported: 25/03/1996 **Weight:** 75.00
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Nervousness Weight increased		Listlessness	

Medicine Details:

PROZAC (Suspected) **Reason:** Unspecified neurosis

Capsule 4.0 Dose Unspecified Daily Oral

Batch: **Started:** **Stopped:** 05Y

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Irritability and listlessness ocurred on reduction of prozac dose.

Report Detail

Case Number: 107278 **Seq:** 1 **Gender:** M
Reported: 25/03/1996 **Weight:** 75.00
Hospitalisation: **Age:** 51Y
Onset Date: 17/03/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erythema multiforme			

Medicine Details:

NICABATE (Suspected) **Reason:**
Cream 0.0 Topical
Batch: **Started:** 20/07/1995 **Stopped:**

FUNGILIN (Suspected) **Reason:**
Lozenge 4.0 Dose Unspecified Daily Oral
Batch: **Started:** 12/03/1996 **Stopped:** 16/03/1996

PROZAC (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 19/06/1995 **Stopped:** 22/03/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 107295 **Seq:** 1 **Gender:** F
Reported: 25/03/1996 **Weight:** 58.00
Hospitalisation: **Age:** 47Y
Onset Date: 31/01/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation Headache Thinking abnormal			

Medicine Details:

MERSYNDOL (Interaction) **Reason:** Headache
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

PROZAC (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/10/1995 **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.

Report Detail

Case Number: 107343 **Seq:** 1 **Gender:** F
Reported: 27/03/1996 **Weight:** 60.00
Hospitalisation: **Age:** 49Y
Onset Date: 03/12/1995 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia	Severe		

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** 02/12/1995 **Stopped:** 25/12/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 107765 **Seq:** 1 **Gender:** F
Reported: 09/04/1996 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Confusional state Hyponatraemia			

Medicine Details:

RENITEC (Other drug) **Reason:** Essential benign hypertension
10.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 15/03/1996

WARFARIN SODIUM (Other drug) **Reason:** Prophylaxis
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 15/03/1996

ZANTAC (Other drug) **Reason:** Other diseases of esophagus
300.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 15/03/1996

TRANSIDERM-NITRO (Other drug) **Reason:** Angina pectoris w/o hyperten
25.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 15/03/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		30/12/1995	139	
	Sodium		27/01/1996	132	
	Sodium		31/01/1996	118	

Additional Information:

Patient admitted to hospital for 1 week. see original for other drugs

Report Detail

Case Number: 107765 **Seq:** 1
Reported: 09/04/1996
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

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

Reaction Detail

Medicine Details:

NORVASC (Other drug)			**Reason:**	Angina pectoris w/o hyperten
Tablet	5.0	Milligram	Daily	Oral
Batch:	**Started:**	19/02/1996	**Stopped:**	21/03/1996
PROZAC (Suspected)			**Reason:**	Depression
Oral application	20.0	Milligram	Daily	Oral
Batch:	**Started:**	22/01/1996	**Stopped:**	30/01/1996

Laboratory Investigations:

Additional Information:

Patient admitted to hospital for 1 week. see original for other drugs

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 107822 **Seq:** 1 **Gender:** F
Reported: 12/04/1996 **Weight:** 65.00
Hospitalisation: **Age:** 38Y
Onset Date: 20/03/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fixed eruption			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 06/02/1996 **Stopped:** 20/03/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 107918 **Seq:** 1 **Gender:** M
Reported: 17/04/1996 **Weight:** 65.00
Hospitalisation: **Age:** 36Y
Onset Date: 05/03/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nail disorder Alopecia		Brittle nails	

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:**
2.0 Dose Unspecified As necessary
Batch: **Started:** L TERM **Stopped:** CONTIN

VALIUM (Other drug) **Reason:** Anxiety neurosis
5.0 Milligram As necessary
Batch: **Started:** L TERM **Stopped:** CONTIN

ENDEP (Other drug) **Reason:** Specific disorders of sleep
50.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

PROZAC (Suspected) **Reason:** Depression
0.0
Batch: **Started:** 22/11/1995 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 107919 **Seq:** 1 **Gender:** M
Reported: 17/04/1996 **Weight:** 65.00
Hospitalisation: **Age:** 34Y
Onset Date: 11/04/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

METHADONE HYDROCHLORIDE (Other drug) **Reason:** Migraine
0.0 As necessary
Batch: **Started:** L TERM **Stopped:** CONTIN

VALIUM (Other drug) **Reason:**
12.5 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

PROZAC (Suspected) **Reason:**
0.0
Batch: **Started:** 06/03/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 108211 **Seq:** 1 **Gender:** F
Reported: 02/05/1996 **Weight:** 70.00
Hospitalisation: **Age:** 32Y
Onset Date: 01/07/1994 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 01/07/1994 **Stopped:** 28/11/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

When patient restarted prozac on 7/12/95, reaction recurred. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Detail

Case Number: 108411 **Seq:** 1 **Gender:** F
Reported: 13/05/1996 **Weight:** 77.00
Hospitalisation: **Age:** 41Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Apathy		Emotional detatchment	
Amnesia		Short term memory loss	
Agitation			
Alcohol intolerance			
Palpitations			
Psoriasis			

Medicine Details:

HERBAL MEDICINES (Other drug) **Reason:** Menopausal symptoms
0.0
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 108420 **Seq:** 1 **Gender:** F
Reported: 13/05/1996 **Weight:**
Hospitalisation: **Age:** 32Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia		Muscle tension (jaw)	
Tremor		Teeth chattering	
Hypoaesthesia			
Neuropathy			
Paraesthesia			

Medicine Details:

CLONAZEPAM (Other drug) **Reason:** Anxiety neurosis
0.5 Milligram Daily
Batch: **Started:** **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 21/04/1996 **Stopped:** 05/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had same drug in past with side-effects eg "bursting head" as if ants eating her brain. recently on paroxetine (feb-march 1996) with similar reaction.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 108480 **Seq:** 1
Reported: 15/05/1996
Hospitalisation: Admitted to hospital
Onset Date: 04/03/1996
Outcome: Unknown

Gender: F
Weight:
Age: 39Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Migraine Orthostatic hypotension Quadriplegia			

Medicine Details:

PROTHIADEN (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** **Stopped:** 05/02/1996

PROZAC (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** **Stopped:** 14/02/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Fell down a spiral staircase as a result of which she sustained a very severe fracture of the neck and she is quadriplegic. she may have had a viral infection.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 108535 **Seq:** 1 **Gender:** F
Reported: 17/05/1996 **Weight:**
Hospitalisation: **Age:** 48Y
Onset Date: 31/12/1995 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Hyperprolactinaemia			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
0.0
Batch: **Started:** 06/12/1990 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	2.9-24MCG/L	16/05/1996	61.4	

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 108623 **Seq:** 1 **Gender:** F
Reported: 22/05/1996 **Weight:** 60.00
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast enlargement Galactorrhoea			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
80.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on prozac 4 years ago with similar effect. see origional report for other drugs. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 108721 **Seq:** 1 **Gender:** F
Reported: 27/05/1996 **Weight:** 60.00
Hospitalisation: **Age:** 49Y
Onset Date: 14/05/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Agitation Anxiety Headache Myalgia		Early morning waking	

Medicine Details:

PROZAC (Other drug) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 05/11/1995 **Stopped:** 12/05/1996

ZACTIN (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 13/05/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset of symptoms with change of brand of fluoxetine. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 108797 **Seq:** 1 **Gender:** F
Reported: 29/05/1996 **Weight:** 47.00
Hospitalisation: **Age:** 36Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia Anxiety Diarrhoea Nausea Tremor			

Medicine Details:

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

PROZAC (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: 108804 **Seq:** 1
Reported: 29/05/1996
Hospitalisation:
Onset Date: 23/02/1996
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 54Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

VALIUM (Suspected) **Reason:** Anxiety neurosis
5.0 Milligram As necessary
Batch: **Started:** L TERM **Stopped:**

BETALOC (Suspected) **Reason:** Essential benign hypertension
200.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

PREMARIN (Suspected) **Reason:** Menopausal symptoms
625.0 Microgram Daily
Batch: **Started:** L TERM **Stopped:**

PROVERA (Suspected) **Reason:** Menopausal symptoms
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 108804 **Seq:** 1
Reported: 29/05/1996
Hospitalisation:
Onset Date: 23/02/1996
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 54Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

PROZAC (Suspected)			**Reason:**	Depression
	20.0	Milligram	Daily	
Batch:	**Started:**	13/02/1996	**Stopped:**	07/05/1996
RIVOTRIL (Suspected)			**Reason:**	Partl,templobe,psychomo epilep
	10.0	Milligram	Daily	
Batch:	**Started:**	L TERM	**Stopped:**	
TEGRETOL (Suspected)			**Reason:**	Partl,templobe,psychomo epilep
	600.0	Milligram	Daily	
Batch:	**Started:**	L TERM	**Stopped:**	

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 108860 **Seq:** 1 **Gender:** F
Reported: 31/05/1996 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 18/05/1996 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Headache	Severe		

Medicine Details:

PROZAC (Other drug) **Reason:**
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1995 **Stopped:**

ZACTIN (Suspected) **Reason:**
Capsule 20.0 Milligram 2 times Oral
Batch: **Started:** 18/05/1996 **Stopped:** 20/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been taking prozac for more than one year. after taking the first 20mg zactin capsule, had severe headache and felt dizzy and 'fuzzy'. the same thing happened the next day - changed back to prozac and felt better. generic substitution problem the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 108937 **Seq:** 1 **Gender:** M
Reported: 03/06/1996 **Weight:** 85.00
Hospitalisation: **Age:** 38Y
Onset Date: 31/08/1995 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure Migraine			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/08/1995 **Stopped:** 28/11/1995

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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 108947 **Seq:** 1 **Gender:** F
Reported: 03/06/1996 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: **DOB:** 01/04/1960
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Systemic lupus erythematosus			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 1Y

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 109050 **Seq:** 1 **Gender:** F
Reported: 11/06/1996 **Weight:** 104.00
Hospitalisation: **Age:** 55Y
Onset Date: 10/05/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Sweating of hands and face	

Medicine Details:

LOSEC (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** 01/01/1991 **Stopped:**

THYROXINE SODIUM (Other drug) **Reason:**
100.0 Microgram Daily
Batch: **Started:** 01/01/1995 **Stopped:**

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 26/04/1996 **Stopped:** 10/05/1996

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.

Report Detail

Case Number: 109068 **Seq:** 1 **Gender:** F
Reported: 11/06/1996 **Weight:**
Hospitalisation: **Age:** 38Y
Onset Date: 27/05/1996 **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium			

Medicine Details:

SEREPAX (Suspected) **Reason:** Specific disorders of sleep
Tablet 23.0 Dose Unspecified Total Oral
Batch: **Started:** 01/01/1996 **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Oral application 80.0 Milligram Daily Oral
Batch: **Started:** 17/04/1996 **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.

Report Detail

Case Number: 109070 **Seq:** 1 **Gender:** F
Reported: 11/06/1996 **Weight:**
Hospitalisation: **Age:** 18Y
Onset Date: 04/05/1996 **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium			

Medicine Details:

TEMAZEPAM (Suspected) **Reason:** Specific disorders of sleep
Oral application 30.0 Milligram As necessary Oral
Batch: **Started:** 02/04/1996 **Stopped:** CONTIN

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 02/04/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Episode of cutting herself but no conscious recollection.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 109140 **Seq:** 1 **Gender:** F
Reported: 14/06/1996 **Weight:**
Hospitalisation: **Age:** 63Y
Onset Date: 14/06/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Rash Suicide attempt			

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 21/05/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Generic substitution problem

Report Detail

Case Number: 109260 **Seq:** 1 **Gender:** F
Reported: 19/06/1996 **Weight:** 60.00
Hospitalisation: **Age:** AD
Onset Date: 07/06/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash	Severe	Severe skin rash mainly on upper body	

Medicine Details:

ALDACTONE (Other drug)			**Reason:**		
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:** 21/08/1995			**Stopped:**	
DIANE-35 ED (Other drug)			**Reason:**		
Tablet	1.0	Dose Unspecified	Daily		Oral
Batch:	**Started:** 03/02/1995			**Stopped:**	
ZACTIN (Suspected)			**Reason:**		
Capsule	1.0	Dose Unspecified	Daily		Oral
Batch:	**Started:** 04/06/1996			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous problem with prozac, therefore suspects zactin is cause of reaction. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 109293 **Seq:** 1 **Gender:** M
Reported: 17/06/1996 **Weight:** 70.00
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysuria Urinary retention			

Medicine Details:

GAVISCON (Other drug) **Reason:** Heartburn
Oral Liquid 0.0 As necessary Oral
Batch: **Started:** **Stopped:**

MYLANTA (Other drug) **Reason:** Heartburn
Oral Liquid 0.0 As necessary Oral
Batch: **Started:** **Stopped:**

MINIPRESS (Other drug) **Reason:** Essential benign hypertension
Tablet 4.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

ZANTAC (Other drug) **Reason:** Heartburn
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 29/05/1996

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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 109293 **Seq:** 1 **Gender:** M
Reported: 17/06/1996 **Weight:** 70.00
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/11/1995 **Stopped:** 28/04/1996

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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 109433 **Seq:** 1 **Gender:** F
Reported: 24/06/1996 **Weight:**
Hospitalisation: **Age:** 48Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea			

Medicine Details:

LITHIUM CARBONATE (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** L TERM **Stopped:**

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

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

ZACTIN (Suspected) **Reason:**
3.0 Dose Unspecified Daily
Batch: **Started:** 01/04/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 109488 **Seq:** 1 **Gender:** M
Reported: 25/06/1996 **Weight:** 71.00
Hospitalisation: **Age:** 47Y
Onset Date: 03/04/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 25/03/1996 **Stopped:** 30/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 109536 **Seq:** 1 **Gender:** F
Reported: 26/06/1996 **Weight:** 80.00
Hospitalisation: **Age:** 34Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

ZACTIN (Suspected) **Reason:**

Capsule 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 1M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 109641 **Seq:** 1 **Gender:** M
Reported: 01/07/1996 **Weight:** 70.00
Hospitalisation: **Age:** A5
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			

Medicine Details:

ZACTIN (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on prozac decided to change to zactin resulting in diarrhoea. changed back to prozac with reaction stopping. re-tested on zactin --> diarrhoea again. generic substitution problem

Report Detail

Case Number: 109703 **Seq:** 1
Reported: 04/07/1996
Hospitalisation:
Onset Date: 10/05/1996
Outcome: Recovered with sequelae

Gender: M
Weight: 78.00
Age: 47Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Drug ineffective		Depression	

Medicine Details:

LOSEC (Other drug) **Reason:** Other diseases of esophagus
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

RITALIN (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 01/02/1996 **Stopped:**

LOVAN (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 03/05/1996 **Stopped:** 17/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Comment: recurrence of depression and other symptoms of post traumatic stress disorder. quite obvious lovan is not bio-equivalent to prozac. generic substitution problem the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 109856 **Seq:** 1 **Gender:** M
Reported: 08/07/1996 **Weight:** 45.00
Hospitalisation: **Age:** 68Y
Onset Date: **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormon			

Medicine Details:

HALOPERIDOL (Other drug) **Reason:**
Oral application 1.5 Milligram Daily Oral
Batch: **Started:** **Stopped:**

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

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:** 24/05/1996

QUININE SULPHATE (Suspected) **Reason:**
300.0 Milligram Daily
Batch: **Started:** **Stopped:** 24/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum osmolality		01/03/1996	269	
	Serum osmolality		14/05/1996	265	
	Serum osmolality		17/05/1996	255	
	Serum osmolality		27/05/1996	269	
	Serum osmolality		20/05/1996	258	
	Sodium		01/03/1996	132	
	Sodium		14/05/1996	130	

Additional Information:

History: metastatic ca of prostate + tumour lesion to t11, acute spinal cord compression. patient deceased 27/5/96.

Report Detail

Case Number: 109856 **Seq:** 1
Reported: 08/07/1996
Hospitalisation:
Onset Date:
Outcome: Death, maybe drug

Gender: M
Weight: 45.00
Age: 68Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Suspected)			**Reason:**		
Oral application	40.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
PROCHLORPERAZINE MALEATE (Suspected)			**Reason:**		
Injection	37.5	Milligram	Daily	Intramuscular	
Batch:	**Started:**	21/05/1996		**Stopped:**	24/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		17/05/1996	124	
	Sodium		20/05/1996	125	
	Sodium		27/05/1996	130	
	Urine Sodium		20/05/1996	25MMOL/L	
	Urine osmolality		20/05/1996	647 = OK	

Additional Information:

History: metastatic ca of prostate + tumour lesion to t11, acute spinal cord compression. patient deceased 27/5/96.

Report Detail

Case Number: 109953 **Seq:** 1 **Gender:** F
Reported: 15/07/1996 **Weight:** 47.00
Hospitalisation: **Age:** 73Y
Onset Date: 23/06/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache Insomnia			

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression

Capsule 20.0 Milligram Daily Oral

Batch: **Started:** 21/06/1996 **Stopped:** 28/06/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Given lovan as trial - substituted zactin by pharmacist. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 109976 **Seq:** 1
Reported: 16/07/1996
Hospitalisation:
Onset Date: 18/06/1996
Outcome: Not yet recovered

Gender: F
Weight: 46.00
Age: 28Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Severe		

Medicine Details:

SEREPAX (Other drug) **Reason:** Anxiety neurosis
0.5 Dose Unspecified As necessary
Batch: **Started:** 01/03/1996 **Stopped:**

ZACTIN (Suspected) **Reason:** Depression
Capsule 3.0 Dose Unspecified Daily Oral
Batch: **Started:** 18/06/1996 **Stopped:** 26/06/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

On prozac for 12 months, no nausea from this. severe nausea when changing from prozac to cheaper brand. generic substitution problem the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110105 **Seq:** 1
Reported: 22/07/1996
Hospitalisation:
Onset Date: 17/07/1996
Outcome: Recovered

Gender: F
Weight: 43.00
Age: 29
DOB: 04/04/1967
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope Chills Confusional state Hyperhidrosis Insomnia Nausea Tinnitus Tremor		Blackout with no warning	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 07/07/1996 **Stopped:** 17/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110257 **Seq:** 1 **Gender:** F
Reported: 29/07/1996 **Weight:** 55.00
Hospitalisation: **Age:** 16Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Heart disease congenital Coarctation of the aorta		Bicuspid aortic valve	Baby needed surgery

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 27/07/1995 **Stopped:** 19/03/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient discovered pregnancy at 26 weeks gestation, parturition at 30 weeks gestation. female infant born birth weight 1185 grams.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110294 **Seq:** 1 **Gender:** F
Reported: 29/07/1996 **Weight:** 80.00
Hospitalisation: **Age:** 63Y
Onset Date: 15/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Nervousness			

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression

Capsule 20.0 Milligram Daily Oral

Batch: **Started:** 06/07/1996 **Stopped:** 18/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient became aggressive, irritable, belligerent, driving unsafely and picking fights with truck drivers following change from prozac 20 mg daily to zactin 20 mg daily. patient had been stable for 4 years on prozac. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110317 **Seq:** 1 **Gender:** M
Reported: 29/07/1996 **Weight:** 70.00
Hospitalisation: **Age:** 47Y
Onset Date: 10/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence			

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 08/07/1996 **Stopped:** 13/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sedation from zactin not previously experienced on prozac. sedation went when prozac was re-introduced. generic substitution problem

Report Detail

Case Number: 110339 **Seq:** 1 **Gender:** F
Reported: 30/07/1996 **Weight:** 80.00
Hospitalisation: **Age:** 39Y
Onset Date: 25/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension		Bp 210/110	

Medicine Details:

PROZAC (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 15/07/1996 **Stopped:** 25/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110366 **Seq:** 1 **Gender:** F
Reported: 31/07/1996 **Weight:** 81.00
Hospitalisation: **Age:** 74Y
Onset Date: 02/02/1995 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Severe	Tremor of hands and legs.	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 12/01/1995 **Stopped:** 28/03/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Tremor started one month after starting prozac. quite disabling for a year or so and continued for four weeks after stopping prozac. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110372 **Seq:** 1 **Gender:** F
Reported: 26/07/1996 **Weight:** 60.00
Hospitalisation: **Age:** 38Y
Onset Date: 31/05/1996 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective		Depressive symptoms much worse	

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
Capsule 40.0 Milligram Daily Oral
Batch: **Started:** 01/05/1996 **Stopped:** 28/06/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient's condition deteriorated when placed on zactin (previously depression well controlled on prozac). patient improved when back on prozac again. then patient deteriorated again when recommenced on zactin. generic substitution problem - 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110425 **Seq:** 1 **Gender:** F
Reported: 01/08/1996 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Suicide attempt		Patient more depressed.	

Medicine Details:

ZACTIN (Suspected) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Therapy changed back to prozac and patient is feeling better. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110434 **Seq:** 1 **Gender:** M
Reported: 02/08/1996 **Weight:**
Hospitalisation: **Age:** 37Y
Onset Date: 01/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Acute urticarial rash	Antihistamine, prednisolone
Arthritis		Progressive multiple joint swelling	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 05/06/1996 **Stopped:** 10/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110512 **Seq:** 1 **Gender:** F
Reported: 06/08/1996 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache			

Medicine Details:

ZACTIN (Suspected) **Reason:**
3.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** 10D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient switched from prozac to zactin and developed headaches. patient went back to prozac with no further problems. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110516 **Seq:** 1 **Gender:** M
Reported: 06/08/1996 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Insomnia Nervousness			Patient changed back to prozac on 31/7/96.

Medicine Details:

LOVAN (Suspected) **Reason:**
0.0
Batch: **Started:** 17/07/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred when patient changed from prozac to lovan. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110652 **Seq:** 1 **Gender:** F
Reported: 09/08/1996 **Weight:** 80.00
Hospitalisation: **Age:** 40Y
Onset Date: 20/05/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Agitation		Acutely depressed and agitated	

Medicine Details:

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

ZACTIN (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 20/05/1996 **Stopped:** 04/06/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient became acutely depressed and agitated after changing to zactin 2 weeks earlier. have been taking zactin because of cost. had been told of lovan option but was told by pharmacist that lovan also attracted a surcharge! generic substitution problem

Report Detail

Case Number: 110669 **Seq:** 1
Reported: 09/08/1996
Hospitalisation:
Onset Date: 01/07/1996
Outcome: Recovered with sequelae

Gender: M
Weight: 92.00
Age: 25Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase in Pyrexia			

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified psychosis
275.0 Milligram Daily
Batch: **Started:** 28/06/1996 **Stopped:** 03/07/1996

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 26/06/1996

RISPERIDONE (Suspected) **Reason:** Unspecified schizophrenia
6.0 Milligram Daily
Batch: **Started:** **Stopped:** 25/06/1996

TETRACYCLINE (Suspected) **Reason:**
500.0 Milligram Daily
Batch: **Started:** **Stopped:** 25/06/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		02/07/1996	757	

Additional Information:

Suspected neuroleptic malignant syndrome. restarted clozapine on 08/07/96 with no problems.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110671 **Seq:** 1 **Gender:** M
Reported: 09/08/1996 **Weight:** 110.00
Hospitalisation: **Age:** 36Y
Onset Date: 06/06/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Suicide attempt			

Medicine Details:

THYROXINE SODIUM (Other drug) **Reason:**
Tablet 50.0 Microgram Daily Oral
Batch: **Started:** 15/05/1996 **Stopped:**

ZACTIN (Suspected) **Reason:**
Capsule 60.0 Milligram Daily Oral
Batch: **Started:** 22/05/1996 **Stopped:** 06/06/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient depressed and suicidal about 2 weeks after change over from prozac 20mg to zactin 20mg. has recovered on resuming prozac after similar time period. now stable on lovan. generic substitution problem

Report Detail

Case Number: 110738 **Seq:** 1 **Gender:** F
Reported: 13/08/1996 **Weight:**
Hospitalisation: **Age:** 25Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain Diarrhoea Headache Somnolence			Changed therapy to zactin.

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** **Stopped:** 02/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110739 **Seq:** 1 **Gender:** F
Reported: 13/08/1996 **Weight:**
Hospitalisation: **Age:** 25Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia Drug ineffective Insomnia Weight decreased			Changed therapy to lovan.

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 13/06/1996 **Stopped:** 28/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Report Detail

Case Number: 110743 **Seq:** 1 **Gender:** M
Reported: 12/08/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: 24/07/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Proctitis		Acute proctitis	
Rectal haemorrhage		Profuse pr bleeding	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 13/07/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Histology				Reaction proven on colonoscopy/rectal biopsy

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110909 **Seq:** 1 **Gender:** F
Reported: 16/08/1996 **Weight:**
Hospitalisation: **Age:** 32Y
Onset Date: 01/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vasculitis		Rash with appearance of vasculitis	
Urticaria	Severe	Severe urticarial rash	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 04/06/1996 **Stopped:** 01/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110912 **Seq:** 1 **Gender:** F
Reported: 16/08/1996 **Weight:**
Hospitalisation: **Age:** 37Y
Onset Date: 15/07/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence			

Medicine Details:

ZACTIN (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 6W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred when patient's medication was changed from prozac to zactin. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110915 **Seq:** 1 **Gender:** F
Reported: 16/08/1996 **Weight:** 67.00
Hospitalisation: **Age:** A3
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Personality disorder Insomnia Nightmare		Changed personality	

Medicine Details:

ZACTIN (Suspected) **Reason:**

0.0

Batch: **Started:** 29/05/1996 **Stopped:** 18/06/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

On 29/5/96 prozac was substituted with zactin (price differential). patient had been stable on prozac and reported that she had discontinued zactin because of nightmares, disturbed sleep and changed personality. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 110934 **Seq:** 1 **Gender:** F
Reported: 15/08/1996 **Weight:** 63.00
Hospitalisation: **Age:** 40Y
Onset Date: 22/06/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation Drug ineffective Somnolence		Depersonalization and empty mood.	

Medicine Details:

VIGABATRIN (Other drug) **Reason:** Other&unspecified epilepsy
2.0 Gram Daily
Batch: **Started:** 01/02/1996 **Stopped:** CONTIN

CARBAMAZEPINE (Other drug) **Reason:** Other&unspecified epilepsy
800.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

MYSOLINE (Other drug) **Reason:** Other&unspecified epilepsy
500.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Long term treatment with prozac in combination with anti convulsant treatment without any previous episodes. patient changed from prozac to zactin with reaction occurring, reversed 2 days after re-instituting prozac therapy. generic substitution problem the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111032 **Seq:** 1 **Gender:** F
Reported: 21/08/1996 **Weight:**
Hospitalisation: **Age:** 85Y
Onset Date: 05/08/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypernatraemia			Commenced on prothiaden.

Medicine Details:

GLYCERYL TRINITRATE (Other drug) **Reason:** Chron isch heart dis no hyper
0.0
Batch: **Started:** 02/08/1996 **Stopped:**

SENOKOT (Other drug) **Reason:**
0.0
Batch: **Started:** 03/08/1996 **Stopped:**

TEMAZEPAM (Other drug) **Reason:**
0.0
Batch: **Started:** 03/08/1996 **Stopped:**

VOLTAREN (Other drug) **Reason:** Osteoarthritis
50.0 Milligram Daily
Batch: **Started:** 02/08/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		12/08/1996	132	
	Sodium		15/08/1996	129	

Additional Information:

Report Detail

Case Number: 111032 **Seq:** 1
Reported: 21/08/1996
Hospitalisation:
Onset Date: 05/08/1996
Outcome: Not yet recovered

Gender: F
Weight:
Age: 85Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

ASPIRIN (Other drug)			**Reason:**	Chron isch heart dis no hyper	
Oral application	150.0	Milligram	Daily		Oral
Batch:	**Started:** 02/08/1996			**Stopped:**	
IMDUR (Other drug)			**Reason:**	Chron isch heart dis no hyper	
Oral application	60.0	Milligram	Daily		Oral
Batch:	**Started:** 02/08/1996			**Stopped:**	
ANGININE (Other drug)			**Reason:**		
Tablet	0.5	Dose Unspecified	Daily		Sublingual
Batch:	**Started:** 02/08/1996			**Stopped:**	
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**		
	20.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 111082 **Seq:** 1
Reported: 22/08/1996
Hospitalisation:
Onset Date: 17/08/1996
Outcome: Not yet recovered

Gender: M
Weight: 80.00
Age: 67
DOB: 08/05/1929
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Agitation Dizziness Urinary retention		++ confusion	

Medicine Details:

BACLOFEN (Suspected) **Reason:** Otr&unsp vertebrogen pain synd
Tablet 80.0 Milligram Daily Oral
Batch: **Started:** 15/08/1996 **Stopped:** 17/08/1996

PROZAC (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 01/06/1996 **Stopped:**

PANADEINE FORTE (Suspected) **Reason:** Otr&unsp vertebrogen pain synd
4.0 Dose Unspecified Daily
Batch: **Started:** 01/01/1995 **Stopped:**

VALIUM (Suspected) **Reason:** Specific disorders of sleep
Oral application 5.0 Milligram Daily Oral
Batch: **Started:** 01/01/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has previous history of cva 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111125 **Seq:** 1 **Gender:** M
Reported: 23/08/1996 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: 31/07/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nocturia Pollakiuria			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/07/1996 **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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111127 **Seq:** 1 **Gender:** F
Reported: 26/08/1996 **Weight:** 90.00
Hospitalisation: **Age:** 39Y
Onset Date: 01/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia			

Medicine Details:

INDERAL (Other drug) **Reason:** Headache
320.0 Milligram Daily
Batch: **Started:** 11/10/1995 **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/04/1993 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms appeared when dose increased to 40mg and settled when dose reduced to 20mg. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111166 **Seq:** 1
Reported: 26/08/1996
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 103.00
Age: 40Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction	Severe		

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 01/05/1996 **Stopped:** 22/06/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This patient was well controlled on prozac for 2 years. when changed to zactin at pharmacy ---> developed impotence at a severe level. generic substitution problem the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111167 **Seq:** 1 **Gender:** F
Reported: 26/08/1996 **Weight:** 55.00
Hospitalisation: **Age:** 28Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased Nervousness			

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 01/05/1996 **Stopped:** 28/08/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient well controlled for over 2 years on prozac. changed from prozac to zactin ==> much more irritable and greatly reduced libido. generic substitution problem 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111175 **Seq:** 1 **Gender:** M
Reported: 26/08/1996 **Weight:** 79.00
Hospitalisation: **Age:** 36Y
Onset Date: 17/08/1996 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain Oesophagitis	Severe	Severe retrosternal pain	Large doses of mucaine.

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 16/08/1996 **Stopped:** 21/08/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction recurred on re-challenge 3 days later with a similar pain.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111202 **Seq:** 1 **Gender:** F
Reported: 27/08/1996 **Weight:** 65.00
Hospitalisation: **Age:** 36Y
Onset Date: 20/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain		Burning in chest	Changed to lovan.

Medicine Details:

MICROLUT (Other drug) **Reason:** Contraception

Pill 1.0 Dose Unspecified Daily Oral

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

ZACTIN (Suspected) **Reason:** Depression

Capsule 40.0 Milligram Daily Oral

Batch: **Started:** 05/06/1996 **Stopped:** 05/08/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was changed from prozac to zactin because of cost. on zactin, complained of burning in chest. changed to lovan on 5/8/96 and no more chest discomfort. impression: zactin capsule dissolves in eosophagus causing oesophagitis. prozac and lovan do not. generic substitution problem

Report Detail

Case Number: 111209 **Seq:** 1 **Gender:** F
Reported: 27/08/1996 **Weight:** 53.00
Hospitalisation: **Age:**
Onset Date: 12/08/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema Arthralgia Henoch-Schonlein purpura Urticaria			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily
Batch: **Started:** 18/07/1996 **Stopped:** 12/08/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 111254 **Seq:** 1 **Gender:** F
Reported: 29/08/1996 **Weight:** 40.00
Hospitalisation: **Age:** 78Y
Onset Date: 08/08/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pollakiuria Urinary incontinence			

Medicine Details:

PANADEINE FORTE (Suspected) **Reason:** Pain
Tablet 8.0 Dose Unspecified Daily Oral
Batch: **Started:** 17/07/1996 **Stopped:**

ROCALTROL (Suspected) **Reason:** Osteoporosis
Capsule 0.5 Microgram Daily Oral
Batch: **Started:** 11/06/1996 **Stopped:**

PANAMAX (Suspected) **Reason:** Pain
Oral application 4.0 Gram Daily Oral
Batch: **Started:** 16/06/1996 **Stopped:**

PROVERA (Suspected) **Reason:** Menopausal symptoms
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 27/06/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 111254 **Seq:** 1
Reported: 29/08/1996
Hospitalisation:
Onset Date: 08/08/1996
Outcome: Not yet recovered

Gender: F
Weight: 40.00
Age: 78Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

PREMARIN (Suspected)			**Reason:** Menopausal symptoms	
Tablet	625.0	Microgram	Daily	Oral
Batch:	**Started:** 27/06/1996		**Stopped:**	
PROZAC (Suspected)			**Reason:** Depression	
Oral application	20.0	Milligram	Alternate days	Oral
Batch:	**Started:** 26/07/1996		**Stopped:** 05/08/1996	

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111255 **Seq:** 1 **Gender:** M
Reported: 29/08/1996 **Weight:** 95.00
Hospitalisation: **Age:** 59Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression

0.0

Batch: **Started:** **Stopped:** 2W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was well maintained on prozac therapy. after 2 weeks on zactin pat. reported decreased mood and return of old symptoms. went back onto prozac and took further 2-3 weeks to resolve. generic substitution problem

Report Detail

Case Number: 111261 **Seq:** 1 **Gender:** F
Reported: 29/08/1996 **Weight:** 49.00
Hospitalisation: **Age:** 79Y
Onset Date: 08/08/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema Angioedema		Facial oedema (lower, bilateral)	Claratyne 10mg daily

Medicine Details:

PREMARIN (Other drug) **Reason:**
625.0 Microgram Daily
Batch: **Started:** L TERM **Stopped:**

COLGOUT (Other drug) **Reason:**
500.0 Microgram Daily
Batch: **Started:** L TERM **Stopped:**

PRINIVIL (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 111261 **Seq:** 1 **Gender:** F
Reported: 29/08/1996 **Weight:** 49.00
Hospitalisation: **Age:** 79Y
Onset Date: 08/08/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Medicine Details:

MELLERIL (Other drug)			**Reason:**	
	10.0 Milligram		Alternate days	
Batch:	**Started:**	L TERM	**Stopped:**	
PROZAC (Suspected)			**Reason:**	Depression
	20.0 Milligram		Daily	
Batch:	**Started:**	02/08/1996	**Stopped:**	08/08/1996

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111269 **Seq:** 1 **Gender:** M
Reported: 27/08/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: 01/07/1996 **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema		Allergic reaction involving pharynx	
Tongue oedema		Allergic reaction involving tongue	
Anaphylactoid reaction			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had repeated anaphylaxis the next day requiring same treatment twice. patient had been cleaning with an ammonia based disinfectant prior to anaphylaxis.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111273 **Seq:** 1 **Gender:** M
Reported: 30/08/1996 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 15/08/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Nausea		Global increase in hepatic enzymes	

Medicine Details:

VANCOMYCIN HYDROCHLORIDE (Suspected) **Reason:**
Injection 1.5 Gram Daily Intravenous
Batch: **Started:** 19/07/1996 **Stopped:**

TIMENTIN (Suspected) **Reason:**
Injection 9.3 Gram Daily Intravenous
Batch: **Started:** 07/07/1996 **Stopped:**

NILSTAT (Suspected) **Reason:**
Oral application 4.0 Millilitre Daily Oral
Batch: **Started:** 01/07/1996 **Stopped:**

FOLIC ACID (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 02/07/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111273 **Seq:** 1 **Gender:** M
Reported: 30/08/1996 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 15/08/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	
Oral application	20.0	Milligram	Daily	Oral
Batch:	**Started:** 07/07/1996			**Stopped:**
ZANTAC (Suspected)			**Reason:**	
Tablet	300.0	Milligram	Daily	Oral
Batch:	**Started:** 09/08/1996			**Stopped:**

Laboratory Investigations:

Additional Information:

See original report for other drugs.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111296 **Seq:** 1 **Gender:** F
Reported: 30/08/1996 **Weight:** 44.00
Hospitalisation: **Age:** 67Y
Onset Date: 01/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nervousness		Became nervy	
Insomnia		Could not sleep	
Malaise		Felt terrible	

Medicine Details:

OGEN (Other drug) **Reason:**
1.2 Milligram Daily
Batch: **Started:** **Stopped:**

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

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zactin used instead of prozac for one month for cost reasons. when she returned to prozac, she immediatly felt much better. generic substitution problem

Report Detail

Case Number: 111296 **Seq:** 1 **Gender:** F
Reported: 30/08/1996 **Weight:** 44.00
Hospitalisation: **Age:** 67Y
Onset Date: 01/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

NATRILIX (Other drug)		**Reason:**	
	1.0 Dose Unspecified Daily		
Batch:	**Started:**	**Stopped:**	
ZACTIN (Suspected)		**Reason:**	Depression
	0.0		
Batch:	**Started:**	**Stopped:**	1M

Laboratory Investigations:

Additional Information:

Zactin used instead of prozac for one month for cost reasons. when she returned to prozac, she immediatly felt much better. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111298 **Seq:** 1 **Gender:** F
Reported: 30/08/1996 **Weight:**
Hospitalisation: **Age:** 26Y
Onset Date: 31/07/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Personality disorder		Major personality change	

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/04/1996 **Stopped:** 28/08/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on prozac and responded well. patient experienced major personality change when changed to generic zactin. generic substitution problem - 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111341 **Seq:** 1
Reported: 03/09/1996
Hospitalisation: Admitted to hospital
Onset Date: 13/07/1995
Outcome: Unknown

Gender: M
Weight: 70.00
Age: 89Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiac failure			Diuretics.

Medicine Details:

MADOPAR Q (Other drug) **Reason:** Paralysis agitans
3.0 Dose Unspecified Daily
Batch: **Started:** 01/01/1992 **Stopped:**

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 30/05/1995 **Stopped:** 14/07/1995

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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111393 **Seq:** 1 **Gender:** F
Reported: 04/09/1996 **Weight:** 86.00
Hospitalisation: **Age:** 35Y
Onset Date: 04/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Affect lability Anxiety Depression Drug ineffective Nausea			

Medicine Details:

ZACTIN (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient changed therapy from prozac to zactin. regained control when changed back to prozac. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111434 **Seq:** 1 **Gender:** F
Reported: 06/09/1996 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 15/08/1996 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			

Medicine Details:

MENOPREM CONTINUOUS (Other drug) **Reason:** Menopausal symptoms
0.0
Batch: **Started:** **Stopped:**

MORPHINE NOS (Other drug) **Reason:** Pain
Injection 15.0 Milligram Daily Intramuscular
Batch: **Started:** 01/11/1995 **Stopped:**

VALIUM (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** 01/11/1995 **Stopped:**

PANADEINE FORTE (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/11/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: bowel hypomotility disorder --> chronic pain; spondylo- listhesis; suicidal depression; commenced prozac in march 1996 - it was substituted with zactin in may/june 1996. generic substitution problem 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: 111434 **Seq:** 1
Reported: 06/09/1996
Hospitalisation:
Onset Date: 15/08/1996
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 27Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

TEMAZEPAM (Other drug)			**Reason:**	
	40.0 Milligram		Daily	
Batch:	**Started:**			**Stopped:**
ZACTIN (Suspected)			**Reason:**	Depression
Capsule	20.0 Milligram		Daily	Oral
Batch:	**Started:**	01/06/1996		**Stopped:**

Laboratory Investigations:

Additional Information:

Patient history: bowel hypomotility disorder --> chronic pain; spondylo- listhesis; suicidal depression; commenced prozac in march 1996 - it was substituted with zactin in may/june 1996. generic substitution problem 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: 111502 **Seq:** 1 **Gender:** F
Reported: 09/09/1996 **Weight:** 70.00
Hospitalisation: **Age:** 84Y
Onset Date: 19/07/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug level increased			

Medicine Details:

PEXID (Interaction) **Reason:** Chron isch heart dis no hyper
100.0 Milligram Daily
Batch: **Started:** 01/07/1996 **Stopped:** 01/08/1996

PROZAC (Interaction) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 01/03/1995 **Stopped:** 01/08/1996

BURINEX (Other drug) **Reason:** Congestive heart failure
2.0 Milligram Daily
Batch: **Started:** 01/03/1995 **Stopped:** CONTIN

CAPOTEN (Other drug) **Reason:** Congestive heart failure
75.0 Milligram Daily
Batch: **Started:** 01/03/1995 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level	MG/L	01/08/1996	1.5	Perhexitine serum conc
	Serum drug level	MG/L	12/08/1996	1.52	Perhexitine serum conc
	Serum drug level	MG/L	21/08/1996	1.6	Perhexitine serum conc

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 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: 111502 **Seq:** 1
Reported: 09/09/1996
Hospitalisation:
Onset Date: 19/07/1996
Outcome: Not yet recovered

Gender: F
Weight: 70.00
Age: 84Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

ASPIRIN (Other drug)		**Reason:**	Congestive heart failure
	150.0 Milligram	Daily	
Batch:	**Started:** 01/03/1995	**Stopped:**	CONTIN
CARDIZEM (Other drug)		**Reason:**	Congestive heart failure
	180.0 Milligram	Daily	
Batch:	**Started:** 01/03/1995	**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. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111554 **Seq:** 1 **Gender:** M
Reported: 11/09/1996 **Weight:** 75.00
Hospitalisation: **Age:** 35Y
Onset Date: 31/05/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			Patient changed back to aropax

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:** Lumbalgia
Tablet 1.0 Dose Unspecified As necessary Oral
Batch: **Started:** 01/01/1992 **Stopped:**

DIAZEPAM (Other drug) **Reason:** Nervousness
Oral application 5.0 Milligram Daily Oral
Batch: **Started:** 01/01/1994 **Stopped:**

PROZAC (Suspected) **Reason:**
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 01/05/1996 **Stopped:** 10/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on aropax until the end of april. patient requested change to prozac but bedwetting made him go back to aropax. - 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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111585 **Seq:** 1 **Gender:** F
Reported: 12/09/1996 **Weight:** 63.00
Hospitalisation: **Age:** 37Y
Onset Date: 31/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Insomnia			

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient switched from prozac to lovan and experienced the reaction, on return to prozac all symptoms gone. generic substitution problem - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111587 **Seq:** 1 **Gender:** F
Reported: 11/09/1996 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: 28/08/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

PROZAC (Interaction) **Reason:** Depression
0.0
Batch: **Started:** **Stopped:**

CITANEST (Interaction) **Reason:**
2.0 Millilitre 1 time
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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111588 **Seq:** 1 **Gender:** M
Reported: 11/09/1996 **Weight:**
Hospitalisation: **Age:** A5
Onset Date: 31/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flushing Personality disorder			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient tolerates lovan and prozac well. now back on prozac without problems. generic substitution problem - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111705 **Seq:** 1 **Gender:** F
Reported: 19/09/1996 **Weight:**
Hospitalisation: **Age:** 41Y
Onset Date: 25/08/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 01/08/1996 **Stopped:** 26/08/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was treated successfully for major depression with prozac 20mg daily from 1/11/95. pharmacist substituted zactin 20mg in august 1996. over the following 4-6 weeks the patient became depressed again (complete relapse) while still on zactin 20mg daily. she recovered within 2 weeks of restarting prozac. generic substitution problem the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111823 **Seq:** 1 **Gender:** F
Reported: 25/09/1996 **Weight:**
Hospitalisation: **Age:** 28Y
Onset Date: 02/05/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 18/09/1995 **Stopped:** 29/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

All anxiety has gone since changing to prothiaden.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111839 **Seq:** 1 **Gender:** M
Reported: 24/09/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

ZACTIN (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Therapeutic failure following change from prozac to zactin. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111883 **Seq:** 1
Reported: 27/09/1996
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 76Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia Asthenia Hyponatraemia Inappropriate antidiuretic hormon Weight decreased			Fluid restriction, demeclocycline therapy

Medicine Details:

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

PROCHLORPERAZINE MALEATE (Suspected) **Reason:** Nausea and vomiting
5.0 Milligram As necessary
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 1M

OMEPRAZOLE (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum osmolality				On admission the serum osmolality was 244 mosm/kg
	Sodium				One month before admission (whilst on a dose of 20mg daily of fluoxetine) lab investigations revealed that the serum sodium concentration was 133mmol/l. however, on admission the serum sodium was 118mmol/l
	Urine Sodium				On admission the urine sodium concentration was 13mmol/l
	Urine osmolality				On admission the urine osmolality was 612 mosm/kg

Additional Information:

One month prior to admission the patient had commenced fluoxetine treatment for depression and the daily dose had been increased from 40mg to 60mg on the day before admission. the patient died three weeks after admission.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111883 **Seq:** 1
Reported: 27/09/1996
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 76Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

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

Laboratory Investigations:

Additional Information:

One month prior to admission the patient had commenced fluoxetine treatment for depression and the daily dose had been increased from 40mg to 60mg on the day before admission. the patient died three weeks after admission.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 111949 **Seq:** 1
Reported: 01/10/1996
Hospitalisation:
Onset Date: 10/09/1996
Outcome: Not yet recovered

Gender: F
Weight: 80.00
Age: 20Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Maculopapular rash on arm and chest	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

Capsule 0.0 Daily Oral

Batch: **Started:** 01/07/1996 **Stopped:** 29/09/1996

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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 112207 **Seq:** 1
Reported: 11/10/1996
Hospitalisation: Admitted to hospital
Onset Date: 31/12/1996
Outcome: Unknown

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

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting			

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 112230 **Seq:** 1 **Gender:** F
Reported: 14/10/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Nausea			

Medicine Details:

ZACTIN (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred when zactin substituted for prozac. generic substitution problem

Report Detail

Case Number: 112268 **Seq:** 1 **Gender:** F
Reported: 16/10/1996 **Weight:** 60.00
Hospitalisation: **Age:** 25Y
Onset Date: 19/09/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

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

Oral application 20.0 Milligram Daily Oral

Batch: **Started:** 01/04/1996 **Stopped:** 30/09/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 112322 **Seq:** 1 **Gender:** F
Reported: 16/10/1996 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 13/06/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis			

Medicine Details:

AUGMENTIN FORTE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PARACETAMOL (Suspected) **Reason:** Pain
Oral application 6.0 Dose Unspecified Daily Oral
Batch: **Started:** 03/06/1996 **Stopped:**

SAQUINAVIR MESYLATE (Suspected) **Reason:**
Oral application 1.8 Gram Daily Oral
Batch: **Started:** **Stopped:**

3TC (Suspected) **Reason:**
Oral application 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 112322 **Seq:** 1 **Gender:** F
Reported: 16/10/1996 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 13/06/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

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

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 112438 **Seq:** 1 **Gender:** F
Reported: 22/10/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

ZACTIN (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient unstable on zactin as compared to prozac. started zactin for price reasons. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 112487 **Seq:** 1 **Gender:** M
Reported: 24/10/1996 **Weight:** 113.00
Hospitalisation: **Age:** 37Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Depression Weight increased Affect lability Insomnia		Hostility, anger, violence/violent thoughts, Suicidal thoughts, altered personality Weight increased from 96kg to 123kg	Cessation of prozac/zactin

Medicine Details:

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

PROZAC (Suspected) **Reason:** Depression
0.0 Daily
Batch: **Started:** 01/06/1994 **Stopped:** 15/07/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient commenced prozac 20mg in early june 1994. he received varying doses of prozac/zactin (20-80mg) from june 1994 to 15/7/96. since stopping the medication he has "become a completely different person, reverting to his old self". the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 112537 **Seq:** 1 **Gender:** F
Reported: 25/10/1996 **Weight:** 90.00
Hospitalisation: **Age:** 82Y
Onset Date: 31/07/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Coordination abnormal Tremor Weight increased	Severe		

Medicine Details:

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

PROZAC (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.

Report Detail

Case Number: 112597 **Seq:** 1 **Gender:** F
Reported: 28/10/1996 **Weight:** 68.00
Hospitalisation: **Age:** 67Y
Onset Date: 08/10/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Confusional state Insomnia Nausea		Increased anxiety	Prozac ceased

Medicine Details:

CARDIZEM CD (Other drug) **Reason:**
Capsule 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

RENITEC (Other drug) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

OROXINE (Other drug) **Reason:**
Tablet 25.0 Microgram Alternate days Oral
Batch: **Started:** 08/08/1996 **Stopped:**

PROZAC (Suspected) **Reason:**
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 01/10/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

All symptoms developed in first week of prozac commencement. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 112707 **Seq:** 1 **Gender:** M
Reported: 31/10/1996 **Weight:** 100.00
Hospitalisation: **Age:** 51Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting			Treatment changed to zactin

Medicine Details:

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

NAPROSYN (Suspected) **Reason:** Unspecified arthritis
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 112733 **Seq:** 1 **Gender:** F
Reported: 01/11/1996 **Weight:** 60.00
Hospitalisation: **Age:** 82Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Hypotension Malaise Pallor Tremor		Unsteady on feet	

Medicine Details:

ZACTIN (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pharmacist substituted zactin for prozac. when zactin stopped and prozac reintroduced, rapid resolution of symptoms. generic substitution problem

Report Detail

Case Number: 113124 **Seq:** 1 **Gender:** F
Reported: 13/11/1996 **Weight:** 55.00
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria			

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 06/09/1996 **Stopped:** 01/11/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 113186 **Seq:** 1 **Gender:** M
Reported: 15/11/1996 **Weight:**
Hospitalisation: **Age:** 68Y
Onset Date: 11/11/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria			

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 24/10/1996 **Stopped:** 11/11/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 113286 **Seq:** 1 **Gender:** M
Reported: 22/11/1996 **Weight:**
Hospitalisation: **Age:** 72Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state		Acute episode of disorientation	
Anxiety		Acute episode of panic	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Capsule 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 10/09/1996 **Stopped:** 23/09/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 113300 **Seq:** 1 **Gender:** F
Reported: 22/11/1996 **Weight:** 72.00
Hospitalisation: **Age:** 49Y
Onset Date: 06/11/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoxia		Desaturated	
Electrocardiogram QT prolonged		Episode of long qt on ecg	
Cardiac arrest		Vf arrest	
Hypotension			
Ventricular fibrillation			

Medicine Details:

PROZAC (Interaction) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 01/08/1996 **Stopped:** CONTIN

DUROMINE (Interaction) **Reason:** Obesity othr than endoc origin
120.0 Milligram Daily
Batch: **Started:** 01/08/1996 **Stopped:** 05/11/1996

CLARATYNE (Interaction) **Reason:** Hay fever
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** 01/08/1996 **Stopped:** 07/11/1996

LORAZEPAM (Interaction) **Reason:** Anxiety neurosis
7.5 Milligram Daily
Batch: **Started:** 01/01/1976 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				04/11/96 - rate 88, pr 139, qrsd 76, qt 424, qtc 513. axis p 18,

Additional Information:

Severe global dilated cardiomyopathy with marked reduction of lvef. moderate mitral incompetance. 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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 113341 **Seq:** 1 **Gender:** M
Reported: 25/11/1996 **Weight:** 150.00
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Back pain		Failure of analgesics to be effective.	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1996 **Stopped:** 21/08/1996

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.

Report Detail

Case Number: 113343 **Seq:** 1 **Gender:** F
Reported: 25/11/1996 **Weight:** 95.00
Hospitalisation: **Age:** 26Y
Onset Date: 31/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hot flush Hyperhidrosis			

Medicine Details:

MICROGYNON (Other drug) **Reason:**
0.0 Daily
Batch: **Started:** 01/01/1996 **Stopped:** CONTIN

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 05/07/1996 **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.

Report Detail

Case Number: 113428 **Seq:** 1 **Gender:** F
Reported: 26/11/1996 **Weight:** 73.00
Hospitalisation: **Age:** 39Y
Onset Date: 17/08/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bronchospasm			
Cough	Severe		
Headache	Severe		

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 16/08/1996 **Stopped:** 23/09/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 113509 **Seq:** 1
Reported: 28/11/1996
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 82.00
Age: 77Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Mouth ulceration Purpura Rash Thrombocytopenia Weight decreased			Prednisolone, immunoglobulin, methyprednisolone.

Medicine Details:

VENTOLIN (Other drug) **Reason:** Asthma
Inhalation 0.0 As necessary Inhalation
Batch: **Started:** **Stopped:**

FLIXOTIDE (Other drug) **Reason:** Asthma
Inhalation 1.0 Milligram Daily Inhalation
Batch: **Started:** **Stopped:**

LANOXIN (Other drug) **Reason:** Congestive heart failure
Tablet 125.0 Microgram Daily Oral
Batch: **Started:** **Stopped:**

LASIX (Other drug) **Reason:** Otr&nos disord of heart rhythm
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bone marrow				Bone marrow aspirate reported as being either immune thrombocytopenia, idiopathic or drug related.

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 113509 **Seq:** 1
Reported: 28/11/1996
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 82.00
Age: 77Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 17/10/1996 **Stopped:** 21/10/1996

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 113519 **Seq:** 1
Reported: 28/11/1996
Hospitalisation: Admitted to hospital
Onset Date: 13/11/1996
Outcome: Recovered

Gender: F
Weight:
Age: 64Y
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia Coordination abnormal Speech disorder Tremor			

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

Capsule 40.0 Milligram Daily Oral

Batch: **Started:** 01/09/1996 **Stopped:** 17/11/1996

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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 113597 **Seq:** 1 **Gender:** M
Reported: 02/12/1996 **Weight:** 75.00
Hospitalisation: **Age:** 35Y
Onset Date: 30/09/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence Visual disturbance			Switched medication back to

Medicine Details:

RULIDE (Other drug) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

ZACTIN (Suspected) **Reason:** Depression
Capsule 2.0 Dose Unspecified Daily Oral
Batch: **Started:** 30/09/1996 **Stopped:** 07/10/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient noticed haloes around objects after swapping from prozac to zactin. generic substitution problem

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 113642 **Seq:** 1 **Gender:** M
Reported: 03/12/1996 **Weight:** 76.00
Hospitalisation: **Age:** 38Y
Onset Date: 29/11/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			
Headache			
Nausea			
Rash			Antihistamies

Medicine Details:

ZACTIN (Suspected) **Reason:**
Tablet 4.0 Dose Unspecified Total Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had taken prozac for years changed to zactin and within 4 hours developed reactions. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 113778 **Seq:** 1 **Gender:** F
Reported: 09/12/1996 **Weight:** 52.00
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See seq 1 for other drugs. patient did not respond to an increase of 60 mg of prozac daily.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 113820 **Seq:** 1 **Gender:** M
Reported: 11/12/1996 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 04/12/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state		Acute confusional state	Needed serenace to settle

Medicine Details:

PROZAC (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 06/09/1996 **Stopped:** 02/12/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 113822 **Seq:** 1 **Gender:** F
Reported: 11/12/1996 **Weight:** 67.00
Hospitalisation: **Age:** 36Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hair texture abnormal		Dry, frizzy hair.	

Medicine Details:

PROZAC (Suspected) **Reason:**
60.0 Milligram Daily
Batch: **Started:** 01/06/1996 **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.

Report Detail

Case Number: 113827 **Seq:** 1
Reported: 11/12/1996
Hospitalisation:
Onset Date: 05/12/1996
Outcome: Not yet recovered

Gender: M
Weight: 92.00
Age: 71Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Petechial rash-sharp demarcation at	

Medicine Details:

PARACETAMOL (Other drug) **Reason:** Pain
0.0 As necessary
Batch: **Started:** 23/11/1996 **Stopped:** 06/12/1996

OXAZEPAM (Other drug) **Reason:** Depend otr hypnot&sedat,tranql
15.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

THIAMINE (Other drug) **Reason:** Otr&unspec nutritional deficn
100.0 Milligram Daily
Batch: **Started:** 17/11/1996 **Stopped:** CONTIN

SINEMET (Other drug) **Reason:** Paralysis agitans
150.0 Milligram Daily
Batch: **Started:** 03/12/1996 **Stopped:** 06/12/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has abnormal lft's.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 113827 **Seq:** 1
Reported: 11/12/1996
Hospitalisation:
Onset Date: 05/12/1996
Outcome: Not yet recovered

Gender: M
Weight: 92.00
Age: 71Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

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

Oral application 10.0 Milligram Alternate days Oral

Batch: **Started:** 28/11/1996 **Stopped:** 06/12/1996

Laboratory Investigations:

Additional Information:

Patient has abnormal lft's.

Report Detail

Case Number: 113996 **Seq:** 1 **Gender:** F
Reported: 18/12/1996 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 26/11/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Infantile apnoeic attack			Intubated and bagged (positive pressure) - remained no spontaneous respiration 200 mcg narcan imi given with no effect. required oxygen for 5 days

Medicine Details:

PETHIDINE HYDROCHLORIDE (Suspected)			**Reason:**	
Injection	100.0	Milligram	1 time	Intramuscular
Batch:	**Started:**		**Stopped:**	
FENTANYL CITRATE (Suspected)			**Reason:**	
Injection	100.0	Microgram	1 time	Epidural
Batch:	**Started:**		**Stopped:**	
XYLOCAINE (Suspected)			**Reason:**	
	10.0	Millilitre	1 time	
Batch:	**Started:**		**Stopped:**	
BUPIVACAINE HYDROCHLORIDE (Suspected)			**Reason:**	
Injection	10.0	Millilitre	1 time	Epidural
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother treated for severe depression prior to and during pregnancy. usually takes prozac 20 x 2 tabs at 1600 and nortryptylline at 2100. on 26/11/96 mother took both prozac and nortriptylline at 1600, pethidine im at 1735, epidural fentanyl 100 mcg and 1% xylocaine 10mls at 1930. epidural top-up 10mls 0.25% bupivicaine at 2000. baby boy delivered 2030. failed to breathe spontaneously for 20 minutes post birth and did not cry. 200 mcg narcan imi given with no effect. required oxygen for 5 days

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 113996 **Seq:** 1 **Gender:** F
Reported: 18/12/1996 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 26/11/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

PROZAC (Suspected)			**Reason:**	
	40.0	Milligram	Daily	
Batch:	**Started:**		L TERM	**Stopped:**
NORTRIPTYLINE HYDROCHLORIDE (Suspected)			**Reason:**	
	25.0	Milligram	Daily	
Batch:	**Started:**		L TERM	**Stopped:**

Laboratory Investigations:

Additional Information:

Mother treated for severe depression prior to and during pregnancy. usually takes prozac 20 x 2 tabs at 1600 and nortryptylline at 2100. on 26/11/96 mother took both prozac and nortriptylline at 1600, pethidine im at 1735, epidural fentanyl 100 mcg and 1% xylocaine 10mls at 1930. epidural top-up 10mls 0.25% bupivicaine at 2000. baby boy delivered 2030. failed to breathe spontaneously for 20 minutes post birth and did not cry. 200 mcg narcan imi given with no effect. required oxygen for 5 days

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 114039 **Seq:** 1 **Gender:** F
Reported: 19/12/1996 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety		Hyped up during day	
Insomnia		Sleep pattern changed-tossing and turning	
Anorexia			Zactin ceased and replaced

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred when prozac was replaced with zactin on 15/11/96 (patient had been on prozac for 18 months). patient is lactose sensitive and zactin contains lactose. generic substitution problem

Report Detail

Case Number: 114052 **Seq:** 1 **Gender:** M
Reported: 20/12/1996 **Weight:** 86.00
Hospitalisation: **Age:** 52Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic cirrhosis			

Medicine Details:

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

METHOTREXATE (Suspected) **Reason:** Other psoriasis
10.0 Milligram Weekly
Batch: **Started:** 01/06/1994 **Stopped:** 28/11/1996

FELDENE (Suspected) **Reason:**
Capsule 0.0 As necessary Oral
Batch: **Started:** **Stopped:**

MELLERIL (Suspected) **Reason:** Unspecifid affective psychosis
0.0 Daily
Batch: **Started:** 01/01/1978 **Stopped:** 28/11/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Liver biopsy				Liver biopsy 13/11/96: secondary biliary cirrhosis

Additional Information:

Cirrhosis with ductopenia and massive bile ductule proliferation, normal ercp. previous history of chlorpromazine induced jaundice 1962. 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 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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 114052 **Seq:** 1
Reported: 20/12/1996
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 86.00
Age: 52Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)			**Reason:**	Unspecifid affective psychosis	
Oral application	75.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
TEGRETOL (Suspected)			**Reason:**	Unspecifid affective psychosis	
Oral application	300.0	Milligram	Daily		Oral
Batch:	**Started:**	01/10/1996		**Stopped:**	

Laboratory Investigations:

Additional Information:

Cirrhosis with ductopenia and massive bile ductule proliferation, normal ercp. previous history of chlorpromazine induced jaundice 1962. 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 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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 114091 **Seq:** 1 **Gender:** M
Reported: 23/12/1996 **Weight:** 65.00
Hospitalisation: **Age:** 25Y
Onset Date: 12/12/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Herpes simplex	Severe	Severe facial hsv i outbreak	

Medicine Details:

LOVAN (Suspected) **Reason:** Obsessive compulsive neurosis
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 06/11/1996 **Stopped:** 18/12/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 114124 **Seq:** 1 **Gender:** M
Reported: 23/12/1996 **Weight:** 63.00
Hospitalisation: **Age:** 73Y
Onset Date: 23/10/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination		Hallucination (visual)	
Aggression			
Confusional state			Cease madopar plus small dose serenace "prn"; 7/11/96: "brighter and talking more" since parkinson drugs ceased.
Dementia			
Psychotic disorder			

Medicine Details:

ZYLOPRIM (Other drug) **Reason:** Gout
100.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

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

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

MADOPAR (Suspected) **Reason:** Paralysis agitans
3.0 Dose Unspecified Daily
Batch: **Started:** L TERM **Stopped:** 31/10/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 114124 **Seq:** 1 **Gender:** M
Reported: 23/12/1996 **Weight:** 63.00
Hospitalisation: **Age:** 73Y
Onset Date: 23/10/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

COGENTIN (Suspected)			**Reason:**		
	1.0	Milligram		Daily	
Batch:	**Started:**		L TERM	**Stopped:**	04/11/1996
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
	20.0	Milligram		Daily	
Batch:	**Started:**		L TERM	**Stopped:**	12/11/1996

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 114184 **Seq:** 1 **Gender:** M
Reported: 24/12/1996 **Weight:** 88.00
Hospitalisation: **Age:** 69Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Speech disorder Libido decreased		Delayed and slow speech	

Medicine Details:

ASPIRIN (Other drug) **Reason:**
Oral application 150.0 Milligram Daily Oral
Batch: **Started:** 01/01/1995 **Stopped:**

ADALAT (Other drug) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 20/07/1996 **Stopped:**

HALOPERIDOL (Other drug) **Reason:** Hallucinations
2.5 Milligram Daily
Batch: **Started:** 12/08/1996 **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 15/10/1996 **Stopped:** 28/10/1996

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.

Report Detail

Case Number: 114254 **Seq:** 1 **Gender:** F
Reported: 03/01/1997 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: 15/11/1995 **DOB:** 19/05/1964
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic			Augmentin ceased, no other treatment required; symptoms resolved and patient discharged 29/11/95

Medicine Details:

INSULIN NEUTRAL (Other drug) **Reason:** Diabetes mellitus
0.0
Batch: **Started:** L TERM **Stopped:**

PROTAPHANE (Other drug) **Reason:** Diabetes mellitus
0.0
Batch: **Started:** L TERM **Stopped:**

FRUSEMIDE (Other drug) **Reason:** Other renal disease
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

AMLODIPINE (Other drug) **Reason:** Other renal disease
10.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 114254 **Seq:** 1
Reported: 03/01/1997
Hospitalisation:
Onset Date: 15/11/1995
Outcome: Not yet recovered

Gender: F
Weight:
Age: 31
DOB: 19/05/1964
Causality: Causality possible

Reaction Detail

Medicine Details:

METOLAZONE (Other drug)			**Reason:**	Other renal disease
	2.5	Milligram	Daily	
Batch:	**Started:**	L TERM	**Stopped:**	
AUGMENTIN FORTE (Suspected)			**Reason:**	Otr&nos infec&parasit diseases
	3.0	Dose Unspecified	Daily	
Batch:	**Started:**	06/11/1995	**Stopped:**	
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression
	25.0	Milligram	Daily	
Batch:	**Started:**	06/11/1995	**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 114360 **Seq:** 1 **Gender:** M
Reported: 08/01/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Facial twitching, then spread to rest of his	Lovan ceased and patient returned to taking prozac

Medicine Details:

MIXTARD 30/70 (Other drug) **Reason:** Diabetes mellitus
Injection 0.0 Intravenous
Batch: **Started:** **Stopped:** CONTIN

LOVAN (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** 6D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient took lovan (in place of prozac) for 6 days. after ceasing lovan the reaction stopped after approximately 4 weeks. patient had no problems with prozac and is returning to prozac. generic substitution problem - the date of onset is not accurate but indicates that onset occurred sometime during the year.

Report Detail

Case Number: 114526 **Seq:** 1 **Gender:** M
Reported: 13/01/1997 **Weight:**
Hospitalisation: **Age:** 44Y
Onset Date: 04/01/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash erythematous		Red rash	Periactin

Medicine Details:

ZACTIN (Suspected) **Reason:**
Capsule 20.0 Milligram 1 time Oral
Batch: **Started:** 04/01/1997 **Stopped:** 04/01/1997

TENORMIN (Suspected) **Reason:** Essential benign hypertension
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 26/12/1996 **Stopped:** 04/01/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of allergy to penicillin.

Report Detail

Case Number: 114542 **Seq:** 1 **Gender:** F
Reported: 15/01/1997 **Weight:** 50.00
Hospitalisation: **Age:** 80Y
Onset Date: 25/10/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Disturbance in attention Muscle twitching			

Medicine Details:

QUINATE (Other drug) **Reason:** Pain in limb
1.0 Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

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

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

PROZAC (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 12D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 114593 **Seq:** 1 **Gender:** M
Reported: 17/01/1997 **Weight:**
Hospitalisation: **Age:** 72Y
Onset Date: 06/01/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention	Severe		

Medicine Details:

ZACTIN (Suspected) **Reason:** Lumbalgia

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 07/01/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 114624 **Seq:** 1 **Gender:** M
Reported: 20/01/1997 **Weight:** 80.00
Hospitalisation: **Age:** 31Y
Onset Date: 31/12/1996 **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rectal haemorrhage			

Medicine Details:

PROZAC (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Histology				Biopsy: non specific colitis

Additional Information:

When prozac stopped, reaction ceased and recurred when restarted. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 114779 **Seq:** 1 **Gender:** F
Reported: 28/01/1997 **Weight:** 66.00
Hospitalisation: **Age:** 26Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Anorexia Hepatitis cholestatic Nausea Weight decreased		Rt hypochondium discomfort.	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/06/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	(0-40)	10/09/1996	29	
	ALT = SGPT	(0-40)	08/10/1996	44	
	ALT = SGPT	(0-40)	20/11/1996	37	
	ALT = SGPT	(0-40)	18/12/1996	19	
	ALT = SGPT	(0-40)	08/12/1996	18	
	AST = SGOT	(0-40)	10/09/1996	24	
	AST = SGOT	(0-40)	08/10/1996	33	

Additional Information:

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

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 114779 **Seq:** 1
Reported: 28/01/1997
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 66.00
Age: 26Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/06/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	(0-40)	08/12/1996	24	
	AST = SGOT	(0-40)	20/11/1996	35	
	AST = SGOT	(0-40)	18/12/1996	31	
	GGT = SGGT =	(0-45)	10/09/1996	63	
	GGT = SGGT =	(0-45)	08/10/1996	142	
	GGT = SGGT =	(0-45)	20/11/1996	265	
	GGT = SGGT =	(0-45)	18/12/1996	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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 114779 **Seq:** 1
Reported: 28/01/1997
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 66.00
Age: 26Y
DOB:
Causality: Causality possible

Reaction Detai

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/06/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =	(0-45)	08/12/1996	221	
	SAP = ALP	(0-115)	10/09/1996	114	
	SAP = ALP	(0-115)	08/10/1996	146	
	SAP = ALP	(0-115)	20/11/1996	231	
	SAP = ALP	(0-115)	08/12/1996	266	
	SAP = ALP	(0-115)	18/12/1996	246	

Additional Information:

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

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 114877 **Seq:** 1 **Gender:** M
Reported: 31/01/1997 **Weight:** 69.00
Hospitalisation: **Age:** 28Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Felt homicidal	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 114898 **Seq:** 1 **Gender:** F
Reported: 03/02/1997 **Weight:**
Hospitalisation: **Age:** 33Y
Onset Date: 05/11/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormon			

Medicine Details:

TEGRETOL (Suspected) **Reason:** Other&unspecified epilepsy
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 30/10/1996 **Stopped:** 06/11/1996

EPILIM (Suspected) **Reason:** Other&unspecified epilepsy
Tablet 1.2 Gram Daily Oral
Batch: **Started:** **Stopped:**

RIVOTRIL (Suspected) **Reason:** Other&unspecified epilepsy
Oral application 4.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium		05/11/1996	3.5	
	Serum osmolality		05/11/1996	258	
	Sodium		05/11/1996	123	

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 114898 **Seq:** 1
Reported: 03/02/1997
Hospitalisation:
Onset Date: 05/11/1996
Outcome: Not yet recovered

Gender: F
Weight:
Age: 33Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

EVENING PRIMROSE OIL (Suspected)			**Reason:**		
Capsule	2.0	Gram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
AMIZIDE (Suspected)			**Reason:**	Painful menstruation	
Tablet	1.0	Dose Unspecified	Daily	Oral	
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 114910 **Seq:** 1 **Gender:** F
Reported: 03/02/1997 **Weight:** 56.00
Hospitalisation: **Age:** 20Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mydriasis			

Medicine Details:

BENZTROPINE MESYLATE (Interaction) **Reason:**
2.0 Dose Unspecified Total
Batch: **Started:** **Stopped:**

PROZAC (Interaction) **Reason:** Anxiety neurosis
Oral application 60.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

SEREPAX (Interaction) **Reason:** Anxiety neurosis
30.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 114928 **Seq:** 1 **Gender:** M
Reported: 03/02/1997 **Weight:**
Hospitalisation: **Age:** 51Y
Onset Date: 13/01/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Feeling of cold anger and violent toward	

Medicine Details:

NORVASC (Other drug) **Reason:** Essential benign hypertension
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 01/01/1988 **Stopped:**

CAPOTEN (Other drug) **Reason:** Essential benign hypertension
50.0 Milligram Daily
Batch: **Started:** 01/01/1988 **Stopped:**

ZYLOPRIM (Other drug) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 01/01/1994 **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 18/11/1996 **Stopped:** 13/01/1997

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. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 114931 **Seq:** 1
Reported: 03/02/1997
Hospitalisation: Admitted to hospital
Onset Date: 16/01/1997
Outcome: Recovered

Gender: M
Weight:
Age: 22Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypotonia Fatigue Somnolence		Floppy	

Medicine Details:

LOVAN (Suspected) **Reason:**
Capsule 0.0 Oral
Batch: **Started:** 16/01/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was switched to lovan from prozac and became lethargic, floppy and suffered from somnolence. within 2 - 3 days the patient recovered and returned to prozac therapy. the doctor believes the patient may have had an allergic reaction to a colourant in the capsule shell. generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 114978 **Seq:** 1
Reported: 05/02/1997
Hospitalisation: Treated in outpatient department only.
Onset Date: 31/12/1996
Outcome: Recovered

Gender: M
Weight:
Age: 61Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bronchospasm			

Medicine Details:

ZANTAC (Other drug) **Reason:**
300.0 Dose Unspecified Daily
Batch: **Started:** L TERM **Stopped:**

LASIX (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

SLOW-K (Other drug) **Reason:**
600.0 Milligram Daily
Batch: **Started:** **Stopped:**

PREDNISOLONE (Other drug) **Reason:**
1.0 Milligram Daily
Batch: **Started:** L TERM **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.

Report Detail

Case Number: 114978 **Seq:** 1
Reported: 05/02/1997
Hospitalisation: Treated in outpatient department only.
Onset Date: 31/12/1996
Outcome: Recovered

Gender: M
Weight:
Age: 61Y
DOB:
Causality: Causality probable

Reaction Detail

Medicine Details:

THEO-DUR (Other drug)			**Reason:**	
	300.0 Milligram		Daily	
Batch:	**Started:**	L TERM		**Stopped:**
ZOVIRAX (Other drug)			**Reason:**	
	600.0 Milligram		Daily	
Batch:	**Started:**			**Stopped:**
ANDRIOL (Other drug)			**Reason:**	
	80.0 Milligram		Daily	
Batch:	**Started:**			**Stopped:**
PROZAC (Suspected)			**Reason:**	Depression
	20.0 Milligram		Daily	
Batch:	**Started:**	L TERM		**Stopped:**

Laboratory Investigations:

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115067 **Seq:** 1 **Gender:** F
Reported: 07/02/1997 **Weight:** 70.00
Hospitalisation: **Age:** 41Y
Onset Date: 14/12/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			
Headache			
Hepatocellular damage			
Lymphopenia	Required Specialist Consultation		
Nausea			
Vomiting			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 26/11/1996 **Stopped:** 28/12/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	0 - 50 U/L	24/12/1996	694	
	ALT = SGPT	0 - 50 U/L	04/02/1997	20	
	Bilirubin	0 - 20 UMOL/L	24/12/1996	29	
	Bilirubin	0 - 20 UMOL/L	04/02/1997	8	
	GGT = SGGT =	0 - 50 U/L	24/12/1996	1013	
	GGT = SGGT =	0 - 50 U/L	04/02/1997	77	

Additional Information:

Report Detail

Case Number: 115067 **Seq:** 1 **Gender:** F
Reported: 07/02/1997 **Weight:** 70.00
Hospitalisation: **Age:** 41Y
Onset Date: 14/12/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 26/11/1996 **Stopped:** 28/12/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Hepatitis A antibody				Hepatitis serology - hepatitis b surface antigen: not detected (by imx eia). antibody (igm) to hepatitis a antigen : not detected (by imx eia). hepatitis c antibody: not detected (by sanofi eia).
	Lymphocytes	1.0 - 4.0	24/12/1996	0.7	
	SAP = ALP	30 - 120 U/L	24/12/1996	281	
	SAP = ALP	30 - 120 U/L	04/02/1997	62	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115115 **Seq:** 1 **Gender:** M
Reported: 10/02/1997 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: **DOB:** 13/03/1948
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression

0.0

Batch: **Started:** 04/12/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient being treated successfully with prozac. when zactin prescribed, sudden deterioration of mental state with old symptoms of hpyersomnia, sweating and shaking, erratic appetite and marked irritability. patient advised to return to prozac immediately! generic substitution problem

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115450 **Seq:** 1
Reported: 21/02/1997
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 45.00
Age: 25Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Crying Serotonin syndrome			

Medicine Details:

PROZAC (Interaction) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 13/03/1996 **Stopped:** 15/04/1996

AURORIX (Interaction) **Reason:** Depression
900.0 Milligram Daily
Batch: **Started:** 15/04/1996 **Stopped:**

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

AMOXIL (Other drug) **Reason:** Othr diseases of urinary tract
1.5 Gram Daily
Batch: **Started:** 12/04/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115450 **Seq:** 1
Reported: 21/02/1997
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 45.00
Age: 25Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

ZANTAC (Other drug) **Reason:** Gastritis&duodenitis
300.0 Milligram Daily
Batch: **Started:** 02/04/1996 **Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 115534 **Seq:** 1 **Gender:** F
Reported: 24/02/1997 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: 20/05/1996 **DOB:** 31/10/1942
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus Rash			

Medicine Details:

LOVAN (Suspected) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 17/05/1996 **Stopped:** 20/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115535 **Seq:** 1 **Gender:** M
Reported: 24/02/1997 **Weight:** 82.00
Hospitalisation: **Age:** 39
Onset Date: 15/01/1995 **DOB:** 14/03/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety			
Chest pain			
Dizziness			
Dyspnoea			
Flushing			
Palpitations			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Capsule 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 07/01/1995 **Stopped:** 16/01/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115536 **Seq:** 1 **Gender:** F
Reported: 24/02/1997 **Weight:** 60.00
Hospitalisation: **Age:** 55
Onset Date: **DOB:** 21/10/1941
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus Rash maculo-papular			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Capsule 20.0 Milligram Daily Oral

Batch: **Started:** 16/04/1996 **Stopped:** 14/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115537 **Seq:** 1 **Gender:** M
Reported: 24/02/1997 **Weight:** 83.00
Hospitalisation: **Age:** 36
Onset Date: 17/06/1996 **DOB:** 16/02/1960
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia			

Medicine Details:

MURELAX (Other drug) **Reason:** Anxiety neurosis
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 26/05/1996 **Stopped:** 2D

PROZAC (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 16/06/1996 **Stopped:** 19/08/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient discontinued prozac and when restarted the reaction reappeared.

Report Detail

Case Number: 115538 **Seq:** 1 **Gender:** F
Reported: 24/02/1997 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: **DOB:** 18/03/1947
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

BETALOC (Other drug) **Reason:** Otr&nos disord of heart rhythm
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/01/1994 **Stopped:**

TRISEQUENS (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** 01/02/1995 **Stopped:**

LOVAN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 28/08/1996 **Stopped:** 11/11/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Generic substitution problem 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115539 **Seq:** 1 **Gender:** F
Reported: 24/02/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agitation Urinary retention			

Medicine Details:

DESIPRAMINE HYDROCHLORIDE (Other drug) **Reason:**

Tablet 75.0 Milligram Daily Oral

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

PROZAC (Suspected) **Reason:** Depression

Capsule 40.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115540 **Seq:** 1 **Gender:** M
Reported: 24/02/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Nausea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced reaction with prozac and discontinued, recommenced treatment and same event occurred. patient has dystrophia myotonica.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115553 **Seq:** 1 **Gender:** F
Reported: 24/02/1997 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus			

Medicine Details:

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

PROZAC (Suspected) **Reason:** Depression
Capsule 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115554 **Seq:** 1 **Gender:** F
Reported: 24/02/1997 **Weight:** 51.00
Hospitalisation: **Age:** 40
Onset Date: **DOB:** 04/02/1957
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight decreased Abdominal pain Anorexia		Weight loss of 8 kg.	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Capsule 80.0 Milligram Daily Oral
Batch: **Started:** 01/08/1996 **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.

Report Detail

Case Number: 115555 **Seq:** 1 **Gender:** F
Reported: 24/02/1997 **Weight:** 54.00
Hospitalisation: **Age:** 34
Onset Date: 31/01/1997 **DOB:** 13/02/1962
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Hyperprolactinaemia			

Medicine Details:

VENTOLIN (Other drug) **Reason:** Asthma
2.0 Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

DOXYCYCLINE HYDROCHLORIDE (Other drug) **Reason:** Other acne of sebaceous glands
50.0 Milligram Daily
Batch: **Started:** 01/10/1996 **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 16/02/1996 **Stopped:** 06/01/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin				Prolactin 50 (normal 28)

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: 115619 **Seq:** 1 **Gender:** F
Reported: 28/02/1997 **Weight:** 55.00
Hospitalisation: **Age:** 62Y
Onset Date: 20/01/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Headache Hypertension			

Medicine Details:

PROVERA (Other drug) **Reason:** Menopausal symptoms
Tablet 0.0 Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

PREMARIN (Other drug) **Reason:** Menopausal symptoms
Tablet 0.0 Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 20/01/1997 **Stopped:** 10/02/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of allergy to morphine - vomiting.

Report Detail

Case Number: 115635 **Seq:** 1 **Gender:** F
Reported: 28/02/1997 **Weight:** 48.00
Hospitalisation: **Age:** 52Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			
Fatigue			
Hepatic function abnormal			
Hyponatraemia			
Muscle twitching			
Red blood cell sedimentation rate			

Medicine Details:

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

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

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

THEO-DUR (Other drug) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells				Wcc increased to 20,000.

Additional Information:

Report Detail

Case Number: 115635 **Seq:** 1
Reported: 28/02/1997
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 48.00
Age: 52Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

ZANTAC (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**	L TERM	**Stopped:**	
PRIMOLUT-N (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**	L TERM	**Stopped:**	
PROZAC (Suspected)			**Reason:**	Depression
	20.0 Milligram	Daily		
Batch:	**Started:**	10/01/1997	**Stopped:**	19/02/1997

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115813 **Seq:** 1 **Gender:** F
Reported: 06/03/1997 **Weight:**
Hospitalisation: **Age:** 72Y
Onset Date: 11/02/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain Dermatitis bullous		Pain in mouth	 Prednisolone

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
60.0 Milligram Daily
Batch: **Started:** 03/01/1997 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115838 **Seq:** 1
Reported: 12/03/1997
Hospitalisation:
Onset Date: 03/03/1997
Outcome: Not yet recovered

Gender: M
Weight: 67.00
Age: 20Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema Arthralgia Urticaria			Steroids, antihistamine

Medicine Details:

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

0.0

Batch: **Started:** 03/02/1997 **Stopped:** 04/03/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115859 **Seq:** 1 **Gender:** F
Reported: 12/03/1997 **Weight:** 65.00
Hospitalisation: **Age:** A2
Onset Date: 21/02/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Throat tightness Arthralgia Dysphagia Rash	Severe	Swelling of the throat	

Medicine Details:

DEPO-PROVERA (Other drug) **Reason:** Contraception
Injection 150.0 Milligram Daily Intramuscular
Batch: **Started:** 04/10/1996 **Stopped:**

ZACTIN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 18/02/1997 **Stopped:** 24/02/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had prviously taken prozac with no adverse reaction.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115878 **Seq:** 1
Reported: 12/03/1997
Hospitalisation:
Onset Date: 21/02/1997
Outcome: Not yet recovered

Gender: M
Weight: 75.00
Age: 51Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urine analysis abnormal Hepatitis Malaise		Dark urine	

Medicine Details:

AUGMENTIN (Suspected) **Reason:** Mult opn wnds of otr&unsp loca

Tablet 750.0 Milligram Daily Oral

Batch: **Started:** 14/02/1997 **Stopped:** 20/02/1997

PROZAC (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 01/09/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		21/02/1997	1084	

Additional Information:

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

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115995 **Seq:** 1 **Gender:** U
Reported: 12/03/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Cystitis			

Medicine Details:

PROZAC (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 115996 **Seq:** 1 **Gender:** U
Reported: 12/03/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Cystitis			

Medicine Details:

PROZAC (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116005 **Seq:** 1 **Gender:** F
Reported: 12/03/1997 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 31/12/1997 **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Visual disturbance			

Medicine Details:

PROZAC (Suspected) **Reason:**
20.0 Milligram 1 time
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was taking 20mg prozac a couple of years ago and experienced tingling in her fingers on withdrawal and blurred vision whilst on the drug. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116006 **Seq:** 1 **Gender:** M
Reported: 12/03/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			

Medicine Details:

PROZAC (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116007 **Seq:** 1 **Gender:** M
Reported: 12/03/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** 01/01/1995 **Stopped:** 31/01/1997

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. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116008 **Seq:** 1 **Gender:** F
Reported: 12/03/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delusion Hallucination Hyperhidrosis Nausea Tachycardia			

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/09/1996 **Stopped:** 28/09/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was also suffering from hyperthyroidism and idiopathic oedema. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116009 **Seq:** 1 **Gender:** F
Reported: 12/03/1997 **Weight:** 43.00
Hospitalisation: **Age:** 52Y
Onset Date: 17/02/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Hyponatraemia Weight decreased			

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 80.0 Milligram Daily Oral
Batch: **Started:** 01/01/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Laboratory tests were done which showed some abnormalities. the doctor believes that these are caused by prozac and there is no underlying aetiology. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116062 **Seq:** 1 **Gender:** F
Reported: 18/03/1997 **Weight:** 82.00
Hospitalisation: **Age:** 29Y
Onset Date: 31/12/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Disturbance in attention			

Medicine Details:

PROZAC (Suspected) **Reason:**

Tablet 40.0 Milligram Daily Oral

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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116063 **Seq:** 1 **Gender:** F
Reported: 18/03/1997 **Weight:** 70.00
Hospitalisation: **Age:** 52Y
Onset Date: 31/12/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Anxiety Insomnia Speech disorder	Severe		

Medicine Details:

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

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 06/11/1996

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.

Report Detail

Case Number: 116193 **Seq:** 1 **Gender:** M
Reported: 20/03/1997 **Weight:** 88.00
Hospitalisation: **Age:** 41Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sensory disturbance		Decreased sensitivity of penis.	

Medicine Details:

PRAVACHOL (Other drug) **Reason:** Othr&unspec metabolic diseases
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 01/07/1996 **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/12/1995 **Stopped:** 28/02/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Decreased sensitivity of penis while on prozac, recovered when stopped it. 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.

Report Detail

Case Number: 116195 **Seq:** 1
Reported: 20/03/1997
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 65.00
Age: 81
DOB: 29/09/1915
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Hyponatraemia			 Fluid restriction

Medicine Details:

RENITEC (Other drug) **Reason:** Essential benign hypertension
20.0 Milligram Daily
Batch: **Started:** 01/01/1987 **Stopped:** 31/01/1997

PROZAC (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 25/01/1997 **Stopped:** 14/02/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		12/02/1997	107MMOL/L	Serum sodium level

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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116242 **Seq:** 1 **Gender:** F
Reported: 21/03/1997 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea Iron deficiency			

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

0.0

Batch: **Started:** 01/01/1993 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has been on prozac and now lovan for almost 4 years. The dosage start date is not accurate but indicates that start occurred sometime during the year.

Report Detail

Case Number: 116368 **Seq:** 1 **Gender:** F
Reported: 01/04/1997 **Weight:** 85.00
Hospitalisation: **Age:** 69Y
Onset Date: 30/01/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence			

Medicine Details:

COLOXYL WITH SENNA (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

WARFARIN SODIUM (Other drug) **Reason:**
3.0 Milligram Daily
Batch: **Started:** 18/12/1996 **Stopped:**

AMLODIPINE (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** 18/12/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 116368 **Seq:** 1 **Gender:** F
Reported: 01/04/1997 **Weight:** 85.00
Hospitalisation: **Age:** 69Y
Onset Date: 30/01/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

PANADOL (Other drug)			**Reason:**	
	4.0 Gram	Daily		
Batch:	**Started:** 18/12/1996		**Stopped:**	
AMIODARONE HYDROCHLORIDE (Suspected)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
PROZAC (Suspected)			**Reason:**	Depression
	60.0 Milligram	Daily		
Batch:	**Started:** 18/12/1996		**Stopped:**	05/02/1997

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116496 **Seq:** 1 **Gender:** F
Reported: 07/04/1997 **Weight:** 75.00
Hospitalisation: **Age:** 46Y
Onset Date: 03/03/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Severe		

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 28/02/1997 **Stopped:** 28/03/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 116581 **Seq:** 1 **Gender:** M
Reported: 09/04/1997 **Weight:** 115.00
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bruxism			

Medicine Details:

KAPANOL (Other drug) **Reason:** Pain
40.0 Milligram Daily
Batch: **Started:** 16/01/1997 **Stopped:**

PROZAC (Suspected) **Reason:** Pain
20.0 Milligram Daily
Batch: **Started:** 16/10/1996 **Stopped:** 13/03/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 116625 **Seq:** 1 **Gender:** U
Reported: 09/04/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1997 **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Skin discolouration			

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 0.0 Oral
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.

Report Detail

Case Number: 116627 **Seq:** 1 **Gender:** F
Reported: 09/04/1997 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea			Therapy changed to sertraline.

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116630 **Seq:** 1 **Gender:** F
Reported: 09/04/1997 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neuropathy peripheral			

Medicine Details:

PROZAC (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 116631 **Seq:** 1 **Gender:** U
Reported: 09/04/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/03/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			

Medicine Details:

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

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116632 **Seq:** 1 **Gender:** U
Reported: 09/04/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania			

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116633 **Seq:** 1 **Gender:** M
Reported: 09/04/1997 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

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

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 116686 **Seq:** 1
Reported: 14/04/1997
Hospitalisation:
Onset Date: 15/02/1997
Outcome: Not yet recovered

Gender: M
Weight: 75.00
Age: 51Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Diarrhoea Insomnia			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

20.0 Milligram Daily

Batch: **Started:** 12/02/1997 **Stopped:** 25/03/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116936 **Seq:** 1 **Gender:** M
Reported: 21/04/1997 **Weight:** 62.00
Hospitalisation: **Age:** 22Y
Onset Date: 14/04/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/04/1997 **Stopped:** 15/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116951 **Seq:** 1 **Gender:** F
Reported: 21/04/1997 **Weight:** 64.00
Hospitalisation: **Age:** 64Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Drug ineffective			Changed to zoloft.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 16/03/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 116963 **Seq:** 1 **Gender:** M
Reported: 22/04/1997 **Weight:**
Hospitalisation: **Age:** 68Y
Onset Date: 12/04/1997 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Pulmonary embolism Sudden death		Off balance and staggering	

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/01/1997 **Stopped:**

TRYPTANOL (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** 05/04/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died of pulmonary embolus. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 117035 **Seq:** 1 **Gender:** F
Reported: 24/04/1997 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Libido decreased			

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram Daily
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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 117084 **Seq:** 1 **Gender:** M
Reported: 28/04/1997 **Weight:** 100.00
Hospitalisation: **Age:** 31Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Hepatic function abnormal			

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
80.0 Milligram Daily
Batch: **Started:** 01/06/1995 **Stopped:** 28/01/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient commenced on lovan 20mg daily in mid 1995, and gradualy increased to 80mg daily by may 1996. complained about increasing epigastric discomfort august 1996. lovan dose reduced to 40mg over several months - lovan ceased january 1997. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 117138 **Seq:** 1 **Gender:** F
Reported: 30/04/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 23/04/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Systemic lupus erythematosus ra			

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 117273 **Seq:** 1 **Gender:** M
Reported: 05/05/1997 **Weight:**
Hospitalisation: **Age:** 57Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Dyskinesia Thinking abnormal			

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/10/1991 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 117274 **Seq:** 1 **Gender:** F
Reported: 05/05/1997 **Weight:**
Hospitalisation: **Age:** 48Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Sudden recall of memories	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/11/1991 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 117275 **Seq:** 1 **Gender:** M
Reported: 05/05/1997 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal Nightmare		Vivid and intrusive memories and dreams	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/03/1992 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 117276 **Seq:** 1 **Gender:** M
Reported: 05/05/1997 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Experienced frequent vivid, intrusive	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 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 accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 117291 **Seq:** 1 **Gender:** F
Reported: 06/05/1997 **Weight:** 60.00
Hospitalisation: **Age:** 33Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia Therapeutic response decreased		Tightness of front of neck Worsening of mood.	Changed treatment to erocaps

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 01/04/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pharmacist substitution of zactin (first) and then to erocaps (second) for original prozac seems to have resulted in side effects not evident on prozac. (stabilised for approx. 1 year) generic substitution problem the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 117292 **Seq:** 1 **Gender:** F
Reported: 06/05/1997 **Weight:** 60.00
Hospitalisation: **Age:** 33Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache Nervousness			Erocap ceased, resummed

Medicine Details:

EROCAP (Suspected) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 01/04/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pharmacist substitution of zactin (first) and then erocaps (second) for original prozac seems to have resulted in side effects not evident on prozac. (stabilised for approx. 1 year) the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 117431 **Seq:** 1 **Gender:** M
Reported: 12/05/1997 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: 11/11/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia Bruxism		Oro-lingual diskinesia Teeth clenching.	

Medicine Details:

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

Oral application 20.0 Milligram Daily Oral

Batch: **Started:** 09/11/1996 **Stopped:** 06/05/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 117526 **Seq:** 1 **Gender:** F
Reported: 13/05/1997 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Trisomy 21 Ventricular septal defect			

Medicine Details:

PROZAC (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 9D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Trisomy 21. mother took prozac 20mg daily from 5.5 weeks for 9 days total. baby born on 09/02/1997 at 27 weeks, small vsd, birth weight 1140gm.

Report Detail

Case Number: 117898 **Seq:** 1 **Gender:** F
Reported: 27/05/1997 **Weight:** 23.00
Hospitalisation: **Age:** 8Y
Onset Date: 16/05/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria			

Medicine Details:

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

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 22/03/1997 **Stopped:** 16/05/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 117922 **Seq:** 1 **Gender:** M
Reported: 28/05/1997 **Weight:** 70.00
Hospitalisation: **Age:**
Onset Date: 10/01/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dermatitis bullous Photosensitivity reaction			

Medicine Details:

PHYSEPTONE (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 01/07/1996 **Stopped:**

BRUFEN (Other drug) **Reason:**
800.0 Milligram Daily
Batch: **Started:** 01/07/1996 **Stopped:**

METFORMIN HYDROCHLORIDE (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** 01/07/1996 **Stopped:**

PROZAC (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 08/01/1997 **Stopped:** 01/03/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Skin biopsy				Biopsy of skin- subepidermal bulla characterised by necrosis of the elevated epidermis and good preservation of the dermal papillae in the floor of the blister.

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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 117928 **Seq:** 1 **Gender:** F
Reported: 28/05/1997 **Weight:** 70.00
Hospitalisation: **Age:** 43Y
Onset Date: 14/05/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Withdraw lovan changed to

Medicine Details:

LOVAN (Suspected) **Reason:**
Capsule 80.0 Milligram Daily Oral
Batch: **Started:** 01/09/1995 **Stopped:** 14/05/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient returned to normal after dose of lovan was reduced from 80 mg to 20mg daily. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 118091 **Seq:** 1 **Gender:** U
Reported: 05/06/1997 **Weight:**
Hospitalisation: **Age:** 68
Onset Date: 17/02/1997 **DOB:** 20/09/1928
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating		Excessive cns depression	

Medicine Details:

FENTANYL CITRATE (Interaction) **Reason:** Other disturbance of sensation
0.0
Batch: **Started:** **Stopped:**

MIDAZOLAM (Interaction) **Reason:** Other disturbance of sensation
0.0
Batch: **Started:** **Stopped:**

PROPOFOL (Interaction) **Reason:** Other disturbance of sensation
0.0
Batch: **Started:** **Stopped:**

PETHIDINE HYDROCHLORIDE (Interaction) **Reason:** Other disturbance of sensation
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 118091 **Seq:** 1 **Gender:** U
Reported: 05/06/1997 **Weight:**
Hospitalisation: **Age:** 68
Onset Date: 17/02/1997 **DOB:** 20/09/1928
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

TEMAZEPAM (Interaction)		**Reason:**	Premedication
	20.0 Milligram	1 time	
Batch:	**Started:**		**Stopped:**
FLUOXETINE HYDROCHLORIDE (Interaction)		**Reason:**	
	20.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 118200 **Seq:** 1 **Gender:** F
Reported: 12/06/1997 **Weight:** 56.00
Hospitalisation: **Age:** 37
Onset Date: 31/03/1997 **DOB:** 17/05/1959
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Hyperprolactinaemia			Dose reduced as effects were dose related.

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Capsule 40.0 Milligram Daily Oral
Batch: **Started:** 01/09/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	(50 - 500 MIU/L)	07/03/1997	968 MIU/L	

Additional Information:

Commenced at 20mg daily 6 months before onset of reaction. dose increased to 40mg at a later date. - 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 118327 **Seq:** 1 **Gender:** F
Reported: 16/06/1997 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			

Medicine Details:

PROZAC (Suspected) **Reason:**
60.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient is an elderly diabetic.

Report Detail

Case Number: 118433 **Seq:** 1 **Gender:** F
Reported: 20/06/1997 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 01/06/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vascular malformation peripheral Bradycardia		Born with vascular malformation of legs Low heart rate for 2 days.	Oxygen

Medicine Details:

PROZAC (Suspected)			**Reason:**	Unspecified schizophrenia
Oral application	20.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
ARTANE (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	15.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
HALOPERIDOL (Suspected)			**Reason:**	
Oral application	2.5	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Baby boy 3.2kg born with extensive truncal --> legs vascular malformation also had low heart rate for 2 days with little variability. no ekg was obtained. hr then increased on days 3-4 and was normal at discharge. also needed 12 hour oxygen supplement. all medications were taken throughout pregnancy and on morning of delivery.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 118469 **Seq:** 1 **Gender:** M
Reported: 23/06/1997 **Weight:** 65.00
Hospitalisation: **Age:** 66Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			

Medicine Details:

ZACTIN (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 118511 **Seq:** 1 **Gender:** M
Reported: 24/06/1997 **Weight:**
Hospitalisation: **Age:** A9
Onset Date: 22/05/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			Therapy changed back to

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 17/05/1997 **Stopped:** 22/05/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been taking prozac for depression for some time. after starting zactin, depression returned and so changed therapy back to prozac. generic substitution problem

Report Detail

Case Number: 118819 **Seq:** 1
Reported: 03/07/1997
Hospitalisation: Admitted to hospital
Onset Date: 09/05/1997
Outcome: Recovered

Gender: M
Weight:
Age: 30
DOB: 30/05/1966
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Back pain Fatigue Nephritis interstitial			

Medicine Details:

MYSTECLIN (Suspected) **Reason:** Chronic sinusitis
250.0 Milligram As necessary
Batch: **Started:** 01/01/1994 **Stopped:** 09/05/1997

INDOCID (Suspected) **Reason:** Pain
Suppository 100.0 Milligram Daily Rectal
Batch: **Started:** **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 02/05/1997 **Stopped:** 12/05/1997

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.

Report Detail

Case Number: 119168 **Seq:** 1 **Gender:** M
Reported: 17/07/1997 **Weight:** 85.00
Hospitalisation: **Age:** 45Y
Onset Date: 31/12/1995 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

KOMBUCHA TEA (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** 01/01/1995 **Stopped:** 31/01/1995

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1994 **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. the dosage stop date is not accurate but indicates that stoppage 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 119500 **Seq:** 1 **Gender:** F
Reported: 28/07/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 05/07/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration		Painful bleeding mouth ulcers.	

Medicine Details:

LOVAN (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction onset after taking lovan for about two weeks

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 119740 **Seq:** 1 **Gender:** M
Reported: 07/08/1997 **Weight:** 60.00
Hospitalisation: **Age:** 36Y
Onset Date: 03/07/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura Haematoma Bleeding time prolonged		Extensive bruising Large ++soft fluctuant haematoma	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:** 04/07/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bleeding time Bleeding time				Bleeding time >10 mins. all other coag studies normal 04/08/1997 bleeding time = normal 4.5 mins

Additional Information:

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

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 119866 **Seq:** 1 **Gender:** M
Reported: 14/08/1997 **Weight:** 80.00
Hospitalisation: **Age:** 17Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia Hyperprolactinaemia		Bilateral gynaecomastia	Prozac ceased

Medicine Details:

PROZAC (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 22/04/1994 **Stopped:** 23/06/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	45 - 375	18/06/1997	670 MIU/L	Serum prolactin

Additional Information:

Gynaecomastia gradually reduced after prozac stopped

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 119927 **Seq:** 1 **Gender:** F
Reported: 15/08/1997 **Weight:** 52.00
Hospitalisation: **Age:** 35Y
Onset Date: 01/05/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Became very sleeply.	
Drug ineffective		Depression became very severe.	Changed back to prozac from

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/04/1997 **Stopped:** 01/05/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient taking lovan for 1 month following sucessful treatment with prozac for 12 months, is back on prozac and is fine now. generic substitution problem

Report Detail

Case Number: 120000 **Seq:** 1 **Gender:** F
Reported: 15/08/1997 **Weight:**
Hospitalisation: **Age:** 78Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Hyponatraemia			

Medicine Details:

ZANTAC (Other drug) **Reason:** Other diseases of esophagus
300.0 Milligram Daily
Batch: **Started:** 01/01/1995 **Stopped:**

PREMARIN (Other drug) **Reason:** Osteoporosis
625.0 Microgram Daily
Batch: **Started:** 01/01/1995 **Stopped:**

RENITEC (Other drug) **Reason:** Essential benign hypertension
5.0 Milligram Daily
Batch: **Started:** 01/01/1995 **Stopped:**

CARDIPRIN 100 (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chloride				Cl-89
	Serum osmolality				Serum osmolality- 216
	Sodium				Na-129
	Urine osmolality				Urine osmolality-31

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 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 120000 **Seq:** 1 **Gender:** F
Reported: 15/08/1997 **Weight:**
Hospitalisation: **Age:** 78Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/01/1997 **Stopped:** 13/08/1997

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 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.

Report Detail

Case Number: 120028 **Seq:** 1 **Gender:** M
Reported: 18/08/1997 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: 13/11/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis Nausea Vomiting			All medications ceased. restarted on lower dose carbamazepine

Medicine Details:

LARGACTIL (Suspected) **Reason:** Unspecifid affective psychosis
350.0 Milligram Daily
Batch: **Started:** **Stopped:**

TEGRETOL (Suspected) **Reason:**
1.0 Gram Daily
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		13/11/1996	1572	
	ALT = SGPT		20/11/1996	562	
	AST = SGOT		13/11/1996	728	
	AST = SGOT		20/11/1996	110	
	Bilirubin		13/11/1996	63	
	Bilirubin		20/11/1996	27	
	GGT = SGGT =		13/11/1996	696	

Additional Information:

Report Detail

Case Number: 120028 **Seq:** 1 **Gender:** M
Reported: 18/08/1997 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: 13/11/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

LARGACTIL (Suspected)			**Reason:**	Unspecifid affective psychosis
	350.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
TEGRETOL (Suspected)			**Reason:**	
	1.0	Gram	Daily	
Batch:	**Started:**			**Stopped:**
PROZAC (Suspected)			**Reason:**	
	20.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =		20/11/1996	491	
	SAP = ALP		13/11/1996	88	
	SAP = ALP		20/11/1996	127	

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 120081 **Seq:** 1 **Gender:** M
Reported: 20/08/1997 **Weight:**
Hospitalisation: **Age:** 7Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension Serotonin syndrome			

Medicine Details:

TRYPTANOL (Interaction) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PROZAC (Interaction) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reported in a published article (journal of paediatrics and child health, 1996 32(3), 265-266).

Report Detail

Case Number: 120291 **Seq:** 1 **Gender:** F
Reported: 26/08/1997 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: 16/05/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperaesthesia		Altered temperature sensation	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 16/05/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 120450 **Seq:** 1 **Gender:** F
Reported: 01/09/1997 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vascular malformation peripheral		Hamartoma in nasal area of infant	

Medicine Details:

PROZAC LIQUID (Suspected) **Reason:** Depression
Oral Liquid 16.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother took prozac liquid from 13 weeks into pregnancy. no other developmental defects in infant.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 120554 **Seq:** 1 **Gender:** M
Reported: 05/09/1997 **Weight:** 60.00
Hospitalisation: **Age:** A5
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			

Medicine Details:

ZACTIN (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred when patient was changed from prozac to zactin. patient is lactose intolerant. generic substitution problem

Report Detail

Case Number: 120608 **Seq:** 1
Reported: 09/09/1997
Hospitalisation: Admitted to hospital
Onset Date: 03/09/1997
Outcome: Recovered

Gender: F
Weight:
Age: 66Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Hyponatraemia			 Normal saline.

Medicine Details:

ATENOLOL (Other drug) **Reason:**
50.0 Milligram Alternate days
Batch: **Started:** 07/09/1995 **Stopped:**

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 12/08/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 120618 **Seq:** 1 **Gender:** M
Reported: 08/09/1997 **Weight:**
Hospitalisation: **Age:** 41Y
Onset Date: 31/07/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia Ejaculation failure Chest pain Nausea		Oesophageal reflux Sexual dysfunction inable to ejaculate.	Ceased zactin.

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 06/08/1997

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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 120659 **Seq:** 1 **Gender:** F
Reported: 10/09/1997 **Weight:** 63.00
Hospitalisation: **Age:** 16Y
Onset Date: 31/05/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Nausea Vomiting			Cease zactin attempt to change to prozac

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset of symptoms coincidental to taking generic fluoxetine (zactin) as substitute to prozac. generic substitution problem - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 121119 **Seq:** 1 **Gender:** M
Reported: 26/09/1997 **Weight:**
Hospitalisation: **Age:** 47Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram Alternate days
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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 121268 **Seq:** 1 **Gender:** F
Reported: 01/10/1997 **Weight:** 57.00
Hospitalisation: **Age:** 45Y
Onset Date: 27/08/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia Anxiety		Jaw area of face.	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 26/08/1997 **Stopped:** 29/08/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 121393 **Seq:** 1 **Gender:** F
Reported: 03/10/1997 **Weight:**
Hospitalisation: **Age:** 16Y
Onset Date: 03/07/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia Urticaria		Joint pain - knees, hips, wrists, elbow &	Hydrocortisone cream and

Medicine Details:

PROZAC (Suspected) **Reason:**
0.0
Batch: **Started:** 12/06/1997 **Stopped:** 03/07/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 121401 **Seq:** 1
Reported: 08/10/1997
Hospitalisation: Admitted to hospital
Onset Date: 02/09/1997
Outcome: Unknown

Gender: F
Weight:
Age: 67Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Hyponatraemia			Sodium chloride 20% inf, demeclocycline 300mg tds, fluid restriction.

Medicine Details:

ATENOLOL (Other drug) **Reason:** Essential benign hypertension
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

CEPHALEXIN (Other drug) **Reason:** Othr diseases of urinary tract
1.5 Gram Daily
Batch: **Started:** 28/08/1997 **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/08/1997 **Stopped:** 02/09/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	135 - 145 MMOL/L	03/09/1997	112	
	Sodium	135 - 145 MMOL/L	04/09/1997	125	
	Sodium	135 - 145 MMOL/L	05/09/1997	128	
	Urine Sodium		03/09/1997	70	

Additional Information:

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

Report Detail

Case Number: 121602 **Seq:** 1 **Gender:** F
Reported: 15/10/1997 **Weight:**
Hospitalisation: **Age:** 66Y
Onset Date: 24/08/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Hyperhidrosis Nausea Orthostatic hypotension Serotonin syndrome			Withdraw prozac.

Medicine Details:

PROZAC (Interaction)			**Reason:**	Depression	
Tablet	10.0	Milligram	Daily		Oral
Batch:	**Started:**	23/08/1997		**Stopped:**	25/08/1997
PARNATE (Interaction)			**Reason:**	Depression	
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**	L TERM		**Stopped:**	03/08/1997
TENORMIN (Other drug)			**Reason:**	Essential benign hypertension	
Tablet	50.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
LIPEX (Other drug)			**Reason:**	Othr&unspec metabolic diseases	
Tablet	40.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 121602 **Seq:** 1
Reported: 15/10/1997
Hospitalisation:
Onset Date: 24/08/1997
Outcome: Not yet recovered

Gender: F
Weight:
Age: 66Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

KALMA (Other drug)			**Reason:**	Anxiety neurosis	
Tablet	2.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
CARTIA (Other drug)			**Reason:**		
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 121627 **Seq:** 1 **Gender:** F
Reported: 17/10/1997 **Weight:** 56.00
Hospitalisation: **Age:** 60Y
Onset Date: 31/05/1995 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety		Panick attacks.	

Medicine Details:

PROGYNOVA (Other drug) **Reason:** Menopausal symptoms
2.0 Milligram Daily
Batch: **Started:** 01/01/1991 **Stopped:**

ATIVAN (Other drug) **Reason:**
1.0 Milligram Daily
Batch: **Started:** 01/01/1963 **Stopped:**

PROZAC (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/01/1993 **Stopped:** 10/10/1997

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. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 121750 **Seq:** 1 **Gender:** F
Reported: 21/10/1997 **Weight:** 68.00
Hospitalisation: **Age:** 27Y
Onset Date: 23/04/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic Pruritus			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 30/01/1997 **Stopped:** 24/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Lft's improved for several weeks and then worsened again consistent with cholestasis of pregnancy.

Report Detail

Case Number: 121867 **Seq:** 1 **Gender:** F
Reported: 24/10/1997 **Weight:** 60.00
Hospitalisation: **Age:** 64Y
Onset Date: 01/08/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			Betnovate, ecolon, antihistamine, prednisolone.

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/05/1997 **Stopped:** 14/07/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Skin biopsy				Biopsy on 15/08/97 confirms probable drug reacvtion.

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 121880 **Seq:** 1 **Gender:** M
Reported: 24/10/1997 **Weight:** 82.00
Hospitalisation: **Age:** 60Y
Onset Date: 17/07/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Therapy changed from prozac to lovan and patient bacome less contented and more edgy. patient now back on prozac and has improved. generic substitution problem

Report Detail

Case Number: 121957 **Seq:** 1 **Gender:** F
Reported: 28/10/1997 **Weight:** 54.00
Hospitalisation: **Age:** 65Y
Onset Date: 20/10/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Dizziness			

Medicine Details:

PROZAC (Suspected) **Reason:** Anxiety neurosis

Tablet 20.0 Milligram 1 time Oral

Batch: **Started:** 20/10/1997 **Stopped:** 20/10/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 122016 **Seq:** 1 **Gender:** F
Reported: 31/10/1997 **Weight:** 54.00
Hospitalisation: **Age:** 56Y
Onset Date: 07/10/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea			

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

Capsule 20.0 Milligram Daily Oral

Batch: **Started:** 06/10/1997 **Stopped:** 11/10/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has chronic fatigue syndrome.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122110 **Seq:** 1 **Gender:** F
Reported: 03/11/1997 **Weight:** 60.00
Hospitalisation: **Age:** 81Y
Onset Date: 17/04/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Hyponatraemia Nausea			Fluid restriction

Medicine Details:

TRITACE (Other drug) **Reason:**
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 01/01/1996 **Stopped:**

ZOTON (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 11/04/1997 **Stopped:** 28/05/1997

PROZAC (Suspected) **Reason:**
0.0
Batch: **Started:** 07/04/1997 **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.

Report Detail

Case Number: 122114 **Seq:** 1 **Gender:** F
Reported: 04/11/1997 **Weight:** 60.00
Hospitalisation: **Age:** 53Y
Onset Date: 24/10/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			

Medicine Details:

OGEN (Other drug) **Reason:** Menopausal symptoms
1.2 Milligram Daily
Batch: **Started:** 24/07/1996 **Stopped:** CONTIN

PROVERA (Other drug) **Reason:** Menopausal symptoms
5.0 Milligram Daily
Batch: **Started:** 24/07/1997 **Stopped:** CONTIN

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

AURORIX (Suspected) **Reason:** Depression
300.0 Milligram Daily
Batch: **Started:** 27/09/1996 **Stopped:** 23/10/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 122160 **Seq:** 1
Reported: 04/11/1997
Hospitalisation: Admitted to hospital
Onset Date: 29/09/1997
Outcome: Recovered

Gender: F
Weight:
Age: 82
DOB: 18/04/1915
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Asthenia Dizziness		Poor coordination	

Medicine Details:

PANADOL (Other drug) **Reason:**
Oral application 4.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

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

SLOW-K (Other drug) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 122160 **Seq:** 1
Reported: 04/11/1997
Hospitalisation: Admitted to hospital
Onset Date: 29/09/1997
Outcome: Recovered

Gender: F
Weight:
Age: 82
DOB: 18/04/1915
Causality: Causality possible

Reaction Detail

Medicine Details:

MS CONTIN (Suspected)			**Reason:**	Pain		
Oral application	20.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**	02/06/1997	
PROZAC (Suspected)			**Reason:**	Depression		
Tablet	20.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**	02/10/1997	
XANAX (Suspected)			**Reason:**	Anxiety neurosis		
Tablet	2.5	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**	02/10/1997	
NORVASC (Suspected)			**Reason:**	Essential benign hypertension		
	2.5	Milligram	Daily			
Batch:	**Started:**			**Stopped:**	02/10/1997	

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122160 **Seq:** 1
Reported: 04/11/1997
Hospitalisation: Admitted to hospital
Onset Date: 29/09/1997
Outcome: Recovered

Gender: F
Weight:
Age: 82
DOB: 18/04/1915
Causality: Causality possible

Reaction Detail

Medicine Details:

LASIX (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:** 02/10/1997

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122325 **Seq:** 1 **Gender:** F
Reported: 13/11/1997 **Weight:** 53.00
Hospitalisation: **Age:** 27Y
Onset Date: 10/10/1997 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Vomiting	Severe	Abdominal cramps About 1h after taking prozac	Prozac ceased

Medicine Details:

MICROGYNON 50 (Other drug) **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/01/1994 **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 09/10/1997 **Stopped:** 10/10/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Abdominal cramps with first dose. next day severe abdominal cramps and vomiting 1hr after 2nd capsule. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Report Detail

Case Number: 122421 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:** 64.00
Hospitalisation: **Age:** 24Y
Onset Date: 19/06/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration		Painful bleeding mouth ulcerations	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Capsule 40.0 Milligram Daily Oral
Batch: **Started:** 17/06/1997 **Stopped:** 02W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Generic substitution problem

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122425 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/07/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Euphoric mood Drug withdrawal syndrome Dizziness		A high Dizziness and high began 6 days after withdrawal	

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1996 **Stopped:** 28/06/1997

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

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122427 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: 31/07/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention		Intermittent urinary retention	

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122431 **Seq:** 1 **Gender:** U
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Epistaxis			Prozac ceased

Medicine Details:

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

PROZAC (Suspected) **Reason:**
0.0
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.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122442 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Jittery and irritable	
Agitation neonatal		Restless	
Anorexia		Wasn't feeding	

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral application 20.0 Milligram Daily Breast milk transfer
Batch: **Started:** 01/08/1997 **Stopped:** 28/08/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient is a newly born infant who received fluoxetine through their mother's breast milk. the midwife noticed that the patient was jittery restless and irritable. the infant was not feeding very well. the mother stopped breastfeeding and the infant recovered. in-utero exposure to prozac during 2nd and 3rd trimesters, and also during breastfeeding while mother on prozac. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122443 **Seq:** 1 **Gender:** U
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased			

Medicine Details:

PROZAC (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: 122444 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypotension			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/01/1987 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122445 **Seq:** 1 **Gender:** U
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Spontaneous bruising 5-10cm in diameter	

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122447 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:** 53Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Tremor		Sensation of "skin crawling"	

Medicine Details:

PROZAC (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/07/1997 **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.

Report Detail

Case Number: 122470 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			Prozac ceased

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122471 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: 31/01/1996 **DOB:** 18/01/1965
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Breast discharge	
Breast pain		Sore tender breast	
Amenorrhoea			Prozac ceased and serzone commenced
Hyperprolactinaemia			
Unintended pregnancy			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 01/01/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Follow-up 21/10/97: prolactin levels slightly above normal range

Additional Information:

Treated with fluoxetine throughout pregnancy, gave birth to a healthy baby - 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: 122475 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:** 76.00
Hospitalisation: **Age:** 46
Onset Date: 07/08/1997 **DOB:** 01/02/1951
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flatulence		Bloating	
Eructation		Burping	
Hyperglycaemia		Elevated fasting morning glucose	
Hyperprolactinaemia		High prolactin levels	
Hypertonia		Muscle stiffness	
Constipation			
Dry mouth			
Hyperkinesia			
Increased appetite			
Psoriasis			

Medicine Details:

OROXINE (Other drug) **Reason:** Myxedema
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

PROCYCLIDINE HYDROCHLORIDE (Other drug) **Reason:** Other psoriasis
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

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

PROZAC (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin		04/10/1997	35.5	
	Prolactin		22/10/1997	45.3	
	Serum glucose		06/08/1997	7.3	
	Serum glucose		09/08/1997	7.8	
	Serum glucose		16/08/1997	8.3	
	Serum glucose		26/08/1997	9.8	
	Serum glucose		06/09/1997	9.8	

Additional Information:

Patient was rechallenged on zyprexa with same reaction occurring.

Report Detail

Case Number: 122475 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:** 76.00
Hospitalisation: **Age:** 46
Onset Date: 07/08/1997 **DOB:** 01/02/1951
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Medicine Details:

ZYPREXA (Suspected) **Reason:** Myxedema

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 06/08/1997 **Stopped:** 12/09/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose		09/09/1997	9.8	
	Serum glucose		09/09/1997	10.6	
	Serum glucose		14/09/1997	12.5	
	Serum glucose		30/10/1997	4.8	

Additional Information:

Patient was rechallenged on zyprexa with same reaction occurring.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122498 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Vasodilatation		Flushes	

Medicine Details:

PROZAC (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122499 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:** 52Y
Onset Date: 31/12/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vasodilatation Anxiety Hyperthyroidism		Intermittent hot flushes	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 09M

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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122500 **Seq:** 1 **Gender:** M
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:** 51Y
Onset Date: 31/12/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Pyrexia		Increased liver function tests	

Medicine Details:

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

PROZAC (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 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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122501 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/08/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Menorrhagia			

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 01/07/1997 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122502 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/08/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Menorrhagia		Heavy blood loss	

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 01/01/1997 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122503 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/08/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Furuncle		Boils	

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** 01/07/1997 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122529 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:** 44Y
Onset Date: 31/05/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			Prozac ceased

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 21/04/1997 **Stopped:** 14/05/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced itchiness within seven days of therapy with prozac. stopped for a couple of days. then recommenced on zoltin (non lilly generic fluoxetine). itchiness again. same occurred while on lovan. patient is now on sertraline. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122533 **Seq:** 1 **Gender:** U
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Nightmare			

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122535 **Seq:** 1 **Gender:** M
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/05/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		'sleepy eyes'/drowiness	
Ejaculation failure		Prolonged erections and delayed	
Agitation			

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 80.0 Milligram Daily Oral
Batch: **Started:** 01/03/1997 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122539 **Seq:** 1 **Gender:** U
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 29/05/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Influenza like illness		Flu like syndrome	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122540 **Seq:** 1 **Gender:** M
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain		Penile pain during intercourse	

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122541 **Seq:** 1 **Gender:** U
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Somnolence		Excessive sedation	

Medicine Details:

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

PROZAC (Suspected) **Reason:**
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.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122544 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 31/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia Neonatal disorder			

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral application 0.0 Breast milk transfer
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

A breastfeeding mother was taking prozac. it was noticed that her baby developed a dystonic reaction. this was described as the baby's head moving backwards and to the right. these were involuntary movements. mother was withdrawn from prozac therapy and the baby's symptoms resolved. when the mother resumed prozac therapy, the same reaction in the baby was noticed. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122545 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dermatitis exfoliative		Skin on end of fingers peeled off	Prozac ceased

Medicine Details:

PROZAC (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 28/06/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred within days of ceasing prozac. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Detail

Case Number: 122551 **Seq:** 1 **Gender:** M
Reported: 18/11/1997 **Weight:** 85.00
Hospitalisation: **Age:** 50Y
Onset Date: 30/04/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching Hypertonia		Twitching in calf muscle	

Medicine Details:

SEREPAX (Other drug) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 25/03/1996 **Stopped:**

PANADEINE FORTE (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** 19/09/1996 **Stopped:**

FLAGYL (Other drug) **Reason:**
600.0 Milligram Daily
Batch: **Started:** 12/03/1996 **Stopped:** 26/03/1996

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 16/08/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122554 **Seq:** 1 **Gender:** M
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Aggression Anxiety		Hostility	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

TEMAZEPAM (Suspected) **Reason:** Anxiety neurosis
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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122559 **Seq:** 1 **Gender:** M
Reported: 18/11/1997 **Weight:** 80.00
Hospitalisation: **Age:** 55Y
Onset Date: 22/04/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Hepatic function abnormal			

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/03/1996 **Stopped:** 17/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	(7 - 85)	30/06/1997	69	
	GGT = SGGT =	<65	30/06/1997	85	
	Other data				Liver ct scan on 16/08/97 showed geographic reduced attenuation, an apperance which favours fatty infiltration.
	SAP = ALP	30 - 120	30/06/1997	140	
	Serum glucose	3.5 - 5.9	30/06/1997	6.0	Fasting glucose

Additional Information:

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

Report Detail

Case Number: 122561 **Seq:** 1 **Gender:** M
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Tremor Anxiety Dizziness Nausea		Shaking	

Medicine Details:

SANDOMIGRAN (Suspected) **Reason:**

0.0

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

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122563 **Seq:** 1 **Gender:** M
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Severe	Oedema in legs and severe, noticable	

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122566 **Seq:** 1 **Gender:** M
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abnormal dreams		Bad dreams	

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 10/05/1997 **Stopped:** 10/06/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

He stopped taking prozac and the bad dreams stopped. when rechallenged with prozac the bad dreams began again.

Report Detail

Case Number: 122567 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:** 65.00
Hospitalisation: **Age:** 34
Onset Date: 31/05/1997 **DOB:** 28/01/1963
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Nausea		Raciness, agitation and panicky	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 60.0 Milligram Daily Oral

Batch: **Started:** 31/05/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was taking a generic brand of fluoxetine (zactin) without problem and only changed to prozac due to unavailability of zactin. patient has taken prozac in past without problem.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122578 **Seq:** 1 **Gender:** U
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor		Fine tremor of hands, shaking legs.	

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced tremor when dose of prozac was increased to 60mg.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122580 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased			

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122583 **Seq:** 1 **Gender:** F
Reported: 18/11/1997 **Weight:** 76.00
Hospitalisation: **Age:** 52
Onset Date: 15/03/1997 **DOB:** 14/11/1944
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysgeusia		Sour taste	

Medicine Details:

OGEN (Other drug) **Reason:**
125.0 Milligram Daily
Batch: **Started:** 01/01/1995 **Stopped:**

SEREPAX (Other drug) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 15/03/1997 **Stopped:**

PROZAC (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 15/03/1997 **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: 122697 **Seq:** 1
Reported: 24/11/1997
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 84Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Confusional state Dizziness Drug level increased		Unsteadiness and falls	

Medicine Details:

PROZAC (Interaction) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PERHEXILINE MALEATE (Interaction) **Reason:**
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

CAPTOPRIL (Other drug) **Reason:**
112.5 Milligram Daily
Batch: **Started:** **Stopped:**

DILTIAZEM HYDROCHLORIDE (Other drug) **Reason:**
480.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				Trough serum levels perhexille was 1.5mg/l. repeat serum perhexiline concentrations were obtained 7 and 21 days after admission, with no decline in serum perhexiline conc. from levels at the time of admission

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 122697 **Seq:** 1
Reported: 24/11/1997
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 84Y
DOB:
Causality: Causality possible

Reaction Detai

Medicine Details:

BUMETANIDE (Other drug)			**Reason:**	
	6.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
GLYCERYL TRINITRATE (Other drug)			**Reason:**	
	100.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 122790 **Seq:** 1 **Gender:** F
Reported: 26/11/1997 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura			

Medicine Details:

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

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has a history of paranoid schizophrenia and idiopathic thrombocytopenic purpura, about 3 years ago, treated with steroids and then splenectomy.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 123005 **Seq:** 1 **Gender:** F
Reported: 03/12/1997 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation neonatal Hyperhidrosis		Increasingly miserable.	Mother ceased prozac.

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral application 0.0 Breast milk transfer
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother was on prozac during first 3 weeks after birth, baby was breast fed and during this time was increasingly miserable, sweaty. prozac was stopped and baby was fine 2 days later.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 123038 **Seq:** 1 **Gender:** F
Reported: 03/12/1997 **Weight:**
Hospitalisation: **Age:** 79Y
Onset Date: 14/02/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Hallucination Hyponatraemia			Prozac discontinued and imipramine up to 75mg daily

Medicine Details:

RYTHMODAN (Other drug) **Reason:** Otr&nos disord of heart rhythm
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

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

ALPRAZOLAM (Other drug) **Reason:** Anxiety neurosis
Tablet 0.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

SOLPRIN (Other drug) **Reason:** Chron isch heart dis no hyper
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium	3.5-5.0	17/02/1997	3.6	
	Potassium	3.5-5.0	22/02/1997	4.0	
	Potassium	3.5-5.0	26/02/1997	4.5	
	Serum osmolality	280-300	18/02/1997	255	
	Serum osmolality	280-300	22/02/1997	271	
	Sodium	135-145	17/02/1997	118	
	Sodium	135-145	22/02/1997	121	

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 123038 **Seq:** 1 **Gender:** F
Reported: 03/12/1997 **Weight:**
Hospitalisation: **Age:** 79Y
Onset Date: 14/02/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 18/02/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	135-145	26/02/1997	134	
	Urea	2.5-7.8	17/02/1997	10.7	
	Urea	2.5-7.8	22/02/1997	11.6	
	Urea	2.5-7.8	26/02/1997	7.8	

Additional Information:

Report Detail

Case Number: 123105 **Seq:** 1 **Gender:** F
Reported: 04/12/1997 **Weight:**
Hospitalisation: **Age:** 22
Onset Date: 26/10/1997 **DOB:** 11/10/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Menorrhagia		Breakthrough bleeding	

Medicine Details:

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

PROZAC (Interaction) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 21/10/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 123115 **Seq:** 1
Reported: 04/12/1997
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight:
Age:
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema Hyponatraemia		Swelling all over body	Aldactone

Medicine Details:

PROZAC (Suspected) **Reason:**
20.0 Milligram Daily
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.

Report Detail

Case Number: 123131 **Seq:** 1 **Gender:** M
Reported: 04/12/1997 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased			

Medicine Details:

TESTOSTERONE (Suspected) **Reason:**
0.0
Batch: **Started:** 01/07/1997 **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 23/09/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

When patient's dose of prozac was increased to 40mg from 20mg patient experienced symptoms. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 123133 **Seq:** 1 **Gender:** F
Reported: 04/12/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Anorexia Insomnia Nausea			

Medicine Details:

PROZAC (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:** 06D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was treated with sertraline for aproximately 2 weeks prior to being switched to prozac, and experienced much the same adverse events.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 123136 **Seq:** 1 **Gender:** F
Reported: 04/12/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Anorgasmia Asthenia Insomnia			

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** 01/10/1997 **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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 123299 **Seq:** 1
Reported: 12/12/1997
Hospitalisation: Admitted to hospital
Onset Date: 03/12/1997
Outcome: Recovered

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

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arrhythmia		Multiple ventricular arrhythmias	

Medicine Details:

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

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

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

PROZAC (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of ischaemic heart disease and a degree of liver impairment. patient is attempting to slowly come off the methadone programme. patient is also on a benzodiazepine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 123557 **Seq:** 1 **Gender:** F
Reported: 19/12/1997 **Weight:** 48.00
Hospitalisation: **Age:** 45Y
Onset Date: 17/11/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vaginal infection	Severe	Dryness/whitening of mucosa ext/red &	Ceased prozac.

Medicine Details:

PANALGESIC (Other drug) **Reason:** Headache
Capsule 1.0 Gram Daily Oral
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 01/01/1996 **Stopped:** 01/12/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient taking prozac 20-40mg daily for about a year. 40mg makes patient jumpy. prozac was increased to 60mg daily resulting in severe reaction occur- ring. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 123626 **Seq:** 1
Reported: 22/12/1997
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 4.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Feeling jittery Irritability Dyspnoea Neonatal disorder		Jitteriness, possible seizure Persistent postnatal irritability	

Medicine Details:

PROZAC (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** 01/06/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Electroencephalog				Infrequent unilateral spike waves on eeg.
17/12/2002	Other data				Apgars 5 (ist min) 6 (5min) 6 (10 min)

Additional Information:

Term (38w). bw 2780, mother on treatment with Prozac 20mg daily during last 4 months of pregnancy. (1) respiratory distress-headbox oxygen for < 2 days, (2) jitteriness possible seizures, (3) persisting post-natal irritabil- ity and possible seizures, (4) breast fed for first two weeks. (1) link with maternal prozac unproven but recent case reports of interest, (2) mother may have used other drugs (illicit) during pregnancy. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 123833 **Seq:** 1 **Gender:** F
Reported: 09/01/1998 **Weight:** 63.00
Hospitalisation: **Age:** 41Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia Fatigue Hepatitis cholestatic Nausea			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
60.0 Milligram Daily
Batch: **Started:** 01/11/1996 **Stopped:** 28/12/1997

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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124148 **Seq:** 1 **Gender:** M
Reported: 19/01/1998 **Weight:**
Hospitalisation: **Age:** 19Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Hyperactive	

Medicine Details:

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

PROZAC (Suspected) **Reason:**
Oral application 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/10/1997 **Stopped:** 01D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The mother suspects that her son was also taking amphetamines at the time. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 124150 **Seq:** 1 **Gender:** M
Reported: 19/01/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Libido increased		Increased sexual behaviour	

Medicine Details:

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

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

PROZAC (Suspected) **Reason:**
Oral application 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124151 **Seq:** 1 **Gender:** F
Reported: 19/01/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Weight increased			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** 01/06/1997 **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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124152 **Seq:** 1 **Gender:** U
Reported: 19/01/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills		Chills	
Muscle twitching		Twitching of muscles in arms, legs and [illegible]	Benzodiazepine

Medicine Details:

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

PROZAC (Suspected) **Reason:**
Oral application 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 accurate but indicates that onset occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124153 **Seq:** 1 **Gender:** F
Reported: 19/01/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness			

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** 01/11/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

For the first 2 weeks patient treated with 20mg daily but experienced tiredness. - 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124154 **Seq:** 1 **Gender:** F
Reported: 19/01/1998 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: 31/12/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Tingling fingers and feet.	

Medicine Details:

ALPHA-TOCOPHEROL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:**
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 01/03/1997 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124156 **Seq:** 1 **Gender:** M
Reported: 19/01/1998 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		Decreased platelets	
Leukopenia		Decreased polymorphs	
Splenomegaly		Enlarged spleen	

Medicine Details:

PROZAC (Suspected) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124178 **Seq:** 1 **Gender:** F
Reported: 19/01/1998 **Weight:** 65.00
Hospitalisation: **Age:** 28
Onset Date: 23/11/1997 **DOB:** 22/10/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral			

Medicine Details:

ZYPREXA (Suspected) **Reason:**
Tablet 7.5 Milligram Daily Oral
Batch: **Started:** 13/11/1997 **Stopped:**

PROZAC (Suspected) **Reason:**
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** 11/06/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has a history of schizophrenia with morbid paranoia.

Report Detail

Case Number: 124415 **Seq:** 1 **Gender:** F
Reported: 28/01/1998 **Weight:** 108.00
Hospitalisation: **Age:** 56Y
Onset Date: 05/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain		Cramps/ache in epigastrium	
Hyperhidrosis		Sweating +++ (more than climate effect)	

Medicine Details:

OROXINE (Other drug) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** L TERM **Stopped:**

LOVAN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 30/12/1997 **Stopped:** 15/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also has been on hormone replacement therapy (unspecified) for years.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124863 **Seq:** 1 **Gender:** F
Reported: 10/02/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cough		Tickling persisting cough.	Antibiotic

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt also on medication for thyroid condition. (unspecified)

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124865 **Seq:** 1 **Gender:** F
Reported: 10/02/1998 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Menopausal symptoms			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt experienced menopause. reporter isn't physician who prescribed prozac. event part of legal action taken against doctor and hospital.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124866 **Seq:** 1 **Gender:** U
Reported: 10/02/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/01/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal Agitation Headache Nausea		Thought disorder	

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral application 0.0 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.

Report Detail

Case Number: 124867 **Seq:** 1 **Gender:** F
Reported: 10/02/1998 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: 31/01/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pollakiuria		Pt exp urinary freq. 9 days after starting	

Medicine Details:

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

PROZAC (Suspected) **Reason:**
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124868 **Seq:** 1 **Gender:** F
Reported: 10/02/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/01/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Anxiety Pruritus			

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral application 20.0 Milligram Alternate days 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124869 **Seq:** 1 **Gender:** M
Reported: 10/02/1998 **Weight:**
Hospitalisation: **Age:** 63
Onset Date: **DOB:** 31/10/1934
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Goospimples	
Dysuria		Hard to pass urine	
Testicular disorder		Testicles shrunk up.	
Insomnia			
Nausea			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 01/11/1997 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124870 **Seq:** 1 **Gender:** M
Reported: 11/02/1998 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 31/12/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coma		"coma-like state"	Zolft discontinued

Medicine Details:

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

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

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient with lung cancer, leukemia and depression. other medications possibly included fluoxetine. patient was not admitted to hospital at this time. it is not certain that the patient was taking all these medications concomitantly. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124870 **Seq:** 1 **Gender:** M
Reported: 11/02/1998 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 31/12/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

TEMAZEPAM (Other drug)		**Reason:**		
	0.0			
Batch:	**Started:**		**Stopped:**	
CYANOCOBALAMIN (Other drug)		**Reason:**		
	0.0			
Batch:	**Started:**		**Stopped:**	
ZOLOFT (Suspected)		**Reason:**	Depression	
	0.0			
Batch:	**Started:**		**Stopped:**	3D
PROZAC (Suspected)		**Reason:**	Depression	
	0.0			
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Additional Information:

Patient with lung cancer, leukemia and depression. other medications possibly included fluoxetine. patient was not admitted to hospital at this time. it is not certain that the patient was taking all these medications concomitantly. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124870 **Seq:** 1 **Gender:** M
Reported: 11/02/1998 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 31/12/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

MORPHINE NOS (Suspected)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:**
LISINOPRIL (Suspected)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:**

Laboratory Investigations:

Additional Information:

Patient with lung cancer, leukemia and depression. other medications possibly included fluoxetine. patient was not admitted to hospital at this time. it is not certain that the patient was taking all these medications concomitantly. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 124873 **Seq:** 1 **Gender:** M
Reported: 11/02/1998 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 31/12/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Agitation Anxiety Fatigue Insomnia Nausea			Zoloft discontinued

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 4D

PROZAC (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 3Y

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is hiv positive. had been on fluoxetine for three years at doses up to 40mg/day, but recently on 20mg/day. was changed to zoloft because of his multiple other medications (not identified), without a washout period. (he was also on multiple other hiv drugs - protease inhibitors, antivirals etc.). - the date of onset is not accurate but indicates that onset occurred sometime during the year.

Report Detail

Case Number: 124968 **Seq:** 1 **Gender:** M
Reported: 16/02/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 27/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage Prothrombin level decreased			

Medicine Details:

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

COUMADIN (Interaction) **Reason:** Phleb&thrombophleb lowr extrem
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 27/01/1998

NAPROSYN (Interaction) **Reason:** Unspecified arthritis
Tablet 750.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				Steady state of prothrombin time almost 2.0 with warfrin 2 mg, increased to 5.1 with administration of lovan 20 mg.

Additional Information:

Report Detail

Case Number: 125012 **Seq:** 1 **Gender:** M
Reported: 16/02/1998 **Weight:** 92.00
Hospitalisation: **Age:** 63Y
Onset Date: 31/10/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			Therapy changed back to

Medicine Details:

NORVASC (Other drug) **Reason:** Essential benign hypertension
10.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:**

APRINOX (Other drug) **Reason:** Essential benign hypertension
1.0 Dose Unspecified Daily
Batch: **Started:** 01/01/1994 **Stopped:**

FELDENE-D (Other drug) **Reason:** Osteoarthritis
20.0 Milligram Daily
Batch: **Started:** 01/01/1992 **Stopped:**

ASPIRIN (Other drug) **Reason:**
0.5 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Post tramatic stress disorder well controlled on prozac 20 mg x 3 tabs/day. changed to zactin and symptons returned. improved when back to prozac brand. generic substitution problem - 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 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

Report Detail

Case Number: 125012 **Seq:** 1 **Gender:** M
Reported: 16/02/1998 **Weight:** 92.00
Hospitalisation: **Age:** 63Y
Onset Date: 31/10/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

ZACTIN (Suspected)		**Reason:**	
	60.0 Milligram	Daily	
Batch:	**Started:** 01/10/1997		**Stopped:** 28/11/1997
NOTEN (Suspected)		**Reason:**	Essential benign hypertension
	50.0 Milligram	Daily	
Batch:	**Started:** 01/01/1992		**Stopped:**

Laboratory Investigations:

Additional Information:

Post tramatic stress disorder well controlled on prozac 20 mg x 3 tabs/day. changed to zactin and symptons returned. improved when back to prozac brand. generic substitution problem - 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 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

Report Detail

Case Number: 125035 **Seq:** 1
Reported: 16/02/1998
Hospitalisation: Admitted to hospital
Onset Date: 04/12/1997
Outcome: Not yet recovered

Gender: F
Weight:
Age: 70
DOB: 11/10/1927
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria			Hospital admission. promethazine 10mg tds.

Medicine Details:

TEMAZEPAM (Other drug)			**Reason:**	Specific disorders of sleep		
Oral application	10.0	Milligram	Daily	Oral		
Batch:	**Started:**			**Stopped:**	CONTIN	
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression		
Capsule	20.0	Milligram	Daily	Oral		
Batch:	**Started:**			**Stopped:**	34D	
NITROFURANTOIN (Suspected)			**Reason:**	Othr diseases of urinary tract		
Oral Liquid	400.0	Milligram	Daily	Oral		
Batch:	**Started:**			**Stopped:**	10D	
TRIMETHOPRIM (Suspected)			**Reason:**	Othr diseases of urinary tract		
Tablet	300.0	Milligram	Daily	Oral		
Batch:	**Started:**			**Stopped:**	2D	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Past history of penicillin sensitivity (swelling).

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 125053 **Seq:** 1 **Gender:** F
Reported: 17/02/1998 **Weight:** 62.00
Hospitalisation: **Age:** 43Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria			

Medicine Details:

ZACTIN (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 07/02/1998 **Stopped:** 09/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Urticaria type reaction after changing from prozac 20 mg daily to_zactin. reaction ceased when put back on prozac. generic substitution problem

Report Detail

Case Number: 125365 **Seq:** 1 **Gender:** F
Reported: 27/02/1998 **Weight:** 69.00
Hospitalisation: **Age:** 48Y
Onset Date: 13/02/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Abdominal pain Anxiety Insomnia		Tremolousness	Buscopan imi, diazepam 5mg

Medicine Details:

VENTOLIN (Other drug) **Reason:** Asthma
Inhalation 0.0 As necessary Inhalation
Batch: **Started:** L TERM **Stopped:**

ZANTAC (Other drug) **Reason:** Other diseases of esophagus
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 28/01/1998 **Stopped:**

SANDOMIGRAN (Other drug) **Reason:** Migraine
Tablet 500.0 Microgram Daily Oral
Batch: **Started:** 28/01/1998 **Stopped:**

PULMICORT TURBUHALER (Other drug) **Reason:** Asthma
Inhalation 0.0 Daily Inhalation
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 125365 **Seq:** 1 **Gender:** F
Reported: 27/02/1998 **Weight:** 69.00
Hospitalisation: **Age:** 48Y
Onset Date: 13/02/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 12/02/1998 **Stopped:** 13/02/1998

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 125437 **Seq:** 1 **Gender:** F
Reported: 02/03/1998 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased			

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 125463 **Seq:** 1 **Gender:** F
Reported: 02/03/1998 **Weight:** 0.00
Hospitalisation: **Age:** 79
Onset Date: 03/09/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Dehydration Delirium Inappropriate antidiuretic hormon Weight decreased		Suspected SIADH	Fluoxetine ceased. fluids

Medicine Details:

LOSEC (Other drug) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

CARDIZEM (Other drug) **Reason:** Palpitation
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 20/08/1997 **Stopped:** 03/09/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Sodium	135 - 150	13/08/2003	111	

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 125486 **Seq:** 1 **Gender:** F
Reported: 03/03/1998 **Weight:** 60.00
Hospitalisation: **Age:** 65Y
Onset Date: 19/02/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Tinnitus			Fluoxetine reduced to 20mg daily from 20mg bd.

Medicine Details:

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

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 18/02/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient started on fluoxetine 20mg on 29/01/98. dose increased to 20mg bd on 18/02/98 and reaction occurred.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 125516 **Seq:** 1 **Gender:** F
Reported: 04/03/1998 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 31/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia Pruritus Rash	Severe		Prednisone lovan ceased

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 02/12/1997 **Stopped:** 05/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Rechallenged after 2nd episode.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 125532 **Seq:** 1 **Gender:** F
Reported: 05/03/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Influenza like illness Arthralgia Blood creatine phosphokinase in Myalgia		Flu like syndrome	Prozac ceased 01.98 with no improvement of events.

Medicine Details:

PROZAC (Suspected) **Reason:**
Capsule 0.0 Oral
Batch: **Started:** 01/01/1994 **Stopped:** 28/01/1998

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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 125533 **Seq:** 1 **Gender:** M
Reported: 05/03/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Hypersensitivity	Severe	Lesions over body	

Medicine Details:

PROZAC (Suspected) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 125534 **Seq:** 1 **Gender:** M
Reported: 05/03/1998 **Weight:**
Hospitalisation: **Age:** 14Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Falling asleep	

Medicine Details:

PROZAC (Suspected) **Reason:** Obsessive compulsive neurosis
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 01/02/1998 **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: 125535 **Seq:** 1 **Gender:** M
Reported: 05/03/1998 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal Amnesia		Abnormal thoughts/ self mutilation Memory problems	

Medicine Details:

PROZAC (Suspected) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient taking prozac for 12-18 months. feels as thogh recently his logic has decreased and is thinking abnormally, in particular he hears himself talking to himself. recently he cut the skin of his abdomen with a scalpel blade. he is also experiencing memory problems. patient has previously tried to commit suicide twice. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 125935 **Seq:** 1 **Gender:** M
Reported: 19/03/1998 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 31/03/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sexual dysfunction			

Medicine Details:

LOVAN (Suspected) **Reason:**
Capsule 0.0 Oral
Batch: **Started:** 01/03/1998 **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.

Report Detail

Case Number: 126102 **Seq:** 1 **Gender:** F
Reported: 23/03/1998 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Sharp shooting pain from back of tongue to	Aurorix ceased

Medicine Details:

PROVERA (Other drug) **Reason:** Menopausal symptoms
0.0
Batch: **Started:** L TERM **Stopped:** CONTIN

ENALAPRIL MALEATE (Other drug) **Reason:** Essential benign hypertension
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

LASIX (Other drug) **Reason:** Essential benign hypertension
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

FEMTRAN (Other drug) **Reason:** Menopausal symptoms
Cream 0.0 Daily Topical
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Dr thought it was possible that the patient's description of symptoms may be related to buccoglossal syndrome.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 126102 **Seq:** 1 **Gender:** F
Reported: 23/03/1998 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 23/10/1997 **Stopped:**

Laboratory Investigations:

Additional Information:

Dr thought it was possible that the patient's description of symptoms may be related to buccoglossal syndrome.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 126261 **Seq:** 1 **Gender:** U
Reported: 30/03/1998 **Weight:** 78.00
Hospitalisation: **Age:** 28Y
Onset Date: 23/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal		Lack of coordination & using basic	
Gait disturbance		Parkinsonism gait	
Extrapyramidal disorder		Psychomotor retardation	Withdrawal of fluoxetine

Medicine Details:

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 126262 **Seq:** 1 **Gender:** U
Reported: 30/03/1998 **Weight:** 78.00
Hospitalisation: **Age:** 28Y
Onset Date: 23/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Drug withdrawal syndrome			Very large doses of benzodiazepines for 4 weeks

Medicine Details:

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 126325 **Seq:** 1 **Gender:** F
Reported: 02/04/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/03/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia			

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 10D

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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 126616 **Seq:** 1 **Gender:** F
Reported: 14/04/1998 **Weight:** 84.00
Hospitalisation: **Age:** 33Y
Onset Date: 30/03/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			Ceased lovan

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 17/03/1998 **Stopped:** 30/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 126809 **Seq:** 1 **Gender:** U
Reported: 21/04/1998 **Weight:**
Hospitalisation: **Age:** 43Y
Onset Date: 06/03/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue			

Medicine Details:

TIMONIL (Suspected) **Reason:**
1.2 Gram Daily
Batch: **Started:** 16/12/1997 **Stopped:** CONTIN

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
60.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 126928 **Seq:** 1 **Gender:** M
Reported: 24/04/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Paresis Paraesthesia		Decrease in limb coordination Decrease in limb strength	

Medicine Details:

PROZAC (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: 126930 **Seq:** 1 **Gender:** F
Reported: 24/04/1998 **Weight:**
Hospitalisation: **Age:** 24
Onset Date: 25/02/1998 **DOB:** 01/04/1973
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Delayed spontaneous bruising	
Rash		Facial rash	

Medicine Details:

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

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 02/02/1998 **Stopped:** 25/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 126932 **Seq:** 1 **Gender:** F
Reported: 24/04/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dyspepsia		Indigestion/gastrointestinal burning	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 10D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 126933 **Seq:** 1 **Gender:** M
Reported: 24/04/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia		Bilateral gynaecomastia	

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 0.0 Oral
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.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 127035 **Seq:** 1 **Gender:** M
Reported: 28/04/1998 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Glaucoma		Almost doubled	Lovan ceased

Medicine Details:

BETOPTIC (Other drug) **Reason:**
Eye Drops 0.0 Ophthalmic
Batch: **Started:** **Stopped:**

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

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

TRUSOPT (Other drug) **Reason:**
Eye Drops 0.0 Ophthalmic
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: 127035 **Seq:** 1 **Gender:** M
Reported: 28/04/1998 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/01/1998 **Stopped:**

Laboratory Investigations:

Additional Information:

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

Report Detail

Case Number: 127049 **Seq:** 1 **Gender:** F
Reported: 30/04/1998 **Weight:** 48.00
Hospitalisation: **Age:** 33Y
Onset Date: 31/12/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chloasma			

Medicine Details:

MERSYNDOL (Suspected) **Reason:** Pain
0.0 As necessary
Batch: **Started:** **Stopped:** CONTIN

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

DIAZEPAM (Suspected) **Reason:** Pain
5.0 Milligram Daily
Batch: **Started:** L TERM **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: 127074 **Seq:** 1 **Gender:** F
Reported: 01/05/1998 **Weight:** 65.00
Hospitalisation: **Age:** 43Y
Onset Date: 09/04/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorgasmia Insomnia		Sexual dysfunction	Ceased lovan

Medicine Details:

NEULACTIL (Other drug) **Reason:** Anxiety neurosis
10.0 Milligram Daily
Batch: **Started:** 01/01/1995 **Stopped:** 28/04/1998

TEMAZE (Other drug) **Reason:** Specific disorders of sleep
10.0 Milligram Daily
Batch: **Started:** 01/01/1995 **Stopped:** 31/01/1998

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/04/1998 **Stopped:** 28/04/1998

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. 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 accurate but indicates that stoppage occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 127117 **Seq:** 1 **Gender:** M
Reported: 04/05/1998 **Weight:**
Hospitalisation: **Age:** 47Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Muscle twitching	Cogentin added to therapy

Medicine Details:

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

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had the same experience with prozac.

Report Detail

Case Number: 127234 **Seq:** 1 **Gender:** M
Reported: 06/05/1998 **Weight:**
Hospitalisation: **Age:** 55
Onset Date: 16/03/1998 **DOB:** 11/09/1942
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delusion Euphoric mood			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 27/04/1995 **Stopped:** 23/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 127235 **Seq:** 1 **Gender:** M
Reported: 06/05/1998 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Sedated	

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 127236 **Seq:** 1 **Gender:** M
Reported: 06/05/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/03/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **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: 127659 **Seq:** 1 **Gender:** M
Reported: 22/05/1998 **Weight:** 100.00
Hospitalisation: **Age:** 27Y
Onset Date: 14/04/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tongue discolouration		Coated tongue	
Somnolence		Difficult to rouse	
Dysarthria		Dysarthria with eyes rolling back	
Pallor		Pt was pale	Therapy rationalised except neurontin which was increased to 300mg 3 bd
Confusional state			
Coordination abnormal			
Dystonia			

Medicine Details:

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

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

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

ENDEP (Other drug) **Reason:**
100.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 127659 **Seq:** 1 **Gender:** M
Reported: 22/05/1998 **Weight:** 100.00
Hospitalisation: **Age:** 27Y
Onset Date: 14/04/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

MS CONTIN (Other drug)			**Reason:**		
	180.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN
NEURONTIN (Other drug)			**Reason:**		
	1.2	Gram	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN
EPILIM (Other drug)			**Reason:**		
	1.0	Gram	Daily		
Batch:	**Started:**			**Stopped:**	
MELLERIL (Other drug)			**Reason:**		
	20.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 127659 **Seq:** 1 **Gender:** M
Reported: 22/05/1998 **Weight:** 100.00
Hospitalisation: **Age:** 27Y
Onset Date: 14/04/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

PROZAC (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** S TERM **Stopped:** 3D

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 127689 **Seq:** 1 **Gender:** F
Reported: 22/05/1998 **Weight:** 63.00
Hospitalisation: **Age:** 35Y
Onset Date: 01/12/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nervousness		Feels irritable	
Malaise		Felt bad	
Aggression		Short tempered	
Drug withdrawal syndrome			Reintroduced prozac, then ceased again

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 21/07/1997 **Stopped:** 01/12/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 127723 **Seq:** 1 **Gender:** F
Reported: 25/05/1998 **Weight:** 87.00
Hospitalisation: **Age:** 28Y
Onset Date: 22/02/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain		Tight feeling in chest	

Medicine Details:

DUROMINE (Suspected) **Reason:** Obesity othr than endoc origin
Capsule 30.0 Milligram Daily Oral
Batch: **Started:** 15/02/1998 **Stopped:**

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/02/1998 **Stopped:**

VIBRA-TABS 50 (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 15/02/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 128001 **Seq:** 1 **Gender:** M
Reported: 01/06/1998 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain		Severe abdominal pain	Prozac ceased

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/04/1998 **Stopped:** 28/04/1998

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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 128414 **Seq:** 1 **Gender:** M
Reported: 17/06/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Lichenoid keratosis		Lichen planus from anus to arms and legs	

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 128415 **Seq:** 1 **Gender:** F
Reported: 17/06/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Bruising experienced for 4 months	Prozac ceased, aropax

Medicine Details:

PROZAC (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 4M

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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 128510 **Seq:** 1
Reported: 18/06/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight:
Age: 73
DOB: 16/08/1924
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state		Confusion and falls.	Amitriptyline ceased

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Interaction) **Reason:** Pain
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

PROZAC (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

MS CONTIN (Other drug) **Reason:** Pain
90.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

KAPANOL (Other drug) **Reason:** Pain
100.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 128510 **Seq:** 1
Reported: 18/06/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight:
Age: 73
DOB: 16/08/1924
Causality: Causality possible

Reaction Detail

Medicine Details:

EPILIM (Other drug)		**Reason:**	Pain	
	1.0 Gram	Daily		
Batch:	**Started:**		**Stopped:**	CONTIN
TEGRETOL (Other drug)		**Reason:**	Other&unspecified epilepsy	
	200.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	CONTIN
TEMAZEPAM (Other drug)		**Reason:**	Specific disorders of sleep	
	30.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	CONTIN
DUPHALAC (Other drug)		**Reason:**	Constipation	
	30.0 Millilitre	Daily		
Batch:	**Started:**		**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 128649 **Seq:** 1
Reported: 24/06/1998
Hospitalisation:
Onset Date: 20/05/1998
Outcome: Not yet recovered

Gender: M
Weight: 69.00
Age: 26
DOB: 29/02/1972
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Isolated twitches and jerks.	

Medicine Details:

VITAMIN NOS (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 20/05/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				Fluoxetine 0.67 umol/l (0.03-1.37), norfluoxetine 0.58 umol/l

Additional Information:

Report Detail

Case Number: 128991 **Seq:** 1 **Gender:** M
Reported: 07/07/1998 **Weight:** 110.00
Hospitalisation: **Age:** 38Y
Onset Date: 01/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia			
Dizziness			
Flatulence			
Headache			
Hypertonia			
Insomnia			
Nausea			
Pallor			
Rash			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/07/1998 **Stopped:** 02/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Penicillin recent withdrawal from alcohol 2 weeks ago. pt has had an allergic reaction to anafranil, penicillin and sulpher. pt has family history of tremor

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 128996 **Seq:** 1 **Gender:** F
Reported: 07/07/1998 **Weight:** 95.00
Hospitalisation: **Age:** 15Y
Onset Date: 23/06/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash vesicular			

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 18/06/1998 **Stopped:** 25/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 129173 **Seq:** 1 **Gender:** F
Reported: 13/07/1998 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 08/05/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypospadias		Baby born with hypospadias	

Medicine Details:

BRONCHODILATOR NOS (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 01/09/1997 **Stopped:** 28/10/1997

PROZAC (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 01/10/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Baby born with hypospadias. medication taken by mother during pregnancy. surgery planned at 12 months - seen by paediatric surgeon. 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.

Report Detail

Case Number: 129176 **Seq:** 1 **Gender:** F
Reported: 13/07/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Bruxism		Exacerbation of bruxism	

Medicine Details:

TEMAZEPAM (Other drug) **Reason:** Specific disorders of sleep
1.0 Dose Unspecified As necessary
Batch: **Started:** **Stopped:** CONTIN

PROZAC (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/05/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae: the patient has had to have dental work to correct some fillings that have loosened as a result of grinding her teeth. pt has preexisting habit of grinding her teeth. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 129213 **Seq:** 1
Reported: 15/07/1998
Hospitalisation: Admitted to hospital
Onset Date: 28/05/1998
Outcome: Recovered

Gender: F
Weight: 57.00
Age: 54
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Confusional state Convulsion Inappropriate antidiuretic hormon Nausea Vomiting		Suspected SIADH	Given normal saline, oral

Medicine Details:

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

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

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

PREMARIN (Other drug) **Reason:** Menopausal symptoms
0.0
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Chloride		13/08/2003	44	
17/12/2002	Sodium		13/08/2003	109	
17/12/2002	Sodium		13/08/2003	132	
17/12/2002	Urine Potassium		13/08/2003	31.7	
17/12/2002	Urine Sodium		13/08/2003	65	

Additional Information:

Patient history of pancreatitis and is an ex alcoholic. no previous allergies 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: 129213 **Seq:** 1
Reported: 15/07/1998
Hospitalisation: Admitted to hospital
Onset Date: 28/05/1998
Outcome: Recovered

Gender: F
Weight: 57.00
Age: 54
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

XANAX (Other drug)			**Reason:**	Specific disorders of sleep
	3.0 Milligram	Daily		
Batch:	**Started:** 01/12/1996		**Stopped:**	
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression
Capsule	40.0 Milligram	Daily		Oral
Batch:	**Started:** 01/03/1998		**Stopped:**	28/05/1998

Laboratory Investigations:

Additional Information:

Patient history of pancreatitis and is an ex alcoholic. no previous allergies 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 129604 **Seq:** 1 **Gender:** M
Reported: 27/07/1998 **Weight:**
Hospitalisation: **Age:** 9Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flatulence			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 129605 **Seq:** 1 **Gender:** F
Reported: 27/07/1998 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence			Sinutab ceased

Medicine Details:

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

PROZAC (Suspected) **Reason:**
Capsule 80.0 Milligram Daily Oral
Batch: **Started:** 01/01/1996 **Stopped:** CONTIN

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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 130341 **Seq:** 1 **Gender:** F
Reported: 21/08/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/07/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			Pruritus on palmar region of hands and feet extending to ankles and thumbs. also present bilaterally on flexor region of knees. fluoxetine treatment being continued

Medicine Details:

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

PROZAC (Suspected) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 01/06/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also receiving ogen (piperazine oestrone sulfate). - 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 130820 **Seq:** 1 **Gender:** F
Reported: 07/09/1998 **Weight:** 95.00
Hospitalisation: **Age:** 54Y
Onset Date: 03/09/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Loose bowels	
Disturbance in attention		Poor concentration	
Visual disturbance		Vision disturbance	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 14/08/1998 **Stopped:** 20/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

P/h of allergy to penicillin and morphine.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 130844 **Seq:** 1 **Gender:** M
Reported: 07/09/1998 **Weight:**
Hospitalisation: **Age:** 15Y
Onset Date: 31/07/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Epistaxis		Pt has had 5 nosebleeds	

Medicine Details:

PROZAC (Suspected) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 23/07/1998 **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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 131342 **Seq:** 1 **Gender:** F
Reported: 18/09/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia		Hairloss at front hairline and sides of the	Lovan ceased

Medicine Details:

LOVAN (Suspected) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 3W

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.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 131787 **Seq:** 1 **Gender:** M
Reported: 06/10/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/08/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Leg spasms	Pt had various treatments such as ice packs and naprosyn to no avail. prozac ceased

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/07/1998 **Stopped:** 28/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt has a history of depression and has been treated with other antidepressants and other ssri's in the past. the pt was not taking any other medication. pt has always experienced leg spasms, however, these worsened in severity in aug and prozac was discontinued. the leg spasms have continued in the week since prozac was discontinued. pt had tried various treatments such as ice packs and naprosyn to no avail. pt is sensitive to many medications. - 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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 131952 **Seq:** 1 **Gender:** M
Reported: 12/10/1998 **Weight:** 70.00
Hospitalisation: **Age:** 68Y
Onset Date: 24/09/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Syncope Vomiting			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Capsule 20.0 Milligram 2 times Oral

Batch: **Started:** 24/09/1998 **Stopped:** 25/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 132206 **Seq:** 1 **Gender:** M
Reported: 21/10/1998 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 31/12/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Drug withdrawal syndrome		Abdominal muscle cramping	Prozac ceased and changed back to zoloft

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
0.0 Daily
Batch: **Started:** **Stopped:** 2W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt had been taken off zoloft because he felt it wasn't working. the dr changed him to prozac. after approx 2 weeks on prozac, the pt decided he was better of on zoloft so took himself off prozac and the next day commenced therapy with zoloft again. he stated this caused abdominal muscle cramping. the pt is still taking zoloft. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 132265 **Seq:** 1 **Gender:** M
Reported: 19/10/1998 **Weight:**
Hospitalisation: **Age:** 32Y
Onset Date: 31/12/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Euphoric mood			

Medicine Details:

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

PROZAC (Suspected) **Reason:** Schizophrenia
Tablet 0.0 Oral
Batch: **Started:** **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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 132266 **Seq:** 1 **Gender:** M
Reported: 19/10/1998 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention		Inability to urinate, urination impaired.	Dose of prozac was reduced form 40mg/d to 20 mg.

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 132319 **Seq:** 1
Reported: 26/10/1998
Hospitalisation: Admitted to hospital
Onset Date: 18/08/1998
Outcome: Recovered

Gender: F
Weight: 57.00
Age: 82
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Inappropriate antidiuretic hormon		Suspected SIADH	Ceased prozac, tenormin, prepulsid and fluid restriction.

Medicine Details:

OROXINE (Other drug) **Reason:** Myxedema

Tablet 100.0 Microgram Daily Oral

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

PROZAC (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 10/08/1998 **Stopped:** 22/08/1998

TENORMIN (Suspected) **Reason:** Essential benign hypertension

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 01/08/1998 **Stopped:** 22/08/1998

PREPULSID (Suspected) **Reason:** Nausea and vomiting

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 01/06/1998 **Stopped:** 22/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Sodium		13/08/2003	132	
17/12/2002	Sodium		13/08/2003	125	
17/12/2002	Sodium		13/08/2003	115	
17/12/2002	Sodium		13/08/2003	132	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 132421 **Seq:** 1 **Gender:** F
Reported: 26/10/1998 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 31/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia	Severe	Severe reflux.	Changed back to lovan caps form lovan tablets.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/08/1998 **Stopped:** 28/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient developed symptoms after changing from lovan capsules to lovan tablets took a total of 10 tablets over 10 days (20mg/day) and each time experienced symptoms. see original report for other drugs. - 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 132720 **Seq:** 1 **Gender:** F
Reported: 02/11/1998 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 31/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia			

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/08/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was transferred to the dispersable tablet formaulation of lovan. the patient took one 20mg daily and each time experienced severe symptoms. see original report for other drugs. previously taken lovan in the pulvule formulation with no problems. - 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 132721 **Seq:** 1 **Gender:** F
Reported: 02/11/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vaginal haemorrhage Haematuria Renal pain		Continual vaginal bleeding Renal bleeding	Ceased prozac.

Medicine Details:

ORAL CONTRACEPTIVE NOS (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PROZAC (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: 132725 **Seq:** 1 **Gender:** F
Reported: 02/11/1998 **Weight:** 50.00
Hospitalisation: **Age:** 31Y
Onset Date: 01/10/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura			

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 21/09/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				Coag profile - normal, fbe- normal.

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 132770 **Seq:** 1 **Gender:** M
Reported: 02/11/1998 **Weight:** 0.00
Hospitalisation: **Age:** 65Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast cancer male Breast cancer male		Carcinoma of breast	Conservative surgery

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
3.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Remains on Prozac

Report Detail

Case Number: 132803 **Seq:** 1
Reported: 03/11/1998
Hospitalisation:
Onset Date: 23/09/1998
Outcome: Not yet recovered

Gender: M
Weight: 75.00
Age: 42Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Insomnia Nausea			

Medicine Details:

LOVAN (Suspected) **Reason:**

Capsule 20.0 Milligram Daily Oral

Batch: **Started:** 22/09/1998 **Stopped:** 30/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

P/h of allergy to erythromycin.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 133043 **Seq:** 1 **Gender:** M
Reported: 09/11/1998 **Weight:** 80.00
Hospitalisation: **Age:** 77Y
Onset Date: 21/09/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal failure acute			All drugs ceased, later reintroduced except prozac

Medicine Details:

LASIX (Other drug) **Reason:** Congestive heart failure
80.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:** 23/09/1998

SLOW-K (Other drug) **Reason:** Congestive heart failure
600.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:**

PROGOUT (Other drug) **Reason:** Gout
300.0 Milligram Daily
Batch: **Started:** 01/01/1990 **Stopped:** 23/09/1998

VALIUM (Other drug) **Reason:** Anxiety neurosis
5.0 Milligram Daily
Batch: **Started:** 01/01/1994 **Stopped:** 23/09/1998

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.

Report Detail

Case Number: 133043 **Seq:** 1 **Gender:** M
Reported: 09/11/1998 **Weight:** 80.00
Hospitalisation: **Age:** 77Y
Onset Date: 21/09/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

KAPANOL (Other drug)		**Reason:** Pain	
	40.0 Milligram	Daily	
Batch:	**Started:** 01/01/1996		**Stopped:** 23/09/1998
PANAMAX (Other drug)		**Reason:** Pain	
	4.0 Gram	Daily	
Batch:	**Started:** 01/01/1996		**Stopped:** 23/09/1998
PROZAC (Suspected)		**Reason:** Depression	
	20.0 Milligram	Daily	
Batch:	**Started:** 11/09/1998		**Stopped:** 23/09/1998

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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 133069 **Seq:** 1
Reported: 10/11/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 51Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania Suicide attempt		Hypomanic reaction	Pt hospitalised and ceased

Medicine Details:

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

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

LOVAN (Suspected) **Reason:**
60.0 Milligram Daily
Batch: **Started:** 01/10/1996 **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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 133222 **Seq:** 1 **Gender:** M
Reported: 13/11/1998 **Weight:**
Hospitalisation: **Age:** 53Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypercholesterolaemia Hyperlipidaemia			

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 133327 **Seq:** 1
Reported: 19/11/1998
Hospitalisation: Admitted to hospital
Onset Date: 09/10/1998
Outcome: Unrelated death

Gender: F
Weight:
Age: 83
DOB: 28/02/1915
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myositis		Myositis invol. both	
Vasculitis		Severe necrotising vasculitis	Prozac ceased. prednisolone commenced (60mg/day). she also required morphine for pain
Antinuclear antibody positive			
Blood creatine phosphokinase in			
C-reactive protein increased			
Hyponatraemia			
Red blood cell sedimentation rate			

Medicine Details:

BETAXOLOL HYDROCHLORIDE (Other drug) **Reason:**
Eye Drops 0.0 Ophthalmic
Batch: **Started:** **Stopped:**

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

DIAMICRON (Other drug) **Reason:** Diabetes mellitus
80.0 Milligram Daily
Batch: **Started:** 01/01/1994 **Stopped:** CONTIN

TRANSIDERM-NITRO (Other drug) **Reason:** Chron isch heart dis no hyper
Cream 25.0 Milligram Daily Transdermal
Batch: **Started:** 01/01/1994 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Antinuclear factor ANA				Antinuclear antibodies were detected 1:160 (speckled pattern).
	Creatine phosphokinase				Creatinine kinase was 2951 u/l on admission and rose to 4347 u/l by day three.
	Electromyography				Electromyography disclosed occasional fibrillations in the triceps, but no other spontaneous activity was recorded at rest. during attempted voluntary contraction, the interference patterns were markedly reduced and contained low amplitude polyphasic motor units. these finding were consistent with a primary muscle disease such as myositis.

Additional Information:

Patient was hospitalised on oct 10, following two weeks of severe pain, swelling and tenderness of upper arms and shoulders associated with malaise, lethargy, anorexia and vomiting. her past medical history included lacunar cerebral infarcts, hypertension, sensorineural deafness, glaucoma, abdominal aortic aneurysm and non-insulin dependent diabetes mellitus complicated by retinopathy and peripheral neuropathy. on examination, both upper arms and shoulders were oedematous, erythematous and extremely tender. she was unable to move her arms voluntarily because of pain. on day 6 the haemoglobin fell to 79 g/l and she was transfused with four units of packed red blood cells. on day 7 (18/10/98) she died suddenly. aust nz med

Report Detail

Case Number: 133327 **Seq:** 1
Reported: 19/11/1998
Hospitalisation: Admitted to hospital
Onset Date: 09/10/1998
Outcome: Unrelated death

Gender: F
Weight:
Age: 83
DOB: 28/02/1915
Causality: Causality possible

Reaction Detail

Medicine Details:

SOLPRIN (Other drug)		**Reason:**	Chron isch heart dis no hyper	
1.0 Dose Unspecified	Daily			
Batch:	**Started:** 01/01/1994		**Stopped:**	CONTIN
COLOXYL WITH SENNA (Other drug)		**Reason:**	Constipation	
4.0 Dose Unspecified	Daily			
Batch:	**Started:** 01/01/1994		**Stopped:**	CONTIN
PANAMAX (Other drug)		**Reason:**		
1.0 Gram	Daily			
Batch:	**Started:**		**Stopped:**	
PROZAC (Suspected)		**Reason:**	Depression	
20.0 Milligram	Daily			
Batch:	**Started:** 25/09/1998		**Stopped:**	12/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Erythrocyte [illegible] Muscle biopsy	NR LESS THAN [illegible]			Erythrocyte sedimentation rate 124 mm/h, sodium 128 mmol/l (nr [illegible] Muscle biopsy showed an acute myositis with extensive muscle infarction and no organisms were identified.

Additional Information:

Patient was hospitalised on oct 10, following two weeks of severe pain, swelling and tenderness of upper arms and shoulders associated with malaise, lethargy, anorexia and vomiting. her past medical history included lacunar cerebral infarcts, hypertension, sensorineural deafness, glaucoma, abdominal aortic aneurysm and non-insulin dependent diabetes mellitus complicated by retinopathy and peripheral neuropathy. on examination, both upper arms and shoulders were oedematous, erythematous and extremely tender. she was unable to move her arms voluntarily because of pain. on day 6 the haemoglobin fell to 79 g/l and she was transfused with four units of packed red blood cells. on day 7 (18/10/98) she died suddenly. aust nz med

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 133327 **Seq:** 1
Reported: 19/11/1998
Hospitalisation: Admitted to hospital
Onset Date: 09/10/1998
Outcome: Unrelated death

Gender: F
Weight:
Age: 83
DOB: 28/02/1915
Causality: Causality possible

Reaction Detail

Medicine Details:

BETAXOLOL HYDROCHLORIDE (Other drug)			**Reason:**	
Eye Drops	0.0			Ophthalmic
Batch:	**Started:**		**Stopped:**	
PLENDIL (Other drug)			**Reason:**	Essential benign hypertension
	5.0 Milligram	Daily		
Batch:	**Started:** 01/01/1994		**Stopped:**	CONTIN
DIAMICRON (Other drug)			**Reason:**	Diabetes mellitus
	80.0 Milligram	Daily		
Batch:	**Started:** 01/01/1994		**Stopped:**	CONTIN
TRANSIDERM-NITRO (Other drug)			**Reason:**	Chron isch heart dis no hyper
Cream	25.0 Milligram	Daily		Transdermal
Batch:	**Started:** 01/01/1994		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Post mortem examination revealed that the cause of death was partial rupture of the aneurysm of the abdominal aorta. there was also myocardial infarction involving the posterior wall of the left ventricle extending to the apex. microscopically, the post mortem muscle biopsy taken from the right deltoid muscle showed extensive muscle necrosis and severe necrotising vasculitis of

Additional Information:

Patient was hospitalised on oct 10, following two weeks of severe pain, swelling and tenderness of upper arms and shoulders associated with malaise, lethargy, anorexia and vomiting. her past medical history included lacunar cerebral infarcts, hypertension, sensorineural deafness, glaucoma, abdominal aortic aneurysm and non-insulin dependent diabetes mellitus complicated by retinopathy and peripheral neuropathy. on examination, both upper arms and shoulders were oedematous, erythematous and extremely tender. she was unable to move her arms voluntarily because of pain. on day 6 the haemoglobin fell to 79 g/l and she was transfused with four units of packed red blood cells. on day 7 (18/10/98) she died suddenly. aust nz med

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 133327 **Seq:** 1
Reported: 19/11/1998
Hospitalisation: Admitted to hospital
Onset Date: 09/10/1998
Outcome: Unrelated death

Gender: F
Weight:
Age: 83
DOB: 28/02/1915
Causality: Causality possible

Reaction Detail

Medicine Details:

SOLPRIN (Other drug)		**Reason:**	Chron isch heart dis no hyper	
	1.0 Dose Unspecified	Daily		
Batch:	**Started:** 01/01/1994		**Stopped:**	CONTIN
COLOXYL WITH SENNA (Other drug)		**Reason:**	Constipation	
	4.0 Dose Unspecified	Daily		
Batch:	**Started:** 01/01/1994		**Stopped:**	CONTIN
PANAMAX (Other drug)		**Reason:**		
	1.0 Gram	Daily		
Batch:	**Started:**		**Stopped:**	
PROZAC (Suspected)		**Reason:**	Depression	
	20.0 Milligram	Daily		
Batch:	**Started:** 25/09/1998		**Stopped:**	12/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Ultrasound of upper limbs revealed severe inflammatory changes involving arms and shoulders. bilateral nephrosclerosis. emphysema/chronic airways limitation changes in lungs.
	Other data				Contin., of the small and medium sized arteries. there was no evidence of vasculitis in the aorta, coronary arteries or viscera. there was no evidence of malignancy or infection. occlusion of circulflex branch of left coronary artery (no recent thrombosis)

Additional Information:

Patient was hospitalised on oct 10, following two weeks of severe pain, swelling and tenderness of upper arms and shoulders associated with malaise, lethargy, anorexia and vomiting. her past medical history included lacunar cerebral infarcts, hypertension, sensorineural deafness, glaucoma, abdominal aortic aneurysm and non-insulin dependent diabetes mellitus complicated by retinopathy and peripheral neuropathy. on examination, both upper arms and shoulders were oedematous, erythematous and extremely tender. she was unable to move her arms voluntarily because of pain. on day 6 the haemoglobin fell to 79 g/l and she was transfused with four units of packed red blood cells. on day 7 (18/10/98) she died suddenly. aust nz med

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 133456 **Seq:** 1 **Gender:** F
Reported: 20/11/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion Hyperchloraemia		Corticospinal tract dystonia	Ceased mexitil. clonazeapm.

Medicine Details:

MEXITIL (Interaction) **Reason:** Pain
600.0 Milligram Daily
Batch: **Started:** **Stopped:**

FLUOXETINE HYDROCHLORIDE (Interaction) **Reason:**
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 133672 **Seq:** 1 **Gender:** M
Reported: 25/11/1998 **Weight:** 85.00
Hospitalisation: **Age:** 44Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor			Ceased prozac.

Medicine Details:

MIXTARD 30/70 (Other drug) **Reason:** Diabetes mellitus
Injection 0.0 Daily Subcutaneous
Batch: **Started:** 01/01/1989 **Stopped:** CONTIN

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 24/08/1998 **Stopped:** 07/10/1998

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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 133735 **Seq:** 1 **Gender:** F
Reported: 26/11/1998 **Weight:** 62.00
Hospitalisation: **Age:** 56Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Glossitis			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms cleared within 10 days of withdrawal of prozac and reappeared after commencing prozac 6 months later.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 133746 **Seq:** 1 **Gender:** M
Reported: 27/11/1998 **Weight:**
Hospitalisation: **Age:** 33Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Glossitis		Painful and swollen tongue.	The patient is continuing prozac treatment.

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 0.0 Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The general practitioner is unsure if the event is related to the prozac treatment. history of depression and poorly controlled diabetes.

Report Detail

Case Number: 133747 **Seq:** 1 **Gender:** M
Reported: 27/11/1998 **Weight:**
Hospitalisation: **Age:** 38Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased Hyperkinesia Nausea Nervousness Vomiting	 Required Specialist Consultation	Patient has experienced a 10kg weight	

Medicine Details:

OGEN (Other drug)			**Reason:**			
Tablet	0.0		Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
ZYPREXA (Suspected)			**Reason:**	Unspecified schizophrenia		
Tablet	10.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
PROZAC (Suspected)			**Reason:**	Depression		
Oral application	40.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 133767 **Seq:** 1 **Gender:** F
Reported: 27/11/1998 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cerebral haemorrhage Vasodilatation Purpura Headache		Massive intracerebral haemorrhage. Patient complained of feeling hot. Scattered bruises noted over arms and	

Medicine Details:

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

ECSTASY (M.D.M.A.) (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified 1 time Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report received from a literature article: byard rw, gilbert j, james r, lokan rj. amphetamine derivative fatalities in south australia - is "ecstasy" the culprit? american journal of forensic medicine and pathology, (1998) 19/3, pp. 261-265.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 134015 **Seq:** 1 **Gender:** F
Reported: 04/12/1998 **Weight:** 73.00
Hospitalisation: **Age:** 37Y
Onset Date: 20/11/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Took approx 200 tablets of stelazine	Charcoal, tacrine.

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected)			**Reason:**	Depression		
Injection	160.0	Milligram	Weekly		Intramuscular	
Batch:	**Started:**			**Stopped:**		CONTIN
PROZAC (Suspected)			**Reason:**	Depression		
Oral application	40.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
COGENTIN (Suspected)			**Reason:**	Depression		
	1.0	Milligram	Daily			
Batch:	**Started:**			**Stopped:**		CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 134220 **Seq:** 1 **Gender:** F
Reported: 11/12/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Elevated prolactin level.	
Dystonia	Required Specialist Consultation	Jaw muscle spasm and difficulty opening	

Medicine Details:

PROZAC (Suspected) **Reason:** Anxiety neurosis
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 134365 **Seq:** 1 **Gender:** F
Reported: 18/12/1998 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: 11/11/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia	Severe	Severe memory loss	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 24/09/1998 **Stopped:** 21/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 134467 **Seq:** 1 **Gender:** F
Reported: 21/12/1998 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 31/12/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain of approx. 12kg since 1996.	

Medicine Details:

LOVAN (Suspected) **Reason:** Anxiety neurosis
Capsule 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 31/01/1996

LOVAN (Suspected) **Reason:** Anxiety neurosis
Capsule 60.0 Milligram Daily Oral
Batch: **Started:** 01/01/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient is post menopausal. - the date of onset is not accurate but indicates that onset 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 accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 134526 **Seq:** 1 **Gender:** F
Reported: 21/12/1998 **Weight:** 52.00
Hospitalisation: **Age:** 38Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/10/1995 **Stopped:** 28/06/1998

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: 134545 **Seq:** 1 **Gender:** F
Reported: 23/12/1998 **Weight:**
Hospitalisation: **Age:** 56Y
Onset Date: 31/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Eructation			Therapy changed back to lovan caps 20mg/d.

Medicine Details:

GOPTEN (Other drug) **Reason:** Essential benign hypertension
4.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

SPIRONOLACTONE (Other drug) **Reason:** Essential benign hypertension
100.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

DAPA-TABS (Other drug) **Reason:** Essential benign hypertension
5.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient started with lovan capsules 20mg/day in 19996. in aug 98 patient was switched to lovan dispersible tablets. following taking the first lovan dispersible experienced symptoms. after one month resumed treatment with lovan capsules and symptoms resolved. - 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: 134545 **Seq:** 1 **Gender:** F
Reported: 23/12/1998 **Weight:**
Hospitalisation: **Age:** 56Y
Onset Date: 31/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

LOSEC (Other drug)		**Reason:**	Other diseases of esophagus	
	20.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	CONTIN
PREMARIN (Other drug)		**Reason:**	Menopausal symptoms	
	1.2 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	CONTIN
LOVAN (Suspected)		**Reason:**	Depression	
Tablet	20.0 Milligram	Daily	Oral	
Batch:	**Started:** 01/08/1998		**Stopped:** 28/08/1998	

Laboratory Investigations:

Additional Information:

Patient started with lovan capsules 20mg/day in 19996. in aug 98 patient was switched to lovan dispersible tablets. following taking the first lovan dispersible experienced symptoms. after one month resumed treatment with lovan capsules and symptoms resolved. - 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 134638 **Seq:** 1 **Gender:** F
Reported: 24/12/1998 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thyroiditis			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 1Y

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of depression and dysthymic disorder. other anti-depressants were not effective.

Report Detail

Case Number: 134711 **Seq:** 1 **Gender:** M
Reported: 04/01/1999 **Weight:** 77.00
Hospitalisation: **Age:** 36Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Insomnia			

Medicine Details:

LOVAN (Other drug) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 07/07/1997 **Stopped:** 16/12/1998

ZACTIN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 17/07/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 134989 **Seq:** 1 **Gender:** F
Reported: 08/01/1999 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agitation Drug withdrawal syndrome			Pt recommenced zoloft and ceased prozac, then ceased zoloft treatment with no adverse event

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

It is unknown if the patient was taking any other medication. patient attempted three times to reduce the dossage of prozac to 10mg/d. on each occasion experienced agitation and was stressed out.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 135006 **Seq:** 1 **Gender:** M
Reported: 11/01/1999 **Weight:**
Hospitalisation: **Age:** 10Y
Onset Date: 10/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema Urticaria			Prozac & serenace ceased. oral steroids given, prednisolone & claratyne.

Medicine Details:

PROZAC (Suspected) **Reason:** Otr spec symp psychopathol nec
Oral application 0.0 Oral
Batch: **Started:** 01/07/1998 **Stopped:** 18/08/1998

SERENACE (Suspected) **Reason:** Otr spec symp psychopathol nec
Oral application 0.0 Oral
Batch: **Started:** 01/07/1998 **Stopped:** 14/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected agent prozac - prev reports of urticaral & angioedema. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 135017 **Seq:** 1
Reported: 11/01/1999
Hospitalisation: Admitted to hospital
Onset Date: 19/12/1998
Outcome: Recovered

Gender: F
Weight: 60.00
Age: 71Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia			
Anorexia			
Confusional state			
Depersonalisation			
Hyperhidrosis			
Hypertonia			
Neurosis			Short trials of benztropine & cyproheptadine.
Serotonin syndrome			
Torticollis			

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 30/11/1998 **Stopped:** 20/12/1998

HYPERICUM-ST JOHN'S WORT (Suspected) **Reason:** Depression
Oral application 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 10/12/1998 **Stopped:** 19/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 135063 **Seq:** 1
Reported: 11/01/1999
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 82Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Speech disorder Agitation Confusional state Serotonin syndrome Tremor		Could only answer yes or no to questions	4mg cyproheptadine.

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 135317 **Seq:** 1 **Gender:** M
Reported: 29/01/1999 **Weight:**
Hospitalisation: **Age:** A3
Onset Date: 31/12/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sexual dysfunction		Ejaculation problems	

Medicine Details:

LOVAN (Suspected) **Reason:**
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 01/12/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Also experienced the same ejaculation problems with aropax. patient had been taking lovan to help with public speaking, not depression. - 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 135342 **Seq:** 1 **Gender:** M
Reported: 22/01/1999 **Weight:**
Hospitalisation: **Age:** 78Y
Onset Date: 31/12/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Skin exfoliation		Flakey skin.	
Periorbital oedema		Puffy eyes.	
Face oedema		Swollen face.	
Hypersensitivity			Cortisone was given.
Laryngospasm			

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral Liquid 5.0 Millilitre Daily Oral
Batch: **Started:** 01/12/1998 **Stopped:** 28/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of emphysema. - 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 135761 **Seq:** 1
Reported: 02/02/1999
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 76
DOB: 16/09/1922
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Prozac ceased and fluid

Medicine Details:

PROZAC (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 136197 **Seq:** 1 **Gender:** F
Reported: 15/02/1999 **Weight:** 60.00
Hospitalisation: **Age:** 34Y
Onset Date: 06/09/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapeutic response decreased Pruritus Rash		Lovan was not as effective as prozac	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 31/08/1998 **Stopped:** 08/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 136451 **Seq:** 1 **Gender:** F
Reported: 22/02/1999 **Weight:** 63.00
Hospitalisation: **Age:** 28Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haematoma		Perianal haematoma.	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 05/11/1993 **Stopped:** 02/06/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Perianal haematoma first occured in november 1994. patient has had an irritable bowel for years. prozac hardens her faeces.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 136452 **Seq:** 1
Reported: 22/02/1999
Hospitalisation:
Onset Date: 31/01/1999
Outcome: Not yet recovered

Gender: F
Weight: 63.00
Age: 28Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haematoma		Perianal haematoma.	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 16/10/1998 **Stopped:** 28/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Peranal haematoma occured a second time in january 99. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Report Detail

Case Number: 136480 **Seq:** 1 **Gender:** F
Reported: 18/02/1999 **Weight:**
Hospitalisation: **Age:** 81Y
Onset Date: 03/06/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination		Visiual hallucination	Fluoxetine ceased.

Medicine Details:

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

TRIMETHOPRIM (Other drug) **Reason:** Othr diseases of urinary tract
Oral application 300.0 Milligram Daily Oral
Batch: **Started:** 01/06/1998 **Stopped:** 09/06/1998

DIGOXIN (Suspected) **Reason:**
0.0
Batch: **Started:** 03/06/1998 **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** 29/05/1998 **Stopped:** 04/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

05/06/98 - mentally clear

Report Detail

Case Number: 136480 **Seq:** 1 **Gender:** F
Reported: 18/02/1999 **Weight:**
Hospitalisation: **Age:** 81Y
Onset Date: 03/06/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

CEFTRIAXONE (Suspected)			**Reason:**	
Injection	1.0 Gram		Daily	Intravenous
Batch:	**Started:** 03/06/1998		**Stopped:**	04/06/1998
RULIDE (Suspected)			**Reason:**	
Oral application	300.0 Milligram		Daily	Oral
Batch:	**Started:** 03/06/1998		**Stopped:**	04/06/1998

Laboratory Investigations:

Additional Information:
05/06/98 - mentally clear

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 136515 **Seq:** 1 **Gender:** F
Reported: 19/02/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vaginal haemorrhage			

Medicine Details:

ORAL CONTRACEPTIVE NOS (Other drug) **Reason:** Contraception
Oral application 1.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 136548 **Seq:** 1 **Gender:** M
Reported: 24/02/1999 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia Breast pain		Nipple inflam & bilateral gynaecomastia, (r) Patient noticed breast discomfort.	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1999 **Stopped:** 28/02/1999

LOVAN (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/02/1999 **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 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.

Report Detail

Case Number: 136637 **Seq:** 1 **Gender:** F
Reported: 26/02/1999 **Weight:** 65.00
Hospitalisation: **Age:** 44Y
Onset Date: 09/02/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia Flatulence		Belching all the time	Will try gaviscon.

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:** Otr&unsp vertebrogen pain synd
Tablet 2.0 Dose Unspecified As necessary Oral
Batch: **Started:** 01/01/1997 **Stopped:**

NORMISON (Other drug) **Reason:** Specific disorders of sleep
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

LOVAN (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 08/02/1999 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 136843 **Seq:** 1 **Gender:** F
Reported: 01/03/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: 19/02/1999 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Somnolence			Ceased lovan

Medicine Details:

LOVAN (Suspected) **Reason:** Pain
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 18/02/1999 **Stopped:** 21/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms each morning after taking lovan.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 136845 **Seq:** 1 **Gender:** M
Reported: 01/03/1999 **Weight:**
Hospitalisation: **Age:** A2
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug ineffective Fatigue Nausea			

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: C1529 **Started:** 01/01/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient started a new pack (batch c1529, expiry october 2000 in february 1999 and within 24 hours of taking the first capsule, he experienced a return of depression symptoms (lack of efficacy), nausea, dizziness and lethargy. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 136920 **Seq:** 1
Reported: 04/03/1999
Hospitalisation:
Onset Date: 20/02/1999
Outcome: Not yet recovered

Gender: M
Weight: 60.00
Age: 62Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Flatulence			Prozac withdrawn

Medicine Details:

MURELAX (Suspected) **Reason:** Otr spec symp psychopathol nec

Tablet 15.0 Milligram Daily Oral

Batch: **Started:** 20/01/1999 **Stopped:** CONTIN

PROZAC (Suspected) **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 19/02/1999 **Stopped:** 02/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 137258 **Seq:** 1 **Gender:** F
Reported: 12/03/1999 **Weight:**
Hospitalisation: **Age:** 86Y
Onset Date: 01/03/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination		Halucinations (snakes)	Ceased fluoxetine

Medicine Details:

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

Oral application 20.0 Milligram Daily Oral

Batch: **Started:** 18/01/1999 **Stopped:** 04/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 137338 **Seq:** 1 **Gender:** M
Reported: 16/03/1999 **Weight:**
Hospitalisation: **Age:** 23
Onset Date: 22/10/1998 **DOB:** 15/11/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia			

Medicine Details:

MIDAZOLAM (Suspected) **Reason:**
Injection 10.0 Milligram 1 time Intramuscular
Batch: **Started:** 21/10/1998 **Stopped:**

DROPERIDOL (Suspected) **Reason:**
Injection 10.0 Milligram 1 time Intramuscular
Batch: **Started:** 20/10/1998 **Stopped:**

TEMAZEPAM (Suspected) **Reason:**
10.0 Milligram As necessary
Batch: **Started:** **Stopped:**

EFEXOR (Suspected) **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 21/10/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		22/10/1998	0.99	
	White blood cells		22/10/1998	2.62	

Additional Information:

Report Detail

Case Number: 137338 **Seq:** 1 **Gender:** M
Reported: 16/03/1999 **Weight:**
Hospitalisation: **Age:** 23
Onset Date: 22/10/1998 **DOB:** 15/11/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

DIAZEPAM (Suspected)			**Reason:** Anxiety neurosis	
Tablet	20.0 Milligram		Daily	Oral
Batch:	**Started:** 21/10/1998		**Stopped:**	
THIAMINE (Suspected)			**Reason:**	
Oral application	100.0 Milligram		Daily	Oral
Batch:	**Started:** 21/10/1998		**Stopped:**	
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	
	40.0 Milligram		Daily	
Batch:	**Started:** 20/08/1998		**Stopped:**	20/10/1998

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 137590 **Seq:** 1 **Gender:** F
Reported: 19/03/1999 **Weight:**
Hospitalisation: **Age:** 19
Onset Date: **DOB:** 14/04/1979
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Photosensitivity reaction		Rash developed where patient got	

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - oral contraceptive pill. it was reported that on the areas of her body that were sunburnt she developed a rash.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 137591 **Seq:** 1 **Gender:** F
Reported: 19/03/1999 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: 31/12/1998 **DOB:** 20/07/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Drug ineffective Neurosis			Ibuprofen ceased.

Medicine Details:

IBUPROFEN (Interaction) **Reason:** Otr&unsp vertebrogen pain synd

Tablet 400.0 Milligram As necessary Oral

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

PROZAC (Interaction) **Reason:** Depression

Oral application 20.0 Milligram Daily Oral

Batch: **Started:** 01/03/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient experienced a worsening of her depression 1-2 days after these two medications were taken in combination. the ibuprofen treatment was rechallenged in jan 99 and the patient again experienced a worsening of her depression. - 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 137592 **Seq:** 1 **Gender:** M
Reported: 19/03/1999 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 31/12/1998 **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sexual dysfunction		Abnormal ejaculation.	

Medicine Details:

LOVAN (Suspected) **Reason:**
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 01/12/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was receiving lovan to help with public speaking. - 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: 137605 **Seq:** 1 **Gender:** U
Reported: 19/03/1999 **Weight:**
Hospitalisation: **Age:** 16Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sleep walking			Ceased prozac

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 80.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - benzodiazepine.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 137750 **Seq:** 1
Reported: 23/03/1999
Hospitalisation:
Onset Date: 31/03/1998
Outcome: Not yet recovered

Gender: F
Weight: 82.00
Age: 68Y
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Prozac ceased 1 year ago due to brusing. brusing resolved. brusing reappeared 3 days after starting prozac in february 1999. please see original report for details of other drugs - pravachol. - 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 137853 **Seq:** 1 **Gender:** F
Reported: 26/03/1999 **Weight:** 48.00
Hospitalisation: **Age:** 65Y
Onset Date: 10/07/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bradycardia Hyponatraemia			

Medicine Details:

PREMIX (Suspected) **Reason:**
Injection, intravenous infusion 1.3 Litre Daily Intravenous
Batch: **Started:** **Stopped:**

INTRALIPID (Suspected) **Reason:**
Injection, intravenous infusion 600.0 Millilitre Daily Intravenous
Batch: **Started:** **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

VANCOMYCIN HYDROCHLORIDE (Suspected) **Reason:**
Injection, intravenous infusion 1.2 Gram Daily Intravenous
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has history of panhypopituitarism and diabetes insipidus. admitted with laceration of the pancreas on 30-05-98 after a motor vehicle accident. partial pancreotomy was performd on the 31-05-98. this patient has multiple disease states and manifold medical problems coupled with intractable fluid and electrolyte balance. see original report for details of other drugs-octreotide, dextrose/sodium chloride, ranitidine, thyroxine. chloral hydrate, ddavp. and paracetamol.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 137853 **Seq:** 1 **Gender:** F
Reported: 26/03/1999 **Weight:** 48.00
Hospitalisation: **Age:** 65Y
Onset Date: 10/07/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

GENTAMICIN SULPHATE (Suspected)			**Reason:**	
Injection, intravenous infusion	200.0	Milligram	Daily	Intravenous
Batch:	**Started:**			**Stopped:**
HYDROCORTISONE (Suspected)			**Reason:**	
Injection, intravenous infusion	50.0	Milligram	Daily	Intravenous
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Additional Information:

Patient has history of panhypopituitarism and diabetes insipidus. admitted with laceration of the pancreas on 30-05-98 after a motor vehicle accident. partial pancreotomy was performd on the 31-05-98. this patient has multiple disease states and manifold medical problems coupled with intractable fluid and electrolyte balance. see original report for details of other drugs-octreotide, dextrose/sodium chloride, ranitidine, thyroxine. chloral hydrate, ddavp. and paracetamol.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 137977 **Seq:** 1 **Gender:** F
Reported: 30/03/1999 **Weight:**
Hospitalisation: **Age:** 43Y
Onset Date: 12/03/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema		Puffy face	
Oedema peripheral		Puffy feet and wrists	
Urticaria		Rash trunk, arms, leg, patchy red welts.	Oral prednisolone commenced. prozac ceased.

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** 08/03/1999 **Stopped:** 13/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred after dose was increased from 20mg daily 26/2/99 to 40mg daily on 8/3/99. see original report for other drugs: xanax, melleril, temazepam.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 138145 **Seq:** 1 **Gender:** F
Reported: 06/04/1999 **Weight:** 45.00
Hospitalisation: **Age:** 25Y
Onset Date: 20/03/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itchy papules.	
Rash maculo-papular		Rash on neck.	

Medicine Details:

LOVAN (Suspected) **Reason:**
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 18/03/1999 **Stopped:** 23/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had also been using a new shampoo but has reintroduced this after rash cleared & rash hasn't returned.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 138237 **Seq:** 1 **Gender:** F
Reported: 06/04/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: 25/02/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia Rash			

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral application 60.0 Milligram Daily Oral
Batch: **Started:** 01/12/1998 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 138238 **Seq:** 1 **Gender:** M
Reported: 06/04/1999 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia		Bilateral gynaecomastia	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** 01/01/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Approximatley 2-4 days after increasing dose of lovan to 40mg daily, the patient noticed breast discomfort which progressed to nipple inflammation and bilateral gynaecomastia. the patient's right breast is more severly affected. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 138503 **Seq:** 1 **Gender:** F
Reported: 19/04/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash	Severe	Severe skin rash	

Medicine Details:

LOVAN (Suspected) **Reason:** Unspecifid affective psychosis

Tablet 20.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Please see original report for details of other drugs - premarin,

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 138504 **Seq:** 1 **Gender:** M
Reported: 19/04/1999 **Weight:**
Hospitalisation: **Age:** 21Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight decreased			Lovan discontinued

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 01/03/1999 **Stopped:** 5W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was originally 80kg and is now 63kg. the patient experienced a total loss of 17kgs. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 138505 **Seq:** 1 **Gender:** F
Reported: 19/04/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/03/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia Paraesthesia		Numbness in face & extremities	

Medicine Details:

PROZAC (Suspected) **Reason:**

Tablet 5.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is taking the dispersible tablet of prozac. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 138506 **Seq:** 1 **Gender:** F
Reported: 19/04/1999 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenic purpura		Ideopathic thrombocytopenic purpura	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets				The patient recorded a platelet count of 36,000 a few weeks ago. the patient now has a platelet count of 24,000.

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 138635 **Seq:** 1 **Gender:** F
Reported: 22/04/1999 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 29/03/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rhinitis	Severe	Severe rhinitis	
Hyperhidrosis	Severe	Severe sweating	Zoloft discontinued

Medicine Details:

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

ZOLOFT (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** 29/03/1999 **Stopped:** 20/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 138851 **Seq:** 1
Reported: 29/04/1999
Hospitalisation: Admitted to hospital
Onset Date: 19/03/1999
Outcome: Unknown

Gender: F
Weight:
Age: 85
DOB: 11/01/1914
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

RULIDE (Suspected) **Reason:** Pneumonia,unspecified
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 19/03/1999

FRUSEMIDE (Suspected) **Reason:** Congestive heart failure
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 19/03/1999

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 19/03/1999

SPIRONOLACTONE (Suspected) **Reason:** Congestive heart failure
75.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Na 124

Additional Information:

See original report on details of other drugs: paracetamol, potassium, mersalazine.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 138851 **Seq:** 1
Reported: 29/04/1999
Hospitalisation: Admitted to hospital
Onset Date: 19/03/1999
Outcome: Unknown

Gender: F
Weight:
Age: 85
DOB: 11/01/1914
Causality: Causality possible

Reaction Detail

Medicine Details:

DIGOXIN (Suspected)			**Reason:**	Congestive heart failure
	125.0	Milligram	Daily	
Batch:	**Started:**		**Stopped:**	19/03/1999
SOTALOL HYDROCHLORIDE (Suspected)			**Reason:**	Congestive heart failure
	40.0	Milligram	Daily	
Batch:	**Started:**		**Stopped:**	19/03/1999

Laboratory Investigations:

Additional Information:

See original report on details of other drugs: paracetamol, potassium, mersalazine.

Report Detail

Case Number: 138858 **Seq:** 1
Reported: 29/04/1999
Hospitalisation: Admitted to hospital
Onset Date: 08/07/1998
Outcome: Recovered

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

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Confusional state Diarrhoea Nausea Vomiting	Severe	Severe hyponatraemia	Fluoxetine and natrilix were ceased. patient was treated with iv fluids n/s. lisinopril 20mg mane

Medicine Details:

NATRILIX (Suspected) **Reason:**
2.5 Milligram Daily
Batch: **Started:** 01/01/1992 **Stopped:** 08/07/1998

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/01/1994 **Stopped:** 08/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine		08/07/1998	57	
	Potassium		08/07/1998	3.5	
	Sodium		08/07/1998	117	
	Urea		08/07/1998	3.5	

Additional Information:

See original report for details of other drugs - provera, progynova, zocor, tilade, pulmicort. no known allergies. date of recovery: 12/7/98 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 139142 **Seq:** 1
Reported: 03/05/1999
Hospitalisation: Admitted to hospital
Onset Date: 18/03/1999
Outcome: Recovered

Gender: F
Weight:
Age: 61Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion Drug withdrawal syndrome		Grand mal seizure lasting approx. 1 minute	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Oral application 30.0 Milligram Reducing Oral

Batch: **Started:** **Stopped:** 17/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Please see original report for details of other drugs - oxazepam. patient was on 30mg prozac daily, on 30/3/99 dose was reduced to 20mg, then was further decreased to 10mg 16/3/99. patient's last dose was on 17/3/99. the following day the patient suffered symptoms. patient has no history of seizures.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 139147 **Seq:** 1 **Gender:** F
Reported: 03/05/1999 **Weight:**
Hospitalisation: **Age:** 18Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 02/02/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 139197 **Seq:** 1 **Gender:** F
Reported: 04/05/1999 **Weight:** 60.00
Hospitalisation: **Age:** 49Y
Onset Date: 02/03/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia Arthralgia Back pain		Aches & pains in lower back. Left hip & 5th finger on right hand.	Aspirin 300mg bd - 6 weeks.

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 02/02/1999 **Stopped:** 02/03/1999

PROZAC (Suspected) **Reason:**
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** 02/03/1999 **Stopped:** 16/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Slight residual symptoms not considered significant previous intermittent lower back pain, nurses back.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 139548 **Seq:** 1 **Gender:** M
Reported: 14/05/1999 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anuria			
Blood creatine phosphokinase in			
Hyponatraemia			
Oliguria			
Renal failure acute			
Rhabdomyolysis			

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 05/01/1999

PRAZOSIN HYDROCHLORIDE (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:** 05/01/1999

PERINDOPRIL (Suspected) **Reason:** Left ventricular failure
4.0 Milligram Daily
Batch: **Started:** 05/01/1999 **Stopped:** 08/01/1999

FRUSEMIDE (Suspected) **Reason:** Left ventricular failure
160.0 Milligram Daily
Batch: **Started:** 05/01/1999 **Stopped:** 08/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Calcium				Ca 2.31
	Creatine kinase		04/01/1999	-	Ck of 16 374 on 5/1/99 and 17 133 on 6/1/99, 3230 on 9/1/99.
	Creatine kinase		05/01/1999	293	Ck of 16 374 on 5/1/99 and 17 133 on 6/1/99, 3230 on 9/1/99.
	Creatine kinase		07/01/1999	-	Ck of 16 374 on 5/1/99 and 17 133 on 6/1/99, 3230 on 9/1/99.
	Creatine kinase		08/01/1999	-	Ck of 16 374 on 5/1/99 and 17 133 on 6/1/99, 3230 on 9/1/99.
	Creatine kinase		06/01/1999	<16	Ck of 16 374 on 5/1/99 and 17 133 on 6/1/99, 3230 on 9/1/99.
	Creatine kinase		09/01/1999	-	Ck of 16 374 on 5/1/99 and 17 133 on 6/1/99, 3230 on 9/1/99.

Additional Information:

See original report for details of other drugs: omeprazole, oxazepam.

Report Detail

Case Number: 139548 **Seq:** 1 **Gender:** M
Reported: 14/05/1999 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:** Depression	
	20.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:** 05/01/1999	
PRAZOSIN HYDROCHLORIDE (Suspected)			**Reason:**	
	2.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:** 05/01/1999	
PERINDOPRIL (Suspected)			**Reason:** Left ventricular failure	
	4.0 Milligram	Daily		
Batch:	**Started:** 05/01/1999		**Stopped:** 08/01/1999	
FRUSEMIDE (Suspected)			**Reason:** Left ventricular failure	
	160.0 Milligram	Daily		
Batch:	**Started:** 05/01/1999		**Stopped:** 08/01/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine [illegible]		04/01/1999	0.13	
	Creatine [illegible]		05/01/1999	0.13	
	Creatine [illegible]		06/01/1999	0.22	
	Creatine [illegible]		09/01/1999	0.59	
	Creatine [illegible]		08/01/1999	0.54	
	Creatine [illegible]		07/01/1999	0.32	
	Sodium		04/01/1999	116	

Additional Information:

See original report for details of other drugs: omeprazole, oxazepam.

Report Detail

Case Number: 139548 **Seq:** 1 **Gender:** M
Reported: 14/05/1999 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression
	20.0	Milligram	Daily	
Batch:	**Started:**		**Stopped:**	05/01/1999
PRAZOSIN HYDROCHLORIDE (Suspected)			**Reason:**	
	2.0	Milligram	Daily	
Batch:	**Started:**		**Stopped:**	05/01/1999
PERINDOPRIL (Suspected)			**Reason:**	Left ventricular failure
	4.0	Milligram	Daily	
Batch:	**Started:**	05/01/1999	**Stopped:**	08/01/1999
FRUSEMIDE (Suspected)			**Reason:**	Left ventricular failure
	160.0	Milligram	Daily	
Batch:	**Started:**	05/01/1999	**Stopped:**	08/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		05/01/1999	123	
	Sodium		06/01/1999	124	
	Sodium		07/01/1999	125	
	Sodium		08/01/1999	122	
	Sodium		09/01/1999	127	
	pH				Ph 2.35

Additional Information:

See original report for details of other drugs: omeprazole, oxazepam.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 140004 **Seq:** 1
Reported: 28/05/1999
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight:
Age:
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Pruritus			Steriods and promethazine hydrochloride (phenergan).

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 140064 **Seq:** 1 **Gender:** F
Reported: 31/05/1999 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 19/05/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral Periorbital oedema Dyspepsia Nausea Vomiting		Mirrored lesions palms of hand, Puffy eyes	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 16/04/1999 **Stopped:** 19/05/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 140565 **Seq:** 1 **Gender:** F
Reported: 11/06/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flatulence		Chronic wind	

Medicine Details:

PROZAC (Suspected) **Reason:**
Solution 7.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking losec. patient has a medical history pf scleroderma.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 140637 **Seq:** 1 **Gender:** F
Reported: 18/06/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: 26/05/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neonatal disorder		Constipation neonatal	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Breast milk transfer
Batch: **Started:** 01/01/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Marked constipation in a fully breast-fed baby. baby c.b. male 5 months. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 141330 **Seq:** 1 **Gender:** F
Reported: 09/07/1999 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Accommodation disorder		Difficulty judging distance in one eye only.	

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 0.0 Daily Oral
Batch: **Started:** 01/12/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a medical history of eye problems in both eyes prior to commencing prozac treatment. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 141660 **Seq:** 1 **Gender:** M
Reported: 16/07/1999 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: 31/12/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Acne Alopecia		Roughness to skin - very small pimples all	

Medicine Details:

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

LITHICARB (Suspected) **Reason:**
Tablet 1.0 Gram Daily Oral
Batch: **Started:** 01/09/1998 **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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 142244 **Seq:** 1 **Gender:** F
Reported: 02/08/1999 **Weight:** 80.00
Hospitalisation: **Age:** 25Y
Onset Date: 10/07/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Myoclonus	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 25/03/1999 **Stopped:** 20/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs: minulet, pulmicort, ventolin.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 142270 **Seq:** 1 **Gender:** M
Reported: 02/08/1999 **Weight:**
Hospitalisation: **Age:** 76Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia			

Medicine Details:

PROZAC (Suspected) **Reason:** Obsessive compulsive neurosis
Oral application 80.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drug. - stelazine.

Report Detail

Case Number: 142271 **Seq:** 1 **Gender:** F
Reported: 02/08/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		Missed period.	

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral application 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 1M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred 1 month after beginning prozac treatment.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 142418 **Seq:** 1
Reported: 05/08/1999
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 78Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gait disturbance		Unable to walk	Admitted to hospital

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**

0.0

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

ARICEPT (Suspected) **Reason:** Presenile dementia

Tablet 0.0 Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 142451 **Seq:** 1 **Gender:** F
Reported: 06/08/1999 **Weight:**
Hospitalisation: **Age:** 88Y
Onset Date: 05/01/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gait disturbance Tremor Agitation Dizziness Vertigo		Frequent falls Shakiness	Quinine stopped

Medicine Details:

QUININE (Suspected) **Reason:** Pain in limb
300.0 Milligram Daily
Batch: **Started:** 28/11/1998 **Stopped:** 13/01/1999

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 05/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

21/1/99 - patient was noted to be overall "much better" though walking still a little wobbly. see original report for details of other drugs - nifedipine, panadol, imodium.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 142548 **Seq:** 1 **Gender:** F
Reported: 11/08/1999 **Weight:** 50.00
Hospitalisation: **Age:** 70Y
Onset Date: 31/08/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Purpura lasting for 3 years.	

Medicine Details:

CORDARONE X (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

LOVAN (Suspected) **Reason:** Anxiety neurosis
Capsule 0.0 Dose Unspecified 1 time Oral
Batch: **Started:** 01/08/1996 **Stopped:** 28/01/1999

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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 142576 **Seq:** 1
Reported: 11/08/1999
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: U
Weight:
Age: 41Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypotension			

Medicine Details:

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

Tablet 0.0 Oral

Batch: **Started:** 01/05/1990 **Stopped:**

FLUOXETINE HYDROCHLORIDE (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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 142635 **Seq:** 1 **Gender:** F
Reported: 04/08/1999 **Weight:**
Hospitalisation: **Age:** 72Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea			Fluoxetine ceased.

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:** 1W

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.

Report Detail

Case Number: 142743 **Seq:** 1
Reported: 18/08/1999
Hospitalisation:
Onset Date: 22/07/1999
Outcome: Not yet recovered

Gender: F
Weight: 61.00
Age: 26Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

20.0 Milligram Daily

Batch: **Started:** 15/07/1999 **Stopped:** 13/08/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous alopecia with prozac four years ago. see original report for details of other drugs - lasix, slow k, duromine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 142993 **Seq:** 1 **Gender:** F
Reported: 26/08/1999 **Weight:**
Hospitalisation: **Age:** 47Y
Onset Date: 03/08/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Linear purpuric rash on left forearm.	

Medicine Details:

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

Oral application 20.0 Milligram Daily Oral

Batch: **Started:** 21/07/1999 **Stopped:** 06/08/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details on other drugs: risperidone, premarin, becotide.

Report Detail

Case Number: 143308 **Seq:** 1
Reported: 31/08/1999
Hospitalisation: Admitted to hospital
Onset Date: 17/07/1998
Outcome: Recovered

Gender: F
Weight:
Age: 23Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain		Abdominal discomfort	
Headache		Temporal headache	
Paraesthesia		Tingling in fingers	
Insomnia		Unable to sleep	
Agitation			
Anorexia			
Anxiety			
Chills			
Diarrhoea			
Hyperhidrosis			
Nausea			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 17/07/1998 **Stopped:** 19/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details on other drug: oral contraceptive pill. patient took three glasses of wine to assist sleep but caused nausea & vomting

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 143308 **Seq:** 1
Reported: 31/08/1999
Hospitalisation: Admitted to hospital
Onset Date: 17/07/1998
Outcome: Recovered

Gender: F
Weight:
Age: 23Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

40.0 Milligram Daily

Batch: **Started:** 17/07/1998 **Stopped:** 19/07/1998

Laboratory Investigations:

Additional Information:

See original report for details on other drug: oral contraceptive pill. patient took three glasses of wine to assist sleep but caused nausea & vomting

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 143446 **Seq:** 1 **Gender:** F
Reported: 03/09/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain		Body pain	
Rash		Rash all over the body & erythema on feet	
Gravitational oedema		Swelling of hands and feet	
Face oedema			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 143447 **Seq:** 1 **Gender:** M
Reported: 03/09/1999 **Weight:**
Hospitalisation: **Age:** 26Y
Onset Date: 17/07/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Small bite like redish spots	
Paraesthesia		Tingling, painful burning sensat underneath	Discontinuation of prozac

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 03/07/1999 **Stopped:** 17/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Please see original report for details of other drugs - benzodiazepine.

Report Detail

Case Number: 143448 **Seq:** 1 **Gender:** F
Reported: 03/09/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia		Painful joints	
Oedema peripheral		Swollen fingers	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 143547 **Seq:** 1 **Gender:** F
Reported: 10/09/1999 **Weight:**
Hospitalisation: **Age:** 54Y
Onset Date: 31/01/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual field defect Glaucoma		Bilateral constricted visual fields 1/98 &	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Oral application 1.0 Dose Unspecified Daily Oral

Batch: **Started:** 01/01/1994 **Stopped:** 31/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				Electrophysiology tests "general photoreceptor dystrophy" flash uer - very small, eog - very large.

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 stop date is not accurate but indicates that stoppage occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 143796 **Seq:** 1 **Gender:** F
Reported: 16/09/1999 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: 08/09/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hemiparesis		Dense right hemiparesis	
Cerebrovascular disorder		Embolic stroke	Clozaril ceased. patient remains on seizure prophylaxis iv phenytoin
Convulsion		Seizure	

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:** 09/09/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on 400-450mg daily of clozaril, daily dose had reached 800mg at one stage but had developed a seizure. patient has suffered fits in the past has been on epilim. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 143827 **Seq:** 1 **Gender:** F
Reported: 17/09/1999 **Weight:**
Hospitalisation: **Age:** A2
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypokinesia Thinking abnormal			

Medicine Details:

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 144301 **Seq:** 1 **Gender:** F
Reported: 05/10/1999 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Osteoarthritis Talipes Neonatal disorder		Arthrogryposis of both wrists Bilateral talipes	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 23/10/1998 **Stopped:** 17/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient became pregnant whilst on prozac, ceased prozac at 5-6 weeks pregnancy baby was born with arthrogryposis of both wrists & bilateral talipes, doing well otherwise (born 10/08/1999) husband (father of baby) had chemotherapy 1986 + 1990 for hodgkins lymphoma, very low sperm count.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 144748 **Seq:** 1 **Gender:** F
Reported: 18/10/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema			

Medicine Details:

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

Oral application 20.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient commenced fluoxetine treatment approximately 12 weeks ago. the patient expereinced facial oedema gradually during this time and the patient's husband initally noticed the event on 12.8.99.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 145576 **Seq:** 1 **Gender:** F
Reported: 09/11/1999 **Weight:**
Hospitalisation: **Age:** 20Y
Onset Date: 23/04/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Bizaqrre movements/gestures.	Risperidone ceased and changed to olanzepine and molleril
Depersonalisation		Patient states she felt strange.	
Speech disorder		Speech slow and childlike.	
Hypertonia			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 20/04/1998 **Stopped:** 30/04/1998

RISPERIDONE (Suspected) **Reason:**
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 21/04/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - lithium. patient history: older brother has scz, abused by father and husband, depression.

Report Detail

Case Number: 145805 **Seq:** 1 **Gender:** F
Reported: 11/11/1999 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: 05/11/1999 **DOB:** 19/02/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Congenital foot malformation		Congenital abnormality of left foot	Planning surgery to remove three toes and possibly a metatarsal bone at one year of age
Neonatal disorder		Permanent deformity	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
0.0
Batch: **Started:** 01/01/1997 **Stopped:** 28/04/1999

ZACTIN (Suspected) **Reason:**
0.0
Batch: **Started:** 01/04/1999 **Stopped:** 28/07/1999

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

MELLERIL (Suspected) **Reason:** Depression
Tablet 3.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:** 28/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Hypertrophic foot from his mid foot distally with an extra toe diagnosed as localised giantism.

Additional Information:

In 1997 mother started taking zoloft and 6 mths later started taking melleril. then she became pregnant. she was taking zoloft, melleril, zactin and largactil during pregnancy, also smoking 20-30 cigarettes per day, no alcohol. she is heb b vacc., syphilis neg. and rubella immunised. on 5/11/99 she had her 4th baby boy, born by spontaneous vaginal delivery at full term. he was noted as having a congenital abnormality of his left foot. he had a hypertrophic foot from his mid foot distally with an extra toe. his first two toes and his little toe and the medial side of his foot are normal. he has been seen by an orthopaedic surgeon and diagnosed with localised giantism. surgery is planned. otherwise the baby is doing well. he is bottle fed and gaining weight normally. he is due to

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 146268 **Seq:** 1 **Gender:** M
Reported: 26/11/1999 **Weight:** 85.00
Hospitalisation: **Age:** 63Y
Onset Date: 15/11/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction		Poor erectile function.	Will be withdrawn from fluoxetine gradually.

Medicine Details:

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

Oral application 20.0 Milligram Daily Oral

Batch: **Started:** 13/11/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details: zantac, naprosyn, & aspirin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 146373 **Seq:** 1 **Gender:** M
Reported: 01/12/1999 **Weight:** 72.00
Hospitalisation: **Age:** 63Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Apathy Somnolence Tinnitus		Extreme lethargy Lack of motivation	Ceased prozac

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** 01/09/1999 **Stopped:** 28/11/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

On stopping prozac patient recovered from lethargy and drowsiness but tinnitus persists. 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: 146521 **Seq:** 1 **Gender:** F
Reported: 02/12/1999 **Weight:**
Hospitalisation: **Age:** A7
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage		Gastrointestinal bleed.	Feldene discontinued.

Medicine Details:

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

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

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 146521 **Seq:** 1 **Gender:** F
Reported: 02/12/1999 **Weight:**
Hospitalisation: **Age:** A7
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Medicine Details:

ZOCOR (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
CAPOTEN (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
INSULIN NOS (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
CARTIA (Suspected)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 146521 **Seq:** 1 **Gender:** F
Reported: 02/12/1999 **Weight:**
Hospitalisation: **Age:** A7
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Medicine Details:

LOVAN (Suspected)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
FELDENE (Suspected)		**Reason:**	Unspecified arthritis
	20.0 Milligram	Daily	
Batch:	**Started:** 01/10/1999		**Stopped:** 08/11/1999

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 146844 **Seq:** 1 **Gender:** M
Reported: 13/12/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Epistaxis		Patient experienced nose bleeds.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

After taking lovan, the patient suffered nose bleeds.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 147003 **Seq:** 1
Reported: 16/12/1999
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

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

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 147156 **Seq:** 1 **Gender:** F
Reported: 21/12/1999 **Weight:** 108.00
Hospitalisation: **Age:** 41Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Nausea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was rechallenged on zactin with same reaction accurring.

Report Detail

Case Number: 147414 **Seq:** 1
Reported: 24/12/1999
Hospitalisation: Admitted to hospital
Onset Date: 12/07/1999
Outcome: Recovered

Gender: F
Weight:
Age: 77Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Thinking abnormal		Worsening cognitive dysfunction	Aricept ceased.

Medicine Details:

ARICEPT (Interaction) **Reason:** Presenile dementia

Tablet 5.0 Milligram Daily Oral

Batch: **Started:** 05/07/1999 **Stopped:** 19/07/1999

PROZAC (Interaction) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt also taking aspirin, folic acid, caltrate.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 147415 **Seq:** 1 **Gender:** F
Reported: 24/12/1999 **Weight:** 0.00
Hospitalisation: **Age:** 77
Onset Date: 18/07/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

ARICEPT (Interaction) **Reason:** Presenile dementia
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 05/07/1999 **Stopped:** 19/07/1999

PROZAC (Interaction) **Reason:** Depression
40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	ALT = SGPT		27/10/2003	190	
17/12/2002	ALT = SGPT		27/10/2003	-	
17/12/2002	ALT = SGPT		27/10/2003	25	
17/12/2002	AST = SGOT	<35	27/10/2003	213	
17/12/2002	AST = SGOT	<35	27/10/2003	34	
17/12/2002	AST = SGOT	<35	27/10/2003	20	
17/12/2002	GGT = SGGT =	<50	27/10/2003	111	

Additional Information:

Report Detail

Case Number: 147415 **Seq:** 1
Reported: 24/12/1999
Hospitalisation:
Onset Date: 18/07/1999
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 77
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

ARICEPT (Interaction)			**Reason:**	Presenile dementia
Tablet	5.0 Milligram	Daily		Oral
Batch:	**Started:** 05/07/1999		**Stopped:**	19/07/1999
PROZAC (Interaction)			**Reason:**	Depression
	40.0 Milligram	Daily		Oral
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	GGT = SGGT = SGTP	<50	27/10/2003	107	
17/12/2002	GGT = SGGT = SGTP	<50	27/10/2003	54	
17/12/2002	SAP = ALP	30 - 120	27/10/2003	155	
17/12/2002	SAP = ALP	30 - 120	27/10/2003	178	
17/12/2002	SAP = ALP	30 - 120	27/10/2003	114	

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 147801 **Seq:** 1 **Gender:** F
Reported: 10/01/2000 **Weight:**
Hospitalisation: **Age:** 90
Onset Date: 13/12/1999 **DOB:** 28/11/1909
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Vomiting			

Medicine Details:

PROZAC (Suspected) **Reason:**
2.0 Gram Alternate days
Batch: **Started:** **Stopped:** 13/12/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt also taking enalapril, frusemide, colchicine, digoxin, hydrea, imdur.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 147961 **Seq:** 1 **Gender:** M
Reported: 12/01/2000 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dry mouth			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 148270 **Seq:** 1 **Gender:** F
Reported: 24/01/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Pruritus			

Medicine Details:

PROZAC (Suspected) **Reason:** Obsessive compulsive neurosis
Oral application 80.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 148292 **Seq:** 1 **Gender:** F
Reported: 24/01/2000 **Weight:**
Hospitalisation: **Age:** A4
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Cogentin 20mg/day.

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Oral application 5.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 148713 **Seq:** 1 **Gender:** M
Reported: 09/02/2000 **Weight:** 100.00
Hospitalisation: **Age:** 41
Onset Date: **DOB:** 09/09/1958
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression			

Medicine Details:

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

PROZAC (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/11/1999 **Stopped:** 29/11/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

At this time pt had also been abusing alcohol. pt previously been on prozac and same reaction occurred.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 148714 **Seq:** 1 **Gender:** M
Reported: 09/02/2000 **Weight:** 68.00
Hospitalisation: **Age:** 76Y
Onset Date: 21/01/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 21/01/2000 **Stopped:** 23/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking prozac, plaquenil, isoptin, avapro, cartia.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 149205 **Seq:** 1 **Gender:** F
Reported: 16/02/2000 **Weight:** 69.00
Hospitalisation: **Age:** 31
Onset Date: 21/01/2000 **DOB:** 09/01/1969
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Rash on both lower limbs.	

Medicine Details:

ZACTIN (Suspected) **Reason:** Obsessive compulsive neurosis
20.0 Milligram Daily
Batch: **Started:** 11/01/2000 **Stopped:** 22/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 149693 **Seq:** 1 **Gender:** F
Reported: 28/02/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor		Coarse rest tremor	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking hormone replacement.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 150142 **Seq:** 1
Reported: 09/03/2000
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight:
Age: 81Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor		Shaking motion all over her body	Lovan ceased

Medicine Details:

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

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 17/02/2000 **Stopped:** 25/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 150356 **Seq:** 1 **Gender:** F
Reported: 13/03/2000 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 07/03/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion neonatal Drug withdrawal syndrome neona Jaundice neonatal Muscle twitching			

Medicine Details:

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

Oral application 40.0 Milligram Alternate days Breast milk transfer

Batch: **Started:** **Stopped:** 08/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother on fluoxetine throughtout pregnancy. the baby was born on 7/3/2000. jitteriness was first reported on the same day at 2100 hours. sepsis, hypoglycaemia and fluoxetine withdrawal were suspected causes of the problem. sepsis and hypoglycaemia were subsequently ruled out. the baby was discharged on 10/3/2000. he had a little jitteriness and mild jaundice, but was otherwise well.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 150594 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:** 90.00
Hospitalisation: **Age:** 62Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nail disorder Alopecia		Brittle nails.	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/05/1999 **Stopped:** 28/06/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking di-gesic, voltaren, temazepam, provelle. 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: 150603 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:**
Hospitalisation: **Age:** 32Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Galactorrhoea		Prolonged diarrhoea	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 29/01/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has normal prolactin level.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 150607 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:**
Hospitalisation: **Age:** 33Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia Galactorrhoea		Raised prolactin levels.	Prozac treatment was

Medicine Details:

PROZAC (Suspected) **Reason:**
80.0 Milligram Daily
Batch: **Started:** 01/07/1999 **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.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 151072 **Seq:** 1 **Gender:** F
Reported: 31/03/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Experienced lactation (continuos breast	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 80.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Continuous breast secretions has been occurring for over 1 year, since having had a baby. the patient did not breast feed this baby.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 152211 **Seq:** 1 **Gender:** M
Reported: 01/05/2000 **Weight:** 0.00
Hospitalisation: **Age:** 49Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Platelet aggregation abnormal Thrombocytopenia		Abnormal platelet aggregation	

Medicine Details:

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

BENZTROPINE MESYLATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

DESIPRAMINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Platelets				Platelets count 112.

Additional Information:

Report Detail

Case Number: 153002 **Seq:** 1 **Gender:** F
Reported: 24/05/2000 **Weight:**
Hospitalisation: **Age:** 28Y
Onset Date: 20/04/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Vertigo Vomiting			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 17/04/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking epilim. 3 days afer ceasing prozac patient suffered acute symptoms.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 153110 **Seq:** 1 **Gender:** M
Reported: 26/05/2000 **Weight:** 89.00
Hospitalisation: **Age:** 57Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sleep disorder Neurosis Aggression Headache		Abusive verbally at times in his sleep. Was throwing himself out of bed & woke on floor	Zactin ceased

Medicine Details:

ZACTIN (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 01/01/1993 **Stopped:** 12/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking lipex. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Report Detail

Case Number: 153351 **Seq:** 1 **Gender:** F
Reported: 02/06/2000 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: **DOB:** 20/09/1962
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cholecystitis			Cholecystectomy

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**

Oral application 90.0 Milligram Daily Oral

Batch: **Started:** 08/02/2000 **Stopped:** 29/04/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Adr accurred in postmarketing trial.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 154026 **Seq:** 1 **Gender:** M
Reported: 23/06/2000 **Weight:** 90.00
Hospitalisation: **Age:** 44
Onset Date: **DOB:** 03/08/1955
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Fatigue Psoriasis Suicide attempt		Mood worsened	Prozac ceased. date of recovery 21/06/00. required a visit to doctor

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
80.0 Milligram Weekly
Batch: **Started:** 01/02/2000 **Stopped:** 16/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking methotrexate, norvasc. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 154034 **Seq:** 1
Reported: 23/06/2000
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight:
Age: 18Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome Headache Nausea			

Medicine Details:

PROZAC (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 01/01/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has been taking prozac therapy 50mg/day since 1997. dose was gradually decreased to 10mg/day when symptoms occurred. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 154326 **Seq:** 1
Reported: 03/07/2000
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

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

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures.	Diazepam and sodium valproate 1500mg (500 mg im and 1000 mg ie), flucloxacillin and cefotaxime. sodium valproate ceased. leg
Arthritis Sepsis		Septic arthritis of the left knee.	

Medicine Details:

PROZAC (Interaction) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

EPILIM (Interaction) **Reason:** Other&unspecified epilepsy
2.5 Gram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics Microbiology				Electrographics (eeg) - was performed and the result was Infection was confirmed to be caused by staphylococcus aureus.

Additional Information:

The sodium valproate had been ceased and one month later the patient was prescribed fluoxetine 20mg. eight days later the patient had a fall and suffered seizures after the fall. the patient's medical history includes probable pseudo seizures (epilepsy). on the fourth day of the second hospital admission, patient had her left leg amputated - sequelae. patient was also given morphine and morphine sulphate on regular basis.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 154370 **Seq:** 1 **Gender:** M
Reported: 01/07/2000 **Weight:**
Hospitalisation: **Age:** 76Y
Onset Date: 13/05/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysarthria		Difficulty talking	
Convulsion		Myoclonus of limbs.	
Chills			Given diazepam 5mg iv x 1 dose, cyproheptadine 4mg po x 1dose
Confusional state			
Coordination abnormal			
Gait disturbance			
Serotonin syndrome			

Medicine Details:

KLACID (Suspected) **Reason:** Otr&nos infec&parasit diseases
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 27/04/2000 **Stopped:** 14/05/2000

LOVAN (Suspected) **Reason:** Depression
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** 01/04/2000 **Stopped:** 15/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking androcur, calcitriol, aspirin, atrovent forte, ventolin. patient recovered 16/5/00.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 154591 **Seq:** 1
Reported: 07/07/2000
Hospitalisation: Admitted to hospital
Onset Date: 30/04/2000
Outcome: Unknown

Gender: U
Weight:
Age: 68
DOB: 09/08/1931
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Dyspnoea		Exacerbation of pre-existing anxiety. Worsening of shortness of breath.	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 02/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking prednisolone, gtn 25 ptach, calcitriol, theodur, flixotide, bactim ds, ventolin and atrovent. history: severe copd.

Report Detail

Case Number: 154853 **Seq:** 1 **Gender:** F
Reported: 17/07/2000 **Weight:** 60.00
Hospitalisation: **Age:** 79Y
Onset Date: 01/07/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Anxiety Diarrhoea			

Medicine Details:

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

CIPRAMIL (Interaction) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking ativan, karvea, durabolin, lipitor and pepcidine.

Report Detail

Case Number: 155302 **Seq:** 1 **Gender:** M
Reported: 21/06/2000 **Weight:**
Hospitalisation: **Age:** 44
Onset Date: **DOB:** 03/08/1955
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psoriasis			Prozac ceased.

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 01/04/2000 **Stopped:** 28/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking alcohol, methotrexate, folic acid. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 155710 **Seq:** 1 **Gender:** F
Reported: 31/07/2000 **Weight:** 125.00
Hospitalisation: **Age:** 51
Onset Date: **DOB:** 20/01/1949
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

METHOTREXATE (Suspected) **Reason:**
15.0 Milligram Weekly
Batch: **Started:** 01/01/1996 **Stopped:**

ARAVA (Suspected) **Reason:** Other rheumatoid arthritis
20.0 Milligram Daily
Batch: **Started:** 01/03/2000 **Stopped:** 28/07/2000

WARFARIN SODIUM (Suspected) **Reason:**
5.0 Milligram Daily
Batch: **Started:** 01/01/1998 **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	5 - 40	17/05/2000	60	
	ALT = SGPT	5 - 40	13/06/2000	76	
	ALT = SGPT	5 - 40	03/07/2000	47	
	ALT = SGPT	5 - 40	23/08/2000	51	
	ALT = SGPT	5 - 40	26/07/2000	61	
	AST = SGOT	5 - 40	17/05/2000	33	
	AST = SGOT	5 - 40	13/06/2000	45	

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

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 155710 **Seq:** 1
Reported: 31/07/2000
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 125.00
Age: 51
DOB: 20/01/1949
Causality: Causality possible

Reaction Detail

Medicine Details:

ROCALTROL (Suspected)			**Reason:**	
	0.5	Microgram	Daily	
Batch:	**Started:**			**Stopped:**
CELEBREX (Suspected)			**Reason:**	
	400.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
LOSEC (Suspected)			**Reason:**	
	40.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	5 - 40	26/07/2000	36	
	AST = SGOT	5 - 40	03/07/2000	41	
	AST = SGOT	5 - 40	23/08/2000	34	
	Bilirubin	3 - 20	17/05/2000	9	
	Bilirubin	3 - 20	13/06/2000	10	
	Bilirubin	3 - 20	03/07/2000	6	
	Bilirubin	3 - 20	26/07/2000	8	

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. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 155710 **Seq:** 1
Reported: 31/07/2000
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 125.00
Age: 51
DOB: 20/01/1949
Causality: Causality possible

Reaction Detail

Medicine Details:

METHOTREXATE (Suspected)		**Reason:**	
	15.0 Milligram	Weekly	
Batch:	**Started:** 01/01/1996		**Stopped:**
ARAVA (Suspected)		**Reason:**	Other rheumatoid arthritis
	20.0 Milligram	Daily	
Batch:	**Started:** 01/03/2000		**Stopped:** 28/07/2000
WARFARIN SODIUM (Suspected)		**Reason:**	
	5.0 Milligram	Daily	
Batch:	**Started:** 01/01/1998		**Stopped:**
PROZAC (Suspected)		**Reason:**	
	20.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	3 - 20	23/08/2000	6	
	GGT = SGGT =	5 - 65	17/05/2000	87	
	GGT = SGGT =	5 - 65	13/06/2000	86	
	GGT = SGGT =	5 - 65	03/07/2000	67	
	GGT = SGGT =	5 - 65	26/07/2000	80	
	GGT = SGGT =	5 - 65	23/08/2000	63	
	SAP = ALP	30 - 115	17/05/2000	203	

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

Report Detail

Case Number: 155710 **Seq:** 1
Reported: 31/07/2000
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 125.00
Age: 51
DOB: 20/01/1949
Causality: Causality possible

Reaction Detail

Medicine Details:

ROCALTROL (Suspected)			**Reason:**	
	0.5	Microgram	Daily	
Batch:	**Started:**			**Stopped:**
CELEBREX (Suspected)			**Reason:**	
	400.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
LOSEC (Suspected)			**Reason:**	
	40.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	30 - 115	13/06/2000	201	
	SAP = ALP	30 - 115	03/07/2000	188	
	SAP = ALP	30 - 115	26/07/2000	196	
	SAP = ALP	30 - 115	23/08/2000	183	

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

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 155941 **Seq:** 1 **Gender:** M
Reported: 04/08/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Tremor			

Medicine Details:

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

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 156069 **Seq:** 1
Reported: 11/08/2000
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight:
Age: 35
DOB: 03/12/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Apathy		Flat mood and panic feelings.	
Fatigue		Low energy and motivation & feeling of	
Depression		Worsening of depression & anxiety	Patient hospitalised.

Medicine Details:

OLANZAPINE (Suspected) **Reason:** Depression
Tablet 6.0 Milligram Daily Oral
Batch: **Started:** 03/08/2000 **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 03/08/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 156895 **Seq:** 1 **Gender:** M
Reported: 24/08/2000 **Weight:** 69.00
Hospitalisation: **Age:** 34Y
Onset Date: 13/08/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia Diarrhoea			Lovan ceased. reactions settle 2 days after stopping.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 02/08/2000 **Stopped:** 09/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 157226 **Seq:** 1 **Gender:** F
Reported: 31/08/2000 **Weight:** 72.00
Hospitalisation: **Age:** 39
Onset Date: 20/08/2000 **DOB:** 12/04/1961
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast pain Breast pain			Date of recovery 25.8.00. required a visit to doctor.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 17/08/2000 **Stopped:** 23/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 157294 **Seq:** 1 **Gender:** F
Reported: 01/09/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Dyspnoea Rash			

Medicine Details:

PROZAC (Suspected) **Reason:** Obsessive compulsive neurosis

Oral application 20.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Approx 2-3 months ago the patient was commenced on prozac 20mg/day. two weeks following treatment at this dose the patient experienced marked dyspnoea, some anxiousness and a rash. the pateint discontinued prozac. in july 2000 patient recommenced prozac at 20mg/day without any reaction. the dose was then increased to 40mg/day and the patient is experiencing a small degree of respiratory distress, with no rash.

Report Detail

Case Number: 157350 **Seq:** 1
Reported: 04/09/2000
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 96.00
Age: 57
DOB: 14/01/1943
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia		Tender left-sided gynaecomastia.	

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression

20.0 Milligram Daily

Batch: **Started:** 30/05/2000 **Stopped:** 30/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient's symptoms started approx. 4-6 weeks after starting zactin.

Report Detail

Case Number: 157781 **Seq:** 1 **Gender:** M
Reported: 13/09/2000 **Weight:**
Hospitalisation: **Age:** 76Y
Onset Date: 08/08/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Inappropriate antidiuretic hormon			Fluoxetine ceased.

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 11/07/2000 **Stopped:** 08/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrolytes				Sodium = 121, decreased serum osmolality, increased na+

Additional Information:

Patient also taking thiamine, dilantin, ostelin, caltrate.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 157916 **Seq:** 1 **Gender:** M
Reported: 20/09/2000 **Weight:** 80.00
Hospitalisation: **Age:** 33Y
Onset Date: 14/08/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dry mouth Micturition disorder Nausea			Date of recovery 25.8.00.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 12/08/2000 **Stopped:** 22/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 158322 **Seq:** 1 **Gender:** M
Reported: 09/10/2000 **Weight:**
Hospitalisation: **Age:** 55
Onset Date: 08/08/2000 **DOB:** 05/05/1945
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention			Fluoxetine ceased.

Medicine Details:

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

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 26/07/2000 **Stopped:** 17/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 158606 **Seq:** 1
Reported: 16/10/2000
Hospitalisation: Admitted to hospital
Onset Date: 15/09/2000
Outcome: Recovered

Gender: M
Weight: 72.00
Age: 72Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Fatigue Hyponatraemia Personality disorder			Lovan ceased. hospital admission

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

20.0 Milligram Daily

Batch: **Started:** 24/08/2000 **Stopped:** 17/09/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	135 - 145	15/09/2000	128	
	Sodium	135 - 145	26/09/2000	134	

Additional Information:

Patient also taking simvastatin, salbutamol, fluticasone, salmeterol, omeprazole, aspirin, prednisolone, diltiazem, colofac.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 159071 **Seq:** 1 **Gender:** F
Reported: 06/11/2000 **Weight:** 56.00
Hospitalisation: **Age:** 46
Onset Date: 01/07/2000 **DOB:** 05/05/1954
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

PROZAC (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking solprin, oroxine, slow k, fentanyl patch.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 159470 **Seq:** 1
Reported: 22/11/2000
Hospitalisation:
Onset Date: 18/09/2000
Outcome: Not yet recovered

Gender: F
Weight: 51.00
Age: 13Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abnormal dreams Dizziness Euphoric mood Fatigue Increased appetite Myalgia			Fluoxetine ceased.

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Obsessive compulsive neurosis

40.0 Milligram Daily

Batch: **Started:** 18/09/2000 **Stopped:** 13/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Fluoxetine therapy was taken at 20mg/daily on 28/07/2000. reaction occurred when dose was increased to 40mg/daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 159653 **Seq:** 1 **Gender:** F
Reported: 30/11/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bronchospasm			Patient was admitted to

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

Oral application 20.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient's medical history is severe depression and she is 31 weeks pregnant.

Report Detail

Case Number: 159972 **Seq:** 1 **Gender:** F
Reported: 14/12/2000 **Weight:** 65.00
Hospitalisation: **Age:** 31Y
Onset Date: 06/12/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Affect lability Agitation Depression			

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

Oral application 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 07/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 160159 **Seq:** 1 **Gender:** M
Reported: 21/12/2000 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 16/11/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure		Difficulty ejaculating	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/04/2000 **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: 160557 **Seq:** 1 **Gender:** M
Reported: 10/01/2001 **Weight:** 70.00
Hospitalisation: **Age:** 60
Onset Date: 01/01/2001 **DOB:** 13/07/1940
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/01/2000 **Stopped:** 08/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 160581 **Seq:** 1 **Gender:** F
Reported: 15/01/2001 **Weight:** 57.00
Hospitalisation: **Age:** 35
Onset Date: 01/01/2001 **DOB:** 30/09/1965
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia			Required a visit to doctor. date of recovery 10.1.01.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 161061 **Seq:** 1
Reported: 31/01/2001
Hospitalisation: Admitted to hospital
Onset Date: 17/01/2001
Outcome: Unknown

Gender: M
Weight:
Age: 81
DOB: 21/03/1919
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression			Patient hospitalised

Medicine Details:

TIMOLOL MALEATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

LIPEX (Other drug) **Reason:** Othr&unspec metabolic diseases
80.0 Milligram Daily
Batch: **Started:** 05/11/1999 **Stopped:** CONTIN

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Oral application 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Used in ct but not a ct drug.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 161061 **Seq:** 1
Reported: 31/01/2001
Hospitalisation: Admitted to hospital
Onset Date: 17/01/2001
Outcome: Unknown

Gender: M
Weight:
Age: 81
DOB: 21/03/1919
Causality: Causality possible

Reaction Detail

Medicine Details:

OLANZAPINE (Suspected) **Reason:**

Oral application	48.0	Milligram	Daily	Oral

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

Laboratory Investigations:

Additional Information:

Used in ct but not a ct drug.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 161393 **Seq:** 1 **Gender:** F
Reported: 12/02/2001 **Weight:** 85.00
Hospitalisation: **Age:** 34
Onset Date: 31/12/2000 **DOB:** 12/06/1966
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania		Hypomania	Antipsychotics.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/01/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

P/h of hypomania in 1995, depression since 1996. - 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 161429 **Seq:** 1 **Gender:** U
Reported: 12/02/2001 **Weight:** 68.00
Hospitalisation: **Age:** 43
Onset Date: 24/01/2001 **DOB:** 22/04/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			Therapy switched to arima.

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/12/2000 **Stopped:** 20/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking ventolin, pulmicort, ranitidine. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 161560 **Seq:** 1 **Gender:** M
Reported: 16/02/2001 **Weight:**
Hospitalisation: **Age:** 90Y
Onset Date: 02/02/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dehydration Diarrhoea			Ceased fluoxetine, treated with

Medicine Details:

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

Oral application 40.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking cyproterone, nitrazepam, ventolin.

Report Detail

Case Number: 161764 **Seq:** 1 **Gender:** F
Reported: 19/02/2001 **Weight:** 100.00
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Unrelated death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema Rash pustular			Patient died from cardiac

Medicine Details:

SALAZOPYRIN (Suspected) **Reason:** Other rheumatoid arthritis
Oral application 1.0 Gram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

ARTHRO-AID (Suspected) **Reason:** Unspecified arthritis
Oral application 2.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** CONTIN

DORYX (Suspected) **Reason:**
Oral application 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

ENDONE (Suspected) **Reason:** Pain
Oral application 2.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 161764 **Seq:** 1 **Gender:** F
Reported: 19/02/2001 **Weight:** 100.00
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Unrelated death **Causality:** Causality possible

Reaction Detail

Medicine Details:

FLUVASTATIN (Suspected)			**Reason:**	Othr&unspec metabolic diseases		
Oral application	40.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
MS CONTIN (Suspected)			**Reason:**	Pain		
Oral application	20.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
PREDNISOLONE (Suspected)			**Reason:**			
Oral application	12.5	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
PROZAC (Suspected)			**Reason:**	Depression		
Oral application	2.0	Dose Unspecified	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 161764 **Seq:** 1
Reported: 19/02/2001
Hospitalisation:
Onset Date:
Outcome: Unrelated death

Gender: F
Weight: 100.00
Age: 55Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

ROCALTROL (Suspected)			**Reason:**	Osteoporosis		
Oral application	2.0	Dose Unspecified	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
ZANTAC (Suspected)			**Reason:**			
Oral application	300.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 161805 **Seq:** 1 **Gender:** M
Reported: 22/02/2001 **Weight:** 85.00
Hospitalisation: **Age:** 46
Onset Date: 08/02/2001 **DOB:** 22/06/1954
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema Urticaria			Antihistamine. required a visit to doctor. date of recovery 15/02/01

Medicine Details:

TIMOLOL MALEATE EYE DROPS (Other drug) **Reason:** Unspecified glaucoma

Eye Drops 4.0 Dose Unspecified Daily Ophthalmic

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

LOVAN (Suspected) **Reason:** Depression

20.0 Milligram Daily

Batch: **Started:** 05/02/2001 **Stopped:** 09/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 162003 **Seq:** 1 **Gender:** M
Reported: 26/02/2001 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 19/02/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation Somnolence		Floating feeling unable to drive.	

Medicine Details:

CLINDAMYCIN HYDROCHLORIDE (Interaction) **Reason:** Other cellulitis and abscess
Oral application 300.0 Milligram Daily Oral
Batch: **Started:** 19/02/2001 **Stopped:**

PROZAC (Interaction) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/2000 **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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 162153 **Seq:** 1 **Gender:** M
Reported: 03/03/2001 **Weight:**
Hospitalisation: **Age:** 43Y
Onset Date: 28/02/2001 **DOB:**
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sudden death		Patient died from cardiac arrest in his sleep	

Medicine Details:

ZYBAN SR (Suspected) **Reason:** Smoker
0.0
Batch: **Started:** 21/02/2001 **Stopped:**

LOVAN (Suspected) **Reason:** Depression
0.0
Batch: **Started:** 21/02/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 162955 **Seq:** 1 **Gender:** F
Reported: 22/03/2001 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: 09/03/2001 **DOB:** 16/07/1963
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased		Difficulty reaching orgasim.	Not yet recovered date

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/11/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking - levlen ed. 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 163263 **Seq:** 1 **Gender:** M
Reported: 02/04/2001 **Weight:**
Hospitalisation: **Age:** 66
Onset Date: **DOB:** 20/03/1935
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rectal haemorrhage		Reclal bleeding 500ml.	Vitamin k iv, colonoscopy.

Medicine Details:

WARFARIN SODIUM (Suspected) **Reason:**
0.0
Batch: **Started:** 17/11/2000 **Stopped:** 19/11/2000

ASPIRIN (Suspected) **Reason:**
150.0 Milligram Daily
Batch: **Started:** **Stopped:** 17/11/2000

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

CLEXANE (Suspected) **Reason:**
140.0 Milligram Daily
Batch: **Started:** 15/11/2000 **Stopped:** 19/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking lisinopril, zantac, diazepam.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 163374 **Seq:** 1
Reported: 02/04/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight:
Age: 25Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypotonia Syncope		Eyes rolled back and he became Unconscious for 3 minutes.	Patient was hospitalised for 2 days for observation. lovan

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 163781 **Seq:** 1 **Gender:** F
Reported: 18/04/2001 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: 04/03/2001 **DOB:** 02/07/1951
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Convulsion Delirium			Bupropion ceased.

Medicine Details:

ZYBAN SR (Interaction) **Reason:** Smoker
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 28/02/2001 **Stopped:** 23/03/2001

FLUOXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

DOXEPIN HYDROCHLORIDE (Interaction) **Reason:** Anxiety neurosis
Oral application 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 163781 **Seq:** 1 **Gender:** F
Reported: 18/04/2001 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: 04/03/2001 **DOB:** 02/07/1951
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

SULFASALAZINE (Other drug)				**Reason:**	Regional enteritis
	1.5	Gram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	
PANTOPRAZOLE (Other drug)				**Reason:**	Other diseases of esophagus
Oral application	80.0	Milligram	Daily	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 164053 **Seq:** 1 **Gender:** M
Reported: 27/04/2001 **Weight:** 68.00
Hospitalisation: **Age:** 77
Onset Date: 22/03/2001 **DOB:** 16/12/1923
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Diarrhoea Micturition disorder			Mylanta. prozac ceased.

Medicine Details:

CARTIA (Other drug) **Reason:**
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

PLAQUENIL (Other drug) **Reason:**
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

AVAPRO (Other drug) **Reason:** Essential benign hypertension
75.0 Milligram Daily
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 164053 **Seq:** 1

Reported: 27/04/2001

Hospitalisation:

Onset Date: 22/03/2001

Outcome: Recovered

Gender: M

Weight: 68.00

Age: 77

DOB: 16/12/1923

Causality: Causality possible

Reaction Detail

Medicine Details:

ISOPTIN (Other drug)			**Reason:**	Essential benign hypertension
	320.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
PROZAC (Suspected)			**Reason:**	Depression
	20.0	Milligram	Daily	
Batch:	**Started:**	20/03/2001		**Stopped:** 14/04/2001

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 164527 **Seq:** 1 **Gender:** M
Reported: 14/05/2001 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 01/01/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia		Muscle cramps under knee cap severe	Zactin ceased. date of recovery 23/03/01.

Medicine Details:

NUROFEN (Other drug) **Reason:** Otr&unsp vertebrogen pain synd
200.0 Milligram As necessary
Batch: **Started:** **Stopped:**

PANADEINE FORTE (Other drug) **Reason:** Otr&unsp vertebrogen pain synd
2.0 Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

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

ZACTIN (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 01/01/1993 **Stopped:** 20/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Severe muscle cramps under knee cap. last up to hours at a time, relieved by stretching. occurrs up to 3 - 4 times a week. ceased zactin 20/03/01 after a f fall and pain disappeared within 2-3 days. pt is alcoholic - drinks 1 task of wine every night.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 164697 **Seq:** 1
Reported: 21/05/2001
Hospitalisation: Admitted to hospital
Onset Date: 30/04/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 48
DOB: 20/09/1952
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bronchospasm Face oedema Hypersensitivity Nausea Tongue oedema Urticaria			Patient was hospitalised. treated with normal saline iv 2 litres, phenergan 25mg iv, hydrocortisone 100mg iv, valium 5mg oral and commenced on prednisolone

Medicine Details:

ASPRO (Other drug) **Reason:** Migraine
Tablet 0.0 Oral
Batch: **Started:** 01/10/1999 **Stopped:** CONTIN

ASPIRIN (Other drug) **Reason:** Headache
Oral application 0.0 Oral
Batch: **Started:** 28/02/2001 **Stopped:** CONTIN

PEPCIDINE (Other drug) **Reason:** Heartburn
Tablet 0.0 Oral
Batch: **Started:** 20/03/2001 **Stopped:** CONTIN

MYLANTA (Other drug) **Reason:** Heartburn
Oral application 0.0 Oral
Batch: **Started:** 14/03/2001 **Stopped:** 21/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history includes major depressive disorder since 1990.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 164697 **Seq:** 1
Reported: 21/05/2001
Hospitalisation: Admitted to hospital
Onset Date: 30/04/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 48
DOB: 20/09/1952
Causality: Causality possible

Reaction Detail

Medicine Details:

DYMADON (Other drug)			**Reason:**	Headache		
Oral application	0.0				Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
OLANZAPINE (Suspected)			**Reason:**	Depression		
Tablet	12.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression		
Tablet	25.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		

Laboratory Investigations:

Additional Information:

Medical history includes major depressive disorder since 1990.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 164809 **Seq:** 1 **Gender:** F
Reported: 24/05/2001 **Weight:** 78.00
Hospitalisation: **Age:** 46
Onset Date: 06/05/2001 **DOB:** 03/07/1954
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Myalgia Tremor			No medication given. date of recovery 19/05/2001. required a visit to doctor

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 04/05/2001 **Stopped:** 16/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Prozac was reduced from 40mg/daily to 30mg/daily. previously taken at 20mg and 30mg.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 164911 **Seq:** 1 **Gender:** F
Reported: 28/05/2001 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abortion Medication error		At approx 20 weeks gestation- pregnancy	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

A female patient had to have her pregnancy terminated. the patient was taking fluoxetine and fell pregnant. the fluoxetine treatemtn was ceased once the psychiatrist learned of the conception. the patient did not cope and fell apart without the fluoxetine treatment so the psychiatrist recommenced fluoxetine at 20mg every 2nd day. at approx 20 weeks gestation, the patient had to terminate the pregnancy (2/5/01) for reasons unknown. an autopsy on the foetus is pending.

Report Detail

Case Number: 165456 **Seq:** 1
Reported: 15/06/2001
Hospitalisation:
Onset Date:
Outcome: Death, maybe drug

Gender: M
Weight: 0.00
Age: 48Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastric cancer		Carcinoma of the pylorus (stomach)	

Medicine Details:

PROZAC (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

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

Reaction Detail

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

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

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

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

Reaction Detail

Medicine Details:

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 166465 **Seq:** 1
Reported: 16/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 16/06/2001
Outcome: Recovered

Gender: F
Weight:
Age: 60Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormon			Admitted to hospital and treated with fluid restriction.

Medicine Details:

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

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** 08/06/2001 **Stopped:** 16/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chloride		16/06/2001	-	
	Chloride		19/06/2001	95	
	Creatinine		16/06/2001	-	
	Creatinine		19/06/2001	59	
	Potassium		16/06/2001	-	
	Potassium		19/06/2001	3.8	
	Sodium		16/06/2001	123	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 166465 **Seq:** 1
Reported: 16/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 16/06/2001
Outcome: Recovered

Gender: F
Weight:
Age: 60Y
DOB:
Causality: Causality probable

Reaction Detail

Medicine Details:

NORVASC (Other drug)			**Reason:**	Essential benign hypertension	
	5.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
Oral application	40.0	Milligram	Daily	Oral	
Batch:	**Started:**	08/06/2001		**Stopped:**	16/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		19/06/2001	132	
	Urea		16/06/2001	-	
	Urea		19/06/2001	5	
	Urine Sodium		16/06/2001	94	
	Urine Sodium		19/06/2001	-	
	Urine osmolality		16/06/2001	658	
	Urine osmolality		19/06/2001	-	

Additional Information:

Report Detail

Case Number: 166465 **Seq:** 1
Reported: 16/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 16/06/2001
Outcome: Recovered

Gender: F
Weight:
Age: 60Y
DOB:
Causality: Causality probable

Reaction Detail

Medicine Details:

NORVASC (Other drug)			**Reason:**	Essential benign hypertension
	5.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression
Oral application	40.0	Milligram	Daily	Oral
Batch:	**Started:**	08/06/2001		**Stopped:** 16/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	bicarbonate		16/06/2001	-	
	bicarbonate		19/06/2001	30	

Additional Information:

Report Detail

Case Number: 166887 **Seq:** 1 **Gender:** F
Reported: 30/07/2001 **Weight:**
Hospitalisation: **Age:** 85
Onset Date: 09/07/2001 **DOB:** 20/06/1916
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Fluoxetine, captopril, frusemide and omeprazole ceased. treatment fluid restriction.

Medicine Details:

CAPTOPRIL (Suspected) **Reason:**
12.5 Milligram Daily
Batch: **Started:** **Stopped:**

FRUSEMIDE (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		20/07/2001	137	Sodium < 125.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 167283 **Seq:** 1
Reported: 06/08/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight:
Age:
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema Rash			Patient was admitted to hospital; fluoxetine treatment

Medicine Details:

PROZAC (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient's medical history includes an insect bite (type unknown) the day prior to the onset of the event. the patient has a known allergy to bee stings.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 167302 **Seq:** 1 **Gender:** M
Reported: 08/08/2001 **Weight:**
Hospitalisation: **Age:** 15Y
Onset Date: 13/05/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination	Severe		Fluoxetine was ceased.

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 10/05/2001 **Stopped:** 13/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient suffered with major depression since 1/2000. no previous auditory hallucinations or other psychotic phenomenology.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 168205 **Seq:** 1
Reported: 06/09/2001
Hospitalisation:
Onset Date: 02/04/1997
Outcome: Recovered

Gender: F
Weight: 50.00
Age: 49
DOB: 03/05/1947
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Mania Suicide attempt			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

0.0

Batch: **Started:** 01/04/1993 **Stopped:** 30/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start and stop date is not necessarily accurate but indicates the drug was started and stopped sometime in the month.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 168206 **Seq:** 1
Reported: 06/09/2001
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 50.00
Age: 54
DOB: 03/05/1947
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Drug withdrawal syndrome Hypertonia Muscle twitching		Depressive mood swings.	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

0.0

Batch: **Started:** 01/04/1993 **Stopped:** 30/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient have permanent spasms in both legs and right hand, in trunk at night.

Report Detail

Case Number: 168441 **Seq:** 1 **Gender:** M
Reported: 14/09/2001 **Weight:** 56.00
Hospitalisation: **Age:** 87
Onset Date: **DOB:** 04/02/1914
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Stopped prozac. required a visit to doctor.

Medicine Details:

DILTIAZEM HYDROCHLORIDE (Suspected) **Reason:** Essential benign hypertension
180.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 23/08/2001

ACCUPRIL (Suspected) **Reason:** Essential benign hypertension
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 23/08/2001

IMDUR (Suspected) **Reason:** Angina pectoris w/o hyperten
60.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 23/08/2001

BENZHEXOL HYDROCHLORIDE (Suspected) **Reason:** Abnormal involuntary movement
2.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 23/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Serum sodium 128 mmol/l.

Additional Information:

Report Detail

Case Number: 168441 **Seq:** 1

Reported: 14/09/2001

Hospitalisation:

Onset Date:

Outcome: Recovered

Gender: M

Weight: 56.00

Age: 87

DOB: 04/02/1914

Causality: Causality possible

Reaction Detail

Medicine Details:

PROZAC (Suspected)			**Reason:**	Depression	
	20.0	Milligram	Daily		
Batch:	**Started:**	L TERM		**Stopped:**	23/08/2001
FERROUS SULPHATE (Suspected)			**Reason:**	Unspecified anemia	
	1.0	Dose Unspecified	Daily		
Batch:	**Started:**	L TERM		**Stopped:**	23/08/2001

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 168455 **Seq:** 1
Reported: 17/09/2001
Hospitalisation:
Onset Date: 28/02/2001
Outcome: Not yet recovered

Gender: M
Weight: 75.00
Age: 32
DOB: 08/02/1969
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Cardiac failure Mitral valve incompetence Pericardial effusion Pulmonary hypertension	Life Life	Dilated cardiomyopathy with severe Life threatening.	

Medicine Details:

OLANZAPINE (Suspected) **Reason:**
0.0
Batch: **Started:** 01/08/2000 **Stopped:** 05/04/2001

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

BENZTROPINE MESYLATE (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

LITHIUM CARBONATE (Suspected) **Reason:**
900.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Coronary Other data				Normal coronary arteries on angiography. echocardiogram showed marked dilatation of all chambers with severely impaired Echocardiography report 13/2/02: all chambers are markedly dilated. there is moderate to severe impairment of lv systolic function. the right ventricle is also hypokinetic. pulmonary artery systolic pressure is estimated to be 51mmhg there is a small pericardial effusion. conclusion: 1.dilatation of all heart chambers with moderate to sever impairment of left ventricular systolic

Additional Information:

Mild improvement on aggressive treatment for ccf but still has severe left ventricular dysfunction. the dose start date for the drug olanzapine is not necessarily accurate but indicates the drug was started sometime in the month. the date of onset is not necessarily accurate but indicates onset sometime in the month. there is a strong family history of coronary artery disease and cardiomyopathy

Report Detail

Case Number: 168455 **Seq:** 1
Reported: 17/09/2001
Hospitalisation:
Onset Date: 28/02/2001
Outcome: Not yet recovered

Gender: M
Weight: 75.00
Age: 32
DOB: 08/02/1969
Causality: Causality possible

Reaction Detail

Medicine Details:

OLANZAPINE (Suspected) **Reason:**
0.0
Batch: **Started:** 01/08/2000 **Stopped:** 05/04/2001

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

BENZTROPINE MESYLATE (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

LITHIUM CARBONATE (Suspected) **Reason:**
900.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Function. 2. moderate mitral regurgitation. 3. moderate pulmonary hypertension 4. tiny pericardial effusion.

Additional Information:

Mild improvement on aggressive treatment for ccf but still has severe left ventricular dysfunction. the dose start date for the drug olanzapine is not necessarily accurate but indicates the drug was started sometime in the month. the date of onset is not necessarily accurate but indicates onset sometime in the month. there is a strong family history of coronary artery disease and cardiomyopathy

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 168627 **Seq:** 1
Reported: 24/09/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 22Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiac failure Serotonin syndrome			Patient hospitalised

Medicine Details:

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

LOVAN (Suspected) **Reason:**
60.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 169521 **Seq:** 1 **Gender:** F
Reported: 29/10/2001 **Weight:** 54.00
Hospitalisation: **Age:** 48
Onset Date: **DOB:** 20/06/1953
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Choking			Recovered 3-4 days after ceasing prozac.

Medicine Details:

MS CONTIN (Other drug) **Reason:**
30.0 Milligram Daily
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 28/09/2001 **Stopped:** 03/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Choking came within 1.5hr of each tablet.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 169721 **Seq:** 1 **Gender:** M
Reported: 08/11/2001 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: 01/11/2001 **DOB:** 19/03/1975
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention			Date of recovery 2.11.01. required a visit to doctor.

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/11/2001 **Stopped:** 24/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 169952 **Seq:** 1 **Gender:** F
Reported: 08/11/2001 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Colon cancer		Colon cancer	Right hemicolonectomy

Medicine Details:

SOMAC (Suspected) **Reason:** Other diseases of esophagus
0.0
Batch: **Started:** 01/01/1999 **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but indicates somac was started sometime in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 170013 **Seq:** 1 **Gender:** F
Reported: 14/11/2001 **Weight:** 83.00
Hospitalisation: **Age:** 39Y
Onset Date: 28/05/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast pain Pain			Required a visit to doctor. date of recovery october 2001.

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 01/04/1999 **Stopped:** 12/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 170027 **Seq:** 1
Reported: 19/11/2001
Hospitalisation:
Onset Date: 18/10/2001
Outcome: Not yet recovered

Gender: F
Weight: 95.00
Age: 41
DOB: 24/02/1960
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Herpes simplex		Cold sores on lip - more severe than usual.	
Hypoaesthesia		Numbness of left leg.	Treated with zovirax topically. required a visit to doctor. lovan

Medicine Details:

SERETIDE ACCUHALER NOS (Other drug) **Reason:** Asthma
Inhalation 0.0 Inhalation
Batch: **Started:** 22/08/2000 **Stopped:**

LOVAN (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 11/10/2001 **Stopped:** 18/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: asthma and allergic rhinitis. allergies to prepulsid and atrovent.

Report Detail

Case Number: 170472 **Seq:** 1
Reported: 26/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 02/01/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 36
DOB: 24/08/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			Patient was hospitalised.

Medicine Details:

OLANZAPINE (Suspected) **Reason:** Depression

Capsule 6.0 Milligram Daily Oral

Batch: **Started:** 05/12/2000 **Stopped:**

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

Capsule 50.0 Milligram Daily Oral

Batch: **Started:** 05/12/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 170473 **Seq:** 1
Reported: 26/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/11/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 37
DOB: 24/08/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coma Suicide attempt Suicide attempt			Patient admitted to intensive care unit. intubated, monitored, nasogastric tube and charcoal. olanzapine and fluoxetine discontinued.

Medicine Details:

OLANZAPINE (Suspected) **Reason:** Depression
Capsule 0.0 Oral
Batch: **Started:** **Stopped:** 05/11/2001

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Capsule 0.0 Oral
Batch: **Started:** **Stopped:** 05/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 171835 **Seq:** 1
Reported: 14/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/12/2001
Outcome: Recovered

Gender: F
Weight:
Age: 85
DOB: 11/12/1916
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Life		Date of recovery 9.1.02. reaction was life threatening. patient was hospitalised. fluoxetine ceased. fluid restricted

Medicine Details:

RAMIPRIL (Other drug) **Reason:** Congestive heart failure
10.0 Milligram Daily
Batch: **Started:** 11/11/2001 **Stopped:**

PROPRANOLOL HYDROCHLORIDE (Other drug) **Reason:** Essential benign hypertension
160.0 Milligram Daily
Batch: **Started:** 11/11/2001 **Stopped:**

DIGOXIN (Other drug) **Reason:** Otr&nos disord of heart rhythm
62.5 Milligram Daily
Batch: **Started:** 11/11/2001 **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** 20/12/2001 **Stopped:** 07/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Ns+ 121.

Additional Information:

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

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 171894 **Seq:** 1 **Gender:** F
Reported: 08/01/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 28/08/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Nausea Tremor			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 172108 **Seq:** 1 **Gender:** M
Reported: 02/01/2002 **Weight:** 70.00
Hospitalisation: **Age:** 54Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased			

Medicine Details:

PROZAC (Suspected) **Reason:** Obsessive compulsive neurosis
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for prozac is not accurate but indicates the drug was started sometime in the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 172671 **Seq:** 1 **Gender:** F
Reported: 11/02/2002 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 11/02/1975
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Alcohol intolerance			

Medicine Details:

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

PROZAC (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 23/08/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Similar problem with prothiaden.

Report Detail

Case Number: 172743 **Seq:** 1 **Gender:** M
Reported: 13/02/2002 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: 11/12/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperreflexia			
Hypertension			
Hypertonia			
Hypokalaemia			
Hypoxia			
Leukocytosis			
Mydriasis			
Neuroleptic malignant syndrome			
Serotonin syndrome			Therapy ceased. supportive treatment given, rehydration, captopril, kcl
Tachycardia			

Medicine Details:

CIPRAMIL (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 5D

PROTHIADEN (Suspected) **Reason:** Depression
150.0 Milligram Daily
Batch: **Started:** **Stopped:** 7D

PROZAC (Suspected) **Reason:** Depression
60.0 Milligram Daily
Batch: **Started:** **Stopped:** 7D

PERICYAZINE (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 1M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Sao2 90% on air.
	Creatine [illegible]	0 - 270 U/L	11/12/2001	689	
	Creatine [illegible]	0 - 270 U/L	13/12/2001	1670	
	Creatine [illegible]	0 - 270 U/L	12/12/2001	1407	
	Potassium		11/12/2001	2.7	
	White blood cells	4-11	11/12/2001	17.1	
	White blood cells	4-11	13/12/2001	11.9	

Additional Information:

Other reaction terms: creatinine phosphokinase increased, sweating increased.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 172764 **Seq:** 1 **Gender:** F
Reported: 14/02/2002 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence			Neurontin was ceased.

Medicine Details:

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

MORPHINE SULPHATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 172764 **Seq:** 1
Reported: 14/02/2002
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight:
Age: 50Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

NEURONTIN (Suspected)			**Reason:**	Pain	
Oral application	900.0	Milligram	Daily	Oral	
Batch:	**Started:**	S TERM	**Stopped:**	1M	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 173127 **Seq:** 1 **Gender:** F
Reported: 01/02/2002 **Weight:** 131.00
Hospitalisation: **Age:** 31
Onset Date: 30/12/2001 **DOB:** 21/02/1970
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia Asthenia Diarrhoea Dizziness Headache Nausea			Date of recovery 07/01/2002. required a visit to doctor.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 30/12/2001 **Stopped:** 07/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergy to penicillin. no side effects from prozac.

Report Detail

Case Number: 173272 **Seq:** 1
Reported: 01/03/2002
Hospitalisation:
Onset Date: 26/02/2002
Outcome: Recovered

Gender: F
Weight: 65.00
Age: 80
DOB: 17/05/1921
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pollakiuria	Severe	Frequent urination.	Required a visit to doctor.
Back pain		Severe back ache.	
Nausea			
Visual disturbance			

Medicine Details:

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

PEPCIDINE (Other drug)
Reason: Other diseases of esophagus
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

PROZAC (Suspected)
Reason: Depression
20.0 Milligram 1 time
Batch: **Started:** 26/02/2002 **Stopped:** 27/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had kidney removed and has stomach polyps.

Report Detail

Case Number: 173735 **Seq:** 1
Reported: 19/03/2002
Hospitalisation:
Onset Date: 28/01/2002
Outcome: Not yet recovered

Gender: M
Weight: 80.00
Age: 23
DOB: 25/04/1978
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia		Quite significant hair loss from top of scalp.	Required a visit to doctor. considering coming off lovan.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/12/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 173737 **Seq:** 1 **Gender:** F
Reported: 19/03/2002 **Weight:** 65.00
Hospitalisation: **Age:**
Onset Date: 13/02/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain		All body pain.	
Agitation		Fiddling.	
Pruritus		Itch all over.	
Arthralgia			
Drug withdrawal syndrome			
Headache			Required a visit to doctor.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/05/2001 **Stopped:** 10/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for lovan is not necessarily accurate but indicates lovan was started sometime in the month.

Report Detail

Case Number: 173956 **Seq:** 1
Reported: 21/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 21/02/2002
Outcome: Recovered

Gender: M
Weight:
Age: 43Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Increasing spasticity upper limbs.	
Chills			
Confusional state	Required Specialist Consultation		
Hyponatraemia			
Hypothermia	Severe		Tegretol ceased, withheld fluoxetine, sodium valproate, amitriptyline. fluid restrict 1.5l/day, pharmacological washout. patient was hospitalised. ic+ supplement.
Somnolence			

Medicine Details:

PRO-BANTHINE (Other drug) **Reason:**
45.0 Milligram Daily
Batch: **Started:** 01/01/1995 **Stopped:**

CLOFEN (Other drug) **Reason:**
210.0 Milligram Daily
Batch: **Started:** 01/01/1995 **Stopped:**

PAXAM (Other drug) **Reason:**
3.0 Microgram Daily
Batch: **Started:** 01/01/1995 **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium		21/02/2002	3.2	
	Sodium		14/03/2001	130	
	Sodium		21/02/2002	119	
	Sodium		22/02/2002	131	
	Sodium		23/02/2002	129	
	Sodium		25/02/2002	133	

Additional Information:

The dose start dates are not necessarily accurate but indicates valpro, endep, fluoxetine were started sometime in the year.

Report Detail

Case Number: 173956 **Seq:** 1
Reported: 21/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 21/02/2002
Outcome: Recovered

Gender: M
Weight:
Age: 43Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

MEGAFOL (Other drug)			**Reason:**	
	10.0 Milligram	Daily		
Batch:	**Started:** 01/01/1995		**Stopped:**	
ZINCAPS (Other drug)			**Reason:**	
	2.0 Dose Unspecified	Daily		
Batch:	**Started:** 01/01/1999		**Stopped:**	
TEGRETOL (Suspected)			**Reason:**	
	0.0			
Batch:	**Started:** 15/02/2002		**Stopped:**	21/02/2002
VALPRO (Suspected)			**Reason:**	
	1.0 Gram	Daily		
Batch:	**Started:** 01/01/1999		**Stopped:**	

Laboratory Investigations:

Additional Information:

The dose start dates are not necessarily accurate but indicates valpro, endep, fluoxetine were started sometime in the year.

Report Detail

Case Number: 173956 **Seq:** 1
Reported: 21/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 21/02/2002
Outcome: Recovered

Gender: M
Weight:
Age: 43Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

ENDEP (Suspected)			**Reason:**	
	25.0 Milligram		Daily	
Batch:	**Started:**	S TERM		**Stopped:**
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	
	60.0 Milligram		Daily	
Batch:	**Started:** 01/01/1995			**Stopped:**

Laboratory Investigations:

Additional Information:

The dose start dates are not necessarily accurate but indicates valpro, endep, fluoxetine were started sometime in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 174035 **Seq:** 1 **Gender:** F
Reported: 28/03/2002 **Weight:** 68.00
Hospitalisation: **Age:** 31
Onset Date: 30/01/2002 **DOB:** 20/02/1970
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Involuntary tongue movements.	Required a visit to doctor. date of recovery: 14/2/2002.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 16/01/2002 **Stopped:** 14/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Nil other history relevant. stopped and started lovan on several occasions and reaction recurred with restarting and stopped with cessation.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 174132 **Seq:** 1
Reported: 02/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/08/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 37
DOB: 08/09/1963
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular disorder		(l) mca infarct with (r) hemiplegia and	Patient was hospitalised.

Medicine Details:

OMEPRAZOLE (Suspected) **Reason:**
20.0 Milligram As necessary
Batch: **Started:** **Stopped:**

INDAPAMIDE HEMIHYDRATE (Suspected) **Reason:**
2.5 Milligram As necessary
Batch: **Started:** **Stopped:**

TRIFEME 28 (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

PREDNISOLONE (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 174132 **Seq:** 1
Reported: 02/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/08/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 37
DOB: 08/09/1963
Causality: Causality possible

Reaction Detail

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	
	20.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
RANITIDINE (Suspected)			**Reason:**	
	300.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 174171 **Seq:** 1
Reported: 03/04/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight:
Age: 35
DOB: 21/05/1966
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sensory disturbance		Decrease in sensation.	
Pain	Severe	Severe sharp pain on soles of feet.	Given paracetamol, naproxen, tramadol, morphine, telfast and calamine lotion. patient hospitalised. fluoxetine withdrawn. discharged 26/03/2002.
Pruritus			

Medicine Details:

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

20.0 Milligram Daily

Batch: **Started:** 25/03/2001 **Stopped:** 23/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 174942 **Seq:** 1 **Gender:** M
Reported: 26/04/2002 **Weight:** 80.00
Hospitalisation: **Age:** 71
Onset Date: 06/04/2002 **DOB:** 10/11/1930
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea			

Medicine Details:

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

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

ASPIRIN (Other drug) **Reason:**
100.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

CARDIZEM CD (Other drug) **Reason:**
180.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 174942 **Seq:** 1
Reported: 26/04/2002
Hospitalisation:
Onset Date: 06/04/2002
Outcome: Recovered

Gender: M
Weight: 80.00
Age: 71
DOB: 10/11/1930
Causality: Causality probable

Reaction Detail

Medicine Details:

FRUSEMIDE (Other drug)			**Reason:**	
	80.0	Milligram	Daily	
Batch:	**Started:**		L TERM	**Stopped:**
IMDUR (Other drug)			**Reason:**	
	60.0	Milligram	Daily	
Batch:	**Started:**		L TERM	**Stopped:**
LOSEC (Other drug)			**Reason:**	
	20.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
PERINDOPRIL (Other drug)			**Reason:**	
	4.0	Milligram	Daily	
Batch:	**Started:**		L TERM	**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 174942 **Seq:** 1
Reported: 26/04/2002
Hospitalisation:
Onset Date: 06/04/2002
Outcome: Recovered

Gender: M
Weight: 80.00
Age: 71
DOB: 10/11/1930
Causality: Causality probable

Reaction Detail

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** 02/04/2002 **Stopped:** 06/04/2002

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 174971 **Seq:** 1 **Gender:** F
Reported: 29/04/2002 **Weight:** 95.00
Hospitalisation: **Age:** 51Y
Onset Date: 31/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Had sudden urge to murder someone.	Ceased prozac.

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 80.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:** 5M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 175027 **Seq:** 1 **Gender:** F
Reported: 11/04/2002 **Weight:** 53.00
Hospitalisation: **Age:** 48
Onset Date: 28/03/2002 **DOB:** 25/08/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Drug ineffective			Xactin 40mg changed to prozec 40mg. date of recovery 21/03/2002. required a visit to doctor

Medicine Details:

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

ZACTIN (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** **Stopped:** 11/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date of onset is not necessarily accurate but indicates onset sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 175030 **Seq:** 1 **Gender:** F
Reported: 06/03/2002 **Weight:** 65.00
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Drug ineffective Nausea			Zactin ceased. patient changed back to prozac.

Medicine Details:

ZACTIN (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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 175247 **Seq:** 1 **Gender:** F
Reported: 08/05/2002 **Weight:** 55.00
Hospitalisation: **Age:** 93
Onset Date: 01/10/2001 **DOB:** 13/12/1907
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal	Life [illegible]		
Dysarthria	Life [illegible]		
Dyspepsia	Life [illegible]		Ceased prazac. required a visit to doctor.

Medicine Details:

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

LASIX (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 04/04/2001 **Stopped:** 11/11/2001

CARTIA (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** 04/04/2001 **Stopped:**

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 12/09/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered march/april 2002.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 175248 **Seq:** 1 **Gender:** F
Reported: 08/05/2002 **Weight:** 82.00
Hospitalisation: **Age:** 66
Onset Date: 11/10/2001 **DOB:** 11/10/1935
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Date of recovery: 5/12/01

Medicine Details:

LOMOTIL (Other drug) **Reason:** Regional enteritis
Oral application 1.0 Dose Unspecified As necessary Oral
Batch: **Started:** **Stopped:** CONTIN

NATRILIX (Other drug) **Reason:** Essential benign hypertension
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** CONTIN

ISOPTIN (Other drug) **Reason:** Essential benign hypertension
240.0 Milligram Daily
Batch: **Started:** **Stopped:**

DIABEX (Other drug) **Reason:** Diabetes mellitus
1.0 Dose Unspecified Daily
Batch: **Started:** 08/12/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Increased alk phos (123) increased ggt 189.

Additional Information:

The dose stop date for lovan is not necessarily accurate but indicates the drug was stopped sometime in the month. patient was required to take lovan 60mg on the 14/06/01 for depression, then dosage was decreased to 40mg daily on 18/10/2001.

Report Detail

Case Number: 175248 **Seq:** 1 **Gender:** F
Reported: 08/05/2002 **Weight:** 82.00
Hospitalisation: **Age:** 66
Onset Date: 11/10/2001 **DOB:** 11/10/1935
Outcome: Recovered **Causality:** Causality probable

Reaction Detai

Medicine Details:

LIPITOR (Other drug)		**Reason:**	Othr&unspec metabolic diseases
	10.0 Milligram	Daily	
Batch:	**Started:** 26/07/2000	**Stopped:**	CONTIN
KARVEA (Other drug)		**Reason:**	Essential benign hypertension
	150.0 Milligram	Daily	
Batch:	**Started:** 03/02/2001	**Stopped:**	CONTIN
LOVAN (Suspected)		**Reason:**	Depression
	20.0 Milligram	Daily	
Batch:	**Started:** 19/04/2001	**Stopped:**	28/11/2001

Laboratory Investigations:

Additional Information:

The dose stop date for lovan is not necessarily accurate but indicates the drug was stopped sometime in the month. patient was required to take lovan 60mg on the 14/06/01 for depression, then dosage was decreased to 40mg daily on 18/10/2001.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 176182 **Seq:** 1 **Gender:** F
Reported: 13/06/2002 **Weight:** 62.00
Hospitalisation: **Age:** 38
Onset Date: 28/05/2002 **DOB:** 17/01/1964
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura			Lovan ceased. required a visit to doctor.

Medicine Details:

UNISOM SLEEPGELS (Other drug) **Reason:**
Capsule 50.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

ANTENEX (Other drug) **Reason:**
Tablet 2.5 Milligram Daily Oral
Batch: **Started:** **Stopped:**

FELDENE (Other drug) **Reason:**
Capsule 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

LOVAN (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 onset sometime in the month.

Report Detail

Case Number: 176261 **Seq:** 1
Reported: 14/06/2002
Hospitalisation: Admitted to hospital
Onset Date: 27/05/2002
Outcome: Recovered with sequelae

Gender: F
Weight: 70.00
Age: 68
DOB: 13/10/1933
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Oedema Urinary retention			Patient was hospiltalised. date of recovery 6.6.02. fluid restriction. avapro hct and prozac ceased

Medicine Details:

TENORMIN (Other drug) **Reason:** Essential benign hypertension
50.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

ZOCOR (Other drug) **Reason:** Othr&unspec metabolic diseases
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

AVAPRO HCT 150/12.5 (Suspected) **Reason:** Essential benign hypertension
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** 27/05/2002

PROZAC (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 18/05/2002 **Stopped:** 25/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chloride				Cl - 70.
	Potassium				K - 3.1
	Serum osmolality				Serum osmolality - 230.
	Sodium				Na - 111, urine na - 13.
	Urine osmolality				Urine osmolality - 349.

Additional Information:

Sequelae: hallucinations and paranoid concerns.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 176479 **Seq:** 1
Reported: 20/06/2002
Hospitalisation: Admitted to hospital
Onset Date: 20/03/2002
Outcome: Unknown

Gender: F
Weight:
Age: 53
DOB: 13/04/1948
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dehydration Hyperkinesia Nausea			Ceased drug. patient was hospitalised.

Medicine Details:

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

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

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had gi disturbance.

Report Detail

Case Number: 176479 **Seq:** 1
Reported: 20/06/2002
Hospitalisation: Admitted to hospital
Onset Date: 20/03/2002
Outcome: Unknown

Gender: F
Weight:
Age: 53
DOB: 13/04/1948
Causality: Causality possible

Reaction Detail

Medicine Details:

DIAZEPAM (Other drug)			**Reason:**	
	5.0 Milligram		As necessary	
Batch:	**Started:**		**Stopped:**	
GENORAL (Other drug)			**Reason:**	
	1.8 Milligram		Daily	
Batch:	**Started:**		**Stopped:**	
METRONIDAZOLE (Suspected)			**Reason:**	Otr&nos infec&parasit diseases
	1.2 Gram		Daily	
Batch:	**Started:**	17/03/2002	**Stopped:**	20/03/2002
METOCLOPRAMIDE HYDROCHLORIDE (Suspected)			**Reason:**	
	30.0 Milligram		Daily	
Batch:	**Started:**	17/03/2002	**Stopped:**	20/03/2002

Laboratory Investigations:

Additional Information:

Had gi disturbance.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 176479 **Seq:** 1
Reported: 20/06/2002
Hospitalisation: Admitted to hospital
Onset Date: 20/03/2002
Outcome: Unknown

Gender: F
Weight:
Age: 53
DOB: 13/04/1948
Causality: Causality possible

Reaction Detai

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Anxiety neurosis
	20.0	Milligram	Daily	
Batch:	**Started:**		**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Had gi disturbance.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 176610 **Seq:** 1 **Gender:** F
Reported: 24/06/2002 **Weight:**
Hospitalisation: **Age:** 58
Onset Date: 08/06/2002 **DOB:** 21/02/1944
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria			Date of recovery 12/06/2002. required a visit to doctor.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Capsule 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 06/06/2002 **Stopped:** 10/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 177015 **Seq:** 1 **Gender:** M
Reported: 05/12/2001 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: 09/08/2001 **DOB:** 05/01/1954
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Hepatic steatosis Hepatomegaly			

Medicine Details:

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

Oral application 25.0 Milligram Daily Oral

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

OLANZAPINE (Suspected) **Reason:** Depression

Tablet 6.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		10/01/2001	45	
	ALT = SGPT		29/06/2001	101	
	AST = SGOT		29/06/2001	41	
	GGT = SGGT =		10/01/2001	152	
	GGT = SGGT =		12/01/2001	140	
	GGT = SGGT =		29/06/2001	129	

Additional Information:

Used in ct but no a ct drug.

Report Detail

Case Number: 177015 **Seq:** 1
Reported: 05/12/2001
Hospitalisation:
Onset Date: 09/08/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 47
DOB: 05/01/1954
Causality: Causality possible

Reaction Detail

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
Oral application	25.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
OLANZAPINE (Suspected)			**Reason:**	Depression	
Tablet	6.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				9.8.01 - upper abdominal ultrasound whowing an enlarged liver with fatty infiltration. computerised tomography scan shows fatty liver

Additional Information:

Used in ct but no a ct drug.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 177228 **Seq:** 1
Reported: 18/07/2002
Hospitalisation:
Onset Date: 02/07/2002
Outcome: Recovered with sequelae

Gender: F
Weight: 60.00
Age: 44
DOB: 12/03/1958
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain		Central chest pain (heaviness)	
Paraesthesia		Left hand only and roof of mouth, lasted 1	
Muscle twitching		Twitching/spasms right leg.	
Tachycardia			Patient recovered 2/7/02.

Medicine Details:

LOVAN (Suspected) **Reason:** Othr disorders of menstruation
20.0 Milligram Daily
Batch: **Started:** 27/06/2002 **Stopped:** 02/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 177377 **Seq:** 1
Reported: 26/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 17/06/2002
Outcome: Recovered

Gender: F
Weight: 83.00
Age: 54
DOB: 11/07/1947
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase in Malaise Myalgia Pyrexia			Patient hospitalised. given iv rehydration.

Medicine Details:

INTAL FORTE CFC-FREE (Other drug)		**Reason:**	Asthma
Inhalation	0.0		Inhalation
Batch:	**Started:**		**Stopped:**
LOMOTIL (Other drug)		**Reason:**	
Tablet	0.0		Oral
Batch:	**Started:**		**Stopped:**
LOSEC (Other drug)		**Reason:**	Other diseases of esophagus
Tablet	0.0		Oral
Batch:	**Started:**		**Stopped:**
MAXOLON (Other drug)		**Reason:**	
Tablet	0.0		Oral
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine				Ck went up to 2206.

Additional Information:

Patient also taking other drugs - paracetamol, prednisolone, ramipril, tears natural eye drops and ventolin. the dose start date for the drug atorvastatin is not necessarily accurate but indicates the drug was started sometime in the year.

Report Detail

Case Number: 177377 **Seq:** 1
Reported: 26/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 17/06/2002
Outcome: Recovered

Gender: F
Weight: 83.00
Age: 54
DOB: 11/07/1947
Causality: Causality possible

Reaction Detail

Medicine Details:

PANADEINE FORTE (Other drug)				**Reason:**		
Tablet	0.0					Oral
Batch:	**Started:**				**Stopped:**	
FOSAMAX (Other drug)				**Reason:**	Other diseases of bone	
Tablet	1.0	Dose Unspecified	Weekly			Oral
Batch:	**Started:**				**Stopped:**	
ATENOLOL (Other drug)				**Reason:**	Essential benign hypertension	
	50.0	Milligram	Daily			
Batch:	**Started:**		L TERM		**Stopped:**	
F.G.F. (Other drug)				**Reason:**		
Tablet	0.0		Daily			Oral
Batch:	**Started:**				**Stopped:**	

Laboratory Investigations:

Additional Information:

Patient also taking other drugs - paracetamol, prednisolone, ramipril, tears natural eye drops and ventolin. the dose start date for the drug atorvastatin is not necessarily accurate but indicates the drug was started sometime in the year.

Report Detail

Case Number: 177377 **Seq:** 1
Reported: 26/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 17/06/2002
Outcome: Recovered

Gender: F
Weight: 83.00
Age: 54
DOB: 11/07/1947
Causality: Causality possible

Reaction Detail

Medicine Details:

IMURAN (Other drug)			**Reason:**		
Tablet	0.0		Daily		Oral
Batch:	**Started:**			**Stopped:**	
ATORVASTATIN (Suspected)			**Reason:**	Othr&unspec metabolic diseases	
	40.0	Milligram	Daily		
Batch:	**Started:**	31/12/2000		**Stopped:**	17/06/2002
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
	40.0	Milligram	Daily		
Batch:	**Started:**	L TERM		**Stopped:**	17/06/2002
METFORMIN HYDROCHLORIDE (Suspected)			**Reason:**	Diabetes mellitus	
	500.0	Milligram	Daily		
Batch:	**Started:**	L TERM		**Stopped:**	17/06/2002

Laboratory Investigations:

Additional Information:

Patient also taking other drugs - paracetamol, prednisolone, ramipril, tears natural eye drops and ventolin. the dose start date for the drug atorvastatin is not necessarily accurate but indicates the drug was started sometime in the year.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 178303 **Seq:** 1
Reported: 19/08/2002
Hospitalisation:
Onset Date:
Outcome: Recovered

Gender: F
Weight: 77.00
Age: 38
DOB: 11/03/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Oral application 60.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:** 03/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report is the first of two sequences: 178304 seq 1.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 178397 **Seq:** 1 **Gender:** M
Reported: 29/08/2002 **Weight:** 82.00
Hospitalisation: **Age:** 45Y
Onset Date: 25/08/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral Pruritus Rash erythematous			

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Capsule 30.0 Milligram Daily Oral
Batch: **Started:** 22/07/2002 **Stopped:** 25/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 178426 **Seq:** 1 **Gender:** F
Reported: 23/08/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 14/07/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Feeling of displacement	
Tachycardia		Heart rate >150-160	
Dizziness			Ceased fluoxetide.

Medicine Details:

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

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

CAPADEX (Other drug) **Reason:**
Oral application 2.0 Dose Unspecified As necessary Oral
Batch: **Started:** **Stopped:**

CEFTRIAXONE (Other drug) **Reason:**
Injection 1.0 Gram Daily Intravenous
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Has previous adverse effects from sertraline.

Report Detail

Case Number: 178426 **Seq:** 1 **Gender:** F
Reported: 23/08/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 14/07/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

RULIDE (Other drug)			**Reason:**	
Oral application	300.0	Milligram	Daily	Oral
Batch:	**Started:** 12/07/2002			**Stopped:**
FRUSEMIDE (Other drug)			**Reason:**	
Oral application	80.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
OMEPRAZOLE (Other drug)			**Reason:**	
	40.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
PRAZOSIN HYDROCHLORIDE (Other drug)			**Reason:**	
	10.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Additional Information:
Has previous adverse effects from sertraline.

Report Detail

Case Number: 178426 **Seq:** 1 **Gender:** F
Reported: 23/08/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 14/07/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

NORVASC (Other drug)			**Reason:**		
	5.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
PLAVIX (Other drug)			**Reason:**		
Oral application	75.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
ZESTRIL (Other drug)			**Reason:**		
	20.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
Oral application	20.0	Milligram	Daily	Oral	
Batch:	**Started:**	13/07/2002		**Stopped:**	14/07/2002

Laboratory Investigations:

Additional Information:

Has previous adverse effects from sertraline.

Report Detail

Case Number: 179114 **Seq:** 1 **Gender:** M
Reported: 18/09/2002 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: 28/08/2002 **DOB:** 21/04/1975
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiomegaly		Patient was asymptomatic.	Non-drug treatment patient

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** 01/08/1997 **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:** CONTIN

TEGRETOL (Suspected) **Reason:** Other&unspecified epilepsy
Oral application 400.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Enlarged ventricle: reduced ejection fraction of 68% (ejection fraction decreased. echocardiogram showed a slightly enlarged ventricle with reduced ejection fraction of 68% (>60).

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the year. the dose start date for clozaril and tegretol is not necessarily accurate but indicates drugs were started sometime in the year. the patient had received clozaril and tegretol before and did not develop similar or other symptoms.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 179190 **Seq:** 1 **Gender:** F
Reported: 23/09/2002 **Weight:** 100.00
Hospitalisation: **Age:** 37Y
Onset Date: 11/09/2002 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills Tremor Vomiting	Severe Severe		Date of recovery 12.9.02.

Medicine Details:

LOVAN (Suspected) **Reason:** Othr disorders of menstruation
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 11/09/2002 **Stopped:** 13/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug positive rechallenge. 1/2 hour after next dose, same reaction. had prozac previously, 7 years ago with no ill effects.

Report Detail

Case Number: 179782 **Seq:** 1
Reported: 09/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 20/12/2001
Outcome: Recovered

Gender: F
Weight:
Age: 51
DOB: 25/05/1950
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Drug withdrawal syndrome		Watery diarrhoea.	Patient was hospitalised. date of recovery: 10/09/02.

Medicine Details:

ISOPTIN SR (Other drug) **Reason:** Essential benign hypertension
180.0 Milligram As necessary
Batch: **Started:** **Stopped:**

DUCENE (Other drug) **Reason:** Anxiety neurosis
15.0 Milligram Daily
Batch: **Started:** **Stopped:**

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

EPILIM E.C. 200 (Other drug) **Reason:** Convulsions
400.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Associated with other typical withdrawal symptoms.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 179782 **Seq:** 1
Reported: 09/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 20/12/2001
Outcome: Recovered

Gender: F
Weight:
Age: 51
DOB: 25/05/1950
Causality: Causality possible

Reaction Detail

Medicine Details:

LARGACTIL (Other drug)			**Reason:**	Specific disorders of sleep
	40.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	
Oral application	0.0			Oral
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Additional Information:

Associated with other typical withdrawal symptoms.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 180457 **Seq:** 1 **Gender:** U
Reported: 10/11/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haematuria		Blood in urine according to 3 tests.	
Dyspnoea		Easily puffed. short breath on exertion.	
Urinary incontinence		Incontinence (bladder) twice.	
Muscular weakness		Occasional weakness in right arm.	
Thirst		Thirst increased.	
Back pain	Severe		
Chest pain	Severe		
Dysphagia			
Flushing			
Palpitations			
Paraesthesia			

Medicine Details:

LIPITOR (Suspected) **Reason:** Othr&unspec metabolic diseases

Tablet 40.0 Milligram Daily Oral

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

LOVAN (Suspected) **Reason:** Otr&unsp vertebrogen pain synd

Oral application 40.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Ecg at hospital showed changes in heart rhythmn. (angiogram showed healthy arteries).

Additional Information:

Paraesthesia: tingling and numbness in both legs (sometimes only the left leg. flushing: electrial storm all over body - often followed by 'shutdown feeling'. came in 'waves', each lasting a minute or less.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 180457 **Seq:** 1 **Gender:** U
Reported: 10/11/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight decreased			

Medicine Details:

LIPITOR (Suspected) **Reason:** Othr&unspec metabolic diseases

Tablet	40.0	Milligram	Daily	Oral

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

LOVAN (Suspected) **Reason:** Otr&unsp vertebrogen pain synd

Oral application	40.0	Milligram	Daily	Oral

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

Laboratory Investigations:

Additional Information:

Paraesthesia: tingling and numbness in both legs (sometimes only the left leg. flushing: electrial storm all over body - often followed by 'shutdown feeling'. came in 'waves', each lasting a minute or less.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 181108 **Seq:** 1 **Gender:** F
Reported: 06/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: 15/10/2002 **DOB:** 01/02/1967
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Migraine	Severe	Migraine four attacks over six weeks lasting one to five hours.	

Medicine Details:

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

Capsule 30.0 Milligram Daily Oral

Batch: **Started:** 29/09/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No history of migraine and no family history of migraine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 181747 **Seq:** 1 **Gender:** M
Reported: 16/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 28Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction	Required Visit to Doctor	Impotence - gradual onset.	
Erectile dysfunction	Required Visit to Doctor		

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/04/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has experienced symptoms over the 2 months of being on the drug.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 181750 **Seq:** 1 **Gender:** M
Reported: 16/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 65
Onset Date: 24/12/2002 **DOB:** 29/04/1937
Outcome: Recovered 25/12/2002 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Required Visit to Doctor	Tachycardia, loose stool and nausea.	
Diarrhoea	Required Visit to Doctor		
Nausea	Required Visit to Doctor		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Took higher single dose today - 25/12/02.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 182143 **Seq:** 1
Reported: 29/01/2003
Hospitalisation:
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 49
DOB: 02/07/1953
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania Psychotic disorder		Manic syndrome with psychotic features (mood congruent) begining within a week - ten days of Tramadol use.	Fluoxetine ceased.

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:**

Oral

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

FLUOXETINE HYDROCHLORIDE (Interaction) **Reason:**

Capsule 60.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Ongoing marijuana use. History of long standing mood instability.

Report Detail

Case Number: 183030 **Seq:** 1 **Gender:** M
Reported: 18/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 57Y
Onset Date: 23/09/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion Hallucination, visual Muscle twitching Musculoskeletal stiffness		Patient experienced grand mal / focal seizures with left sided sensory loss for one to three hours, visual hallucinations, stiff arms which then twitched, however did not demonstrate an occulogyric crisis.	Ceased Fluoxetine, commenced midazolam, and phenytoin

Medicine Details:

PREDNISOLONE (Other drug) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** contin

DIOCTYL SODIUM SULPHOSUCCINATE (Other drug) **Reason:**
Tablet Daily Oral
Batch: **Started:** **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 03/10/2002

CANNABIS PREPARATION (Suspected) **Reason:**
Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Verapamil, Doxycycline, Esomeprazole, Metoclopramide, paracetamol, Morphine.
Patient did not have a history of epilespy.
Did have a history of "twitching legs" over a number of years.
With left sided sensory loss for one to three hours.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 183362 **Seq:** 1 **Gender:** F
Reported: 03/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 07/01/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sleep disorder		Marked sleep disturbance and poor sleep	
Reflexes abnormal		Reflexes abnormal, increased motor activity, exagerated startle response.	
Drug withdrawal syndrome neona		Withdrawal syndrome neonatal	
Agitation neonatal		agitation	
Infantile colic		colic	
Restlessness		restlessness	
Crying			

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 15/06/2002 **Stopped:** 20/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset day 5 after delivery.
Patient history: Mother required a dose of 40mg to make a full recovery.
Lovan began in 2nd trimester.

Report Detail

Case Number: 183808 **Seq:** 1 **Gender:** F
Reported: 13/12/2002 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 52
Onset Date: 10/12/2002 **DOB:**
Outcome: Recovered 10/12/2002 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	Grand mal seizure with 12 x 50 mg Tramal	

Medicine Details:

TRAMAL (Suspected) **Reason:** Pain
Capsule 50.0 Milligram Oral
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Oral
Batch: **Started:** **Stopped:**

INTERFERON BETA-1B (Suspected) **Reason:** Multiple sclerosis
Injection
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

MS sufferer so seizure could be secondary to that, 181427 is a duplicate

Report Detail

Case Number: 184065 **Seq:** 1
Reported: 18/03/2003
Hospitalisation:
Onset Date: 08/03/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 54
DOB: 18/12/1948
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Required Visit to Doctor	Dizzy, sweating, dry mouth, mood swings, shaking, blurred vision, lack of concentration, itchy rash on arms, poor sleep, loss of appetite.	
Anorexia	Required Visit to Doctor		
Disturbance in attention	Required Visit to Doctor		
Drug withdrawal syndrome	Required Visit to Doctor		
Dry mouth	Required Visit to Doctor		

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 27/02/2003

ZYBAN SR (Suspected) **Reason:** Smoker
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 03/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 184065 **Seq:** 1
Reported: 18/03/2003
Hospitalisation:
Onset Date: 08/03/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 54
DOB: 18/12/1948
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Required Visit to Doctor		
Mood swings	Required Visit to Doctor		
Poor quality sleep	Required Visit to Doctor		
Rash pruritic	Required Visit to Doctor		
Tremor	Required Visit to Doctor		
Vision blurred	Required Visit to Doctor		

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 27/02/2003

ZYBAN SR (Suspected) **Reason:** Smoker
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 03/03/2003

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 184288 **Seq:** 1 **Gender:** F
Reported: 24/03/2003 **Weight:** 55.00
Hospitalisation: **Age:** 31
Onset Date: 06/02/2003 **DOB:** 22/12/1971
Outcome: Recovered 10/03/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise	Required Visit to Doctor	Had shaky hands and felt quite unwell, said it felt like her nerves were twitching.	Substituted brands. Went back to Prazac for 1 month and symptoms ceased.
Tremor	Required Visit to Doctor		

Medicine Details:

PROZAC (Other drug) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** 06/01/2003 **Stopped:** 03/02/2003

LEVLEN ED (Other drug) **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 17/12/2001 **Stopped:**

Fluohexal (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 05/02/2003 **Stopped:** 07/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/03/2003	Electroencephalog				EEG normal.
24/03/2003	Thyroid	(0.27-4.20)			
24/03/2003	Thyroxine	(12.0-22.0)			
24/03/2003	Tri-iodo thyronine	(2.8-7.1)			

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 184528 **Seq:** 1
Reported: 31/03/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: U
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Drug withdrawal syndrome		The infant is experiencing neonatal withdrawal and is in intensive care.	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother was female (age not provided) who took Prozac (dose unknown) at conception and during all 3 trimesters of the pregnancy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 184545 **Seq:** 1
Reported: 01/04/2003
Hospitalisation:
Onset Date: 09/03/2003
Outcome: Not yet recovered

Gender: M
Weight: 82.00
Age: 36
DOB: 02/10/1966
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Anxiety Malaise Serotonin syndrome Tremor		Insomnia, tremor, anxiety, "edginess" and general feeling of not being well. Serotonin Syndrome?	

Medicine Details:

Auscap (Suspected) **Reason:**
Capsule 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 07/03/2003 **Stopped:** 20/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 184796 **Seq:** 1 **Gender:** F
Reported: 08/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 51
Onset Date: 19/12/2002 **DOB:** 09/03/1951
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Tonic clonic seizure.	Tramadol ceased. Phenytoin 200mg twice daily.

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Pain
400.0 Milligram Daily
Batch: **Started:** 12/12/2002 **Stopped:** 19/12/2002

FLUOXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

PMH epilepsy - seizure free 20 years. Patient also taking Avapro HCT, Rofecoxib and Maxolon.

Report Detail

Case Number: 185863 **Seq:** 1 **Gender:** F
Reported: 09/05/2003 **Weight:** 92.00
Hospitalisation: **Age:** 46
Onset Date: 28/04/2003 **DOB:** 31/01/1957
Outcome: Recovered 03/05/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myoclonus	Caused or prolonged inpatient hospitalisation	Myoclonic jerks.	

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug) **Reason:** Diabetes mellitus
1000.0 Milligram Daily
Batch: **Started:** 29/01/2003 **Stopped:**

KARVEA (Other drug) **Reason:** Essential benign hypertension
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 22/04/2003 **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 17/12/2002 **Stopped:** 28/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 186085 **Seq:** 1
Reported: 20/05/2003
Hospitalisation:
Onset Date: 01/05/2003
Outcome: Not yet recovered

Gender: F
Weight: 62.00
Age: 40
DOB: 31/03/1963
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea		Nausea and vomiting	Lovan ceased.
Vomiting		Nausea and vomiting	Lovan ceased.

Medicine Details:

FERRO-GRADUMET (Other drug) **Reason:**
325.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

LOVAN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 01/05/2003 **Stopped:** 15/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Has previously taken Auscap (Fluoxetine generic) 20mg/d with no problems.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 186474 **Seq:** 1
Reported: 02/06/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypokalaemia	Caused or prolonged inpatient hospitalisation	Hypokalaemia, paralysis, metabolic	Admitted to intensive care, treated with potassium
Metabolic acidosis	Caused or prolonged inpatient hospitalisation		
Paralysis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROZAC (Suspected) **Reason:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction ocurred sometime in May 2003.
Prozac was started sometime in Feb 2003.
The reporting intensive care physician does not know if the event is related to the fluoxetine HCL treatment.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 186533 **Seq:** 1 **Gender:** M
Reported: 02/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 40
Onset Date: 19/05/2003 **DOB:** 03/12/1962
Outcome: Recovered 28/05/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysarthria	Required Visit to Doctor	4 days involuntary jaw clenching and mild dysarthria.	
Trismus	Required Visit to Doctor	4 days involuntary jaw clenching and mild dysarthria.	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** 30/01/2003 **Stopped:** 23/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

?buccoglossal syndrome secondary to Lovan.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 186878 **Seq:** 1
Reported: 12/06/2003
Hospitalisation:
Onset Date: 15/05/2003
Outcome: Not yet recovered

Gender: M
Weight: 82.00
Age: 24
DOB: 29/12/1978
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood pressure decreased		Dizziness, blurred vision, mydriasis, postural BP drop	
Dizziness		Dizziness, blurred vision, mydriasis, postural BP drop	Gradual withdrawal of Lovan.
Mydriasis		Dizziness, blurred vision, mydriasis, postural BP drop	
Vision blurred		Dizziness, blurred vision, mydriasis, postural BP drop	

Medicine Details:

LOVAN (Suspected) **Reason:** Obesity othr than endoc origin

Tablet 60.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Lovan was first started in 2001 at a dose up to 60mg and then 40mg from 1/5/03 to 10/06/03.
Reactions occurred on both occasions.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 188343 **Seq:** 1 **Gender:** F
Reported: 10/07/2003 **Weight:** 60.00
Hospitalisation: **Age:** 28
Onset Date: 16/05/2003 **DOB:** 03/09/1974
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypomania	Required Visit to Doctor	Hypomanic episode	Given Olanzapine and

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Manic-depression psycho,manic

Capsule 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 190430 **Seq:** 1 **Gender:** F
Reported: 12/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 30/10/1960
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mood swings Abnormal behaviour Aggression		Mood swings, aggression, behaviour	Lipitor therapy ceased

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram
Batch: **Started:** **Stopped:**

LIPITOR (Suspected) **Reason:** Othr&unspec metabolic diseases
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 18/09/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

reaction onset date: Aug 2003.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 190476 **Seq:** 1 **Gender:** F
Reported: 15/09/2003 **Weight:** 65.00
Hospitalisation: Admitted to hospital **Age:** 44
Onset Date: 10/08/2003 **DOB:** 01/12/1958
Outcome: Recovered 05/09/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastritis	Caused or prolonged inpatient hospitalisation	Severe gastritis and abdominal pain.	
Abdominal pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 06/08/2003 **Stopped:** 01/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 190969 **Seq:** 1 **Gender:** F
Reported: 29/09/2003 **Weight:** 60.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: 27/08/2003 **DOB:** 18/09/1968
Outcome: Recovered 27/08/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Drowsy post surgery for longer than	Sevofluranes
Tremor		Localised migratory tremor after elective minor surgery.	
Mutism		Mutism	
Hypertonia		Patient hypertonic	
Serotonin syndrome		Serotonin syndrome	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

TRAMAL (Suspected) **Reason:** Pain
Injection 100.0 Milligram Daily Intravenous
Batch: **Started:** 27/08/2003 **Stopped:** 27/08/2003

TORADOL (Suspected) **Reason:** Pain
Injection 100.0 Milligram Daily Subcutaneous
Batch: **Started:** 27/08/2003 **Stopped:** 27/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 190969 **Seq:** 1 **Gender:** F
Reported: 29/09/2003 **Weight:** 60.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: 27/08/2003 **DOB:** 18/09/1968
Outcome: Recovered 27/08/2003 **Causality:** Causality possible

Reaction Detail

Medicine Details:

PROPOFOL (Suspected)			**Reason:**		
Injection	150.0	Milligram	Daily		Intravenous
Batch:	**Started:**			**Stopped:**	
ATRACURIUM BESYLATE (Suspected)			**Reason:**		
Injection	15.0	Milligram	Daily		Intravenous
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 190973 **Seq:** 1 **Gender:** M
Reported: 29/09/2003 **Weight:** 95.00
Hospitalisation: **Age:** 99U
Onset Date: 14/09/2003 **DOB:**
Outcome: Recovered 17/09/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Required Visit to Doctor	"Giddy"	
Tremor	Required Visit to Doctor	"Shaking" couldn't drive motor vehicle.	
Hypoaesthesia facial	Required Visit to Doctor	Numbness in face.	Increase Antenex short
Paraesthesia	Required Visit to Doctor	Tingling in fingers	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 08/09/2003 **Stopped:** 14/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Zocor, Aspirin, Antenex and Hydrene.

Report Detail

Case Number: 191340 **Seq:** 1 **Gender:** F
Reported: 15/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 38
Onset Date: 06/10/2003 **DOB:** 19/09/1965
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation	Experienced symptoms hypotension,dizziness. syncope, headache	
Hypotension	Caused or prolonged inpatient hospitalisation	Experienced symptoms of hypotension 80/60mmHg, felt lightheaded, slumed to the floor syncope, "voices" and, headache	1 litre of fluids
Headache	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Interaction) **Reason:** Unspecified schizophrenia

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 24/01/2001 **Stopped:**

LOVAN (Interaction) **Reason:**

20.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient stopped her clozaril treatment for 1-2 weeks, then recommenced and same symptoms occurred.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 191340 **Seq:** 1 **Gender:** F
Reported: 15/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 38
Onset Date: 06/10/2003 **DOB:** 19/09/1965
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Interaction) **Reason:** Unspecified schizophrenia
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 24/01/2001 **Stopped:**

LOVAN (Interaction) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Patient stopped her clozaril treatment for 1-2 weeks, then recommenced and same symptoms occurred.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 191356 **Seq:** 1
Reported: 16/10/2003
Hospitalisation:
Onset Date: 08/07/2003
Outcome: Not yet recovered

Gender: U
Weight: 0.00
Age: 27
DOB: 05/03/1976
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abnormal dreams	Required Visit to Doctor	Vivid dreams	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 21/05/2003 **Stopped:** 03/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 191633 **Seq:** 1 **Gender:** F
Reported: 27/10/2003 **Weight:** 67.00
Hospitalisation: **Age:** 39
Onset Date: 11/10/2003 **DOB:** 30/12/1963
Outcome: Recovered 11/10/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia	Required Visit to Doctor		
Balance disorder	Required Visit to Doctor		
Malaise	Required Visit to Doctor		
Palpitations	Required Visit to Doctor		
Tremor	Required Visit to Doctor		
Vision blurred	Required Visit to Doctor		

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** 11/10/2003 **Stopped:** 21/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 191633 **Seq:** 1 **Gender:** F
Reported: 27/10/2003 **Weight:** 67.00
Hospitalisation: **Age:** 39
Onset Date: 11/10/2003 **DOB:** 30/12/1963
Outcome: Recovered 11/10/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Required Visit to Doctor	Dizziness, Shakes, (tremor), memory loss, blurred vision, unwell, palpitations, no balance.	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** 11/10/2003 **Stopped:** 21/10/2003

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 193016 **Seq:** 1
Reported: 10/12/2003
Hospitalisation:
Onset Date: 21/11/2003
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 99Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Rash	Medication ceased, Calamine

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 08/11/2003 **Stopped:** 21/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Actual age: 100 years. Previous reactions to efexor - dizziness, vomiting, aropax - rash on face, pseudoephedrine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 193139 **Seq:** 1 **Gender:** F
Reported: 15/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 37Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation	Suicidal ideation, nausea, trembling, feeling of despair, anxiety, paronoia and fear.	Psychiatric hospital for rehabilitation for six weeks.
Anxiety	Caused or prolonged inpatient hospitalisation		
Fear	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 193139 **Seq:** 1 **Gender:** F
Reported: 15/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 37Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Feeling of despair	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		
Paranoia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 193139 **Seq:** 1 **Gender:** F
Reported: 15/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 37Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROZAC (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 193421 **Seq:** 1 **Gender:** F
Reported: 22/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Back pain	Severe	Back pain.	
Chest pain	Severe	Crushing pain on the upper central chest.	
Asthenia	Severe	Extreme weakness in legs and occasional weakness in right arm.	
Weight decreased	Severe	Loss of weight	
Hypoaesthesia	Severe	Numbness in both legs.	
Palpitations	Severe	Palpitations on slight exertion.	
Dyspnoea	Severe	Short of breath on exertion.	
Paraesthesia	Severe	Tingling in both legs.	

Medicine Details:

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset date: 08/2003 and recovery date: 11/2003. Other drugs: COQ10, Multivites and Caltrate.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 193421 **Seq:** 1 **Gender:** F
Reported: 22/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thirst	Severe	Unusual thirst increased (craved for eating bananas), difficulty swollowing, took twice as long to finish normal meal.	
Urinary incontinence	Severe	Urinary incontinence (bladder) twice; each time in hospital ER	

Medicine Details:

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

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

Laboratory Investigations:

Additional Information:

Onset date: 08/2003 and recovery date: 11/2003. Other drugs: COQ10, Multivites and Caltrate.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 193476 **Seq:** 1 **Gender:** F
Reported: 22/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 60
Onset Date: **DOB:** 16/09/1943
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced two or three consecutive seizures.	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Oral
Batch: **Started:** **Stopped:**

DUROMINE (Suspected) **Reason:** Obesity othr than endoc origin
Capsule Oral
Batch: **Started:** **Stopped:**

STILNOX (Suspected) **Reason:** Other disturbance of sensation
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had previously taken Zolpidem on a few occasions with no reported side effects.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 193656 **Seq:** 1 **Gender:** F
Reported: 06/01/2004 **Weight:** 70.00
Hospitalisation: **Age:** 13
Onset Date: 02/12/2003 **DOB:** 12/07/1990
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hemiparesis	Caused or prolonged inpatient hospitalisation	Right sided hemiparesis.	Drug ceased as a precaution.

Medicine Details:

PHENTERMINE RESINATE (Suspected) **Reason:** Obesity othr than endoc origin
15.0 Milligram Daily
Batch: **Started:** 15/06/2003 **Stopped:** 22/12/2003

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Obesity othr than endoc origin
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 15/06/2003 **Stopped:** 22/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/01/2004	Other data				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 193763 **Seq:** 1 **Gender:** M
Reported: 09/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 84
Onset Date: 11/12/2003 **DOB:** 12/08/1919
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage	Caused or prolonged inpatient hospitalisation	GI bleed, acute renal failure, gastric [illegible]	Cease Aspirin, ACE I - given IV Losec packed cells.
Gastritis erosive	Caused or prolonged inpatient hospitalisation		
Renal failure acute	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

KETOROLAC (Suspected) **Reason:**
30.0 Milligram 1 time
Batch: **Started:** 23/11/2003 **Stopped:** 23/11/2003

ASPIRIN (Suspected) **Reason:** Chron isch heart dis no hyper
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 11/12/2003

ENALAPRIL MALEATE (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 11/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/01/2004	Creatinine		28/11/2003	0.09	
09/01/2004	Creatinine		11/12/2003	0.7	
09/01/2004	Creatinine		12/12/2003	0.43	
09/01/2004	Creatinine		14/12/2003	0.08	
09/01/2004	Haemoglobin		28/11/2003	152	
09/01/2004	Haemoglobin		11/12/2003	86	
09/01/2004	Haemoglobin		12/12/2003	120	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 193763 **Seq:** 1 **Gender:** M
Reported: 09/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 84
Onset Date: 11/12/2003 **DOB:** 12/08/1919
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

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

Capsule 20.0 Milligram Daily Oral

Batch: **Started:** 09/12/2003 **Stopped:** 11/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/01/2004	Other data				
09/01/2004	Urea		28/11/2003	6.8	
09/01/2004	Urea		11/12/2003	36.6	
09/01/2004	Urea		12/12/2003	27.1	
09/01/2004	Urea		14/12/2003	4.9	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 194012 **Seq:** 1 **Gender:** M
Reported: 21/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 09/12/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Life	Sudden collapse, prolonged unconsciousness, and hypotension.	Quetiapine ceased.
Tachycardia	Life	Tachyarrhythmia	
Electrocardiogram QT prolonged	Life		
Hypotension	Life		
Loss of consciousness	Life		

Medicine Details:

QUETIAPINE (Suspected) **Reason:** Obsessive compulsive neurosis
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 10/11/2003

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Capsule 80.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 10/11/2003

ERYTHROMYCIN (Suspected) **Reason:** Ac upr resp inf,mult,unsp stes
400.0 Milligram Daily
Batch: **Started:** **Stopped:** 10/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/01/2004	Electrocardiograph		09/12/2003	Long QTc on	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 194094 **Seq:** 1 **Gender:** M
Reported: 27/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 16
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination, auditory Agitation		Acute auditory hallucinations, voices telling him to kill his mother, father, sister and himself.	Requried a short course of Clonazepam

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depressive neurosis

Capsule 20.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Depressive disorder and suicidal ideation. Medication was ceased after 3 days. There was no recurrences after 6 months. J Paediatr. child health (2003) 39, 637-8

Report Detail

Case Number: 194237 **Seq:** 1 **Gender:** F
Reported: 03/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation	Suicidal ideation, withdrawal reaction.	
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROZAC (Suspected) **Reason:**
Dose Unspecified
Batch: **Started:** **Stopped:**

ZYPREXA (Suspected) **Reason:**
Dose Unspecified
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 194755 **Seq:** 1 **Gender:** F
Reported: 19/02/2004 **Weight:** 60.00
Hospitalisation: **Age:** 64
Onset Date: **DOB:** 01/01/1940
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Required Visit to Doctor	Anxious and nauseated.	
Nausea	Required Visit to Doctor		

Medicine Details:

GenRx Fluoxetine (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** 30/10/2004 **Stopped:** 04/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking premarin, ralovera, vioxx.
Resolved when changed back to prozac.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 196665 **Seq:** 1 **Gender:** M
Reported: 21/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 52
Onset Date: 09/11/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		Serotonin syndrome with hallucinating hyperreflexia increased sweating - hallucination, confusion and jerky movements	Ceased Fluoxetine and Amitriptyline. Gabapentin restarted

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 11/11/2003 7 years

AMITRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:** Pain
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 06/11/2003 **Stopped:** 11/11/2003

MORPHINE SULPHATE (Suspected) **Reason:**
Tablet 160.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** Months

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Ipratropium, Salbutamol, Calcium, Prednisolone, Omeprazole, Roxithromycin, Ampicillin and Gabapentin. History: Ca lung/emphysema/asbestos exposure. Shingles (mid thoracic) developed and diagnosed 5/11.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 196882 **Seq:** 1 **Gender:** F
Reported: 29/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 43Y
Onset Date: 15/12/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Irritability	Required Visit to Doctor	Feeling very irritable, aggressive, visual hallucinations of people in strange costumes, auditory hallucinations, angry.	Lovan and tramal ceased. Ms Contin given for pain and zyprexa 2mg
Aggression	Required Visit to Doctor		
Anger	Required Visit to Doctor		
Hallucination, auditory	Required Visit to Doctor		
Hallucination, visual	Required Visit to Doctor		

Medicine Details:

LOVAN (Interaction) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

TRAMAL SR (Interaction) **Reason:** Pain
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

HUMALOG (Other drug) **Reason:** Diabetes mellitus
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 196999 **Seq:** 1 **Gender:** F
Reported: 04/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: 15/02/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia Anxiety Feeling hot Headache Hyperhidrosis Nausea		Heart racing, felt hot internally, clammy hands, sweating, nausea, soft stools, headache, anxious	Lovan ceased. Xanax 500mcg

Medicine Details:

LUMIN (Other drug) **Reason:**
Tablet 8.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** Ongoing

STILNOX (Other drug) **Reason:** Specific disorders of sleep
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** Ongoing

LOVAN (Suspected) **Reason:**
1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 18/02/2004 From 02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 197456 **Seq:** 1
Reported: 19/05/2004
Hospitalisation:
Onset Date: 13/04/2004
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 25
DOB: 28/11/1978
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Blood albumin increased, ALT increased.	
Sinus tachycardia		Sinus tachycardia, elevated liver function tests, white blood cell count elevated.	Epilim and Lovan were ceased and Olanzapine was decreased to 20mg/day.
Leukocytosis			
White blood cell count increased			

Medicine Details:

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

OLANZAPINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

LOVAN (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 225.0 Milligram Daily Oral
Batch: **Started:** 06/04/2004 **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/05/2004	Albumin	35-45	19/04/2004	51	
19/05/2004	Electrocardiograph		13/04/2004	Serial ECG's	
19/05/2004	GGT = SGGT =	7-64	19/04/2004	42	
19/05/2004	Haemoglobin	120-180	19/04/2004	170	
19/05/2004	Platelets	150-450	19/04/2004	251	
19/05/2004	SAP = ALP	30-120	19/04/2004	30	

Additional Information:

Medically significant.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 197810 **Seq:** 1 **Gender:** F
Reported: 02/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 79Y
Onset Date: 16/03/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Required Specialist Consultation	A sales representative from Eli Lilly reported that a doctor had discussed a case of a 79 year old lady who had been taking Lovan (fluoxetine) 20mg daily for "about 6 months" when she experienced 2 grand mal seizures. One seizure was witnessed in February 2004 and one on 17th March 2004.	Ceased Lovan without recurrence of seizures

Medicine Details:

SIMVASTATIN (Other drug) **Reason:**
20.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:**

CLOPIDOGREL (Other drug) **Reason:**
15.0 Milligram 1 time Oral
Batch: **Started:** 02/02/2004 **Stopped:**

AVAPRO HCT 300/12.5 (Other drug) **Reason:** Hypertensive heart disease
1.0 Unit 1 time Oral
Batch: **Started:** **Stopped:**

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/06/2004	Electroencephalog				
02/06/2004	Electrolytes				

Additional Information:

The GP stated that a neurologist who saw the patient was certain this reaction was related to Lovan.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 197840 **Seq:** 1 **Gender:** F
Reported: 03/06/2004 **Weight:** 51.00
Hospitalisation: **Age:** 34Y
Onset Date: 05/03/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Anxiety Flushing Palpitations		Severe nausea, palpitations, flushing of skin and intense anxiety.	Ceased Lovan and increased dose of Lumin.

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 02/03/2004 **Stopped:** 19/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Lumin and Stilnox.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 198245 **Seq:** 1 **Gender:** F
Reported: 18/06/2004 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 99u
Onset Date: 24/05/2004 **DOB:**
Outcome: Unknown 01/06/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug exposure during pregnancy	Caused or prolonged inpatient hospitalisation	Maternal drug exposure, hyperactivity, during pregnancy drug exposure and aortic coarctation.	
Coarctation of the aorta	Caused or prolonged inpatient hospitalisation		
Psychomotor hyperactivity	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Initials HS. Baby born on: 24/05/04. Female. Weight 2.39kg

Report Detail

Case Number: 198337 **Seq:** 1 **Gender:** F
Reported: 21/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 34Y
Onset Date: 15/03/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Required Specialist Consultation	Serotonin syndrome; shivering, agitation, panic attacks, highly stimulated, problems with abnormal vision watching TV screen 'flickers'.	Lovan ceased.
Agitation	Required Specialist Consultation		
Chills	Required Specialist Consultation		

Medicine Details:

LUMIN (Suspected) **Reason:**
Tablet 140.0 Milligram Daily Oral
Batch: **Started:** 01/03/2004 **Stopped:**

LOVAN (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/03/2004 **Stopped:** 31/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Rivotril, Xanax and Stilnox.

Report Detail

Case Number: 198337 **Seq:** 1 **Gender:** F
Reported: 21/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 34Y
Onset Date: 15/03/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Panic attack	Required Specialist Consultation		
Psychomotor hyperactivity	Required Specialist Consultation		
Visual disturbance	Required Specialist Consultation		

Medicine Details:

LUMIN (Suspected) **Reason:**
Tablet 140.0 Milligram Daily Oral
Batch: **Started:** 01/03/2004 **Stopped:**

LOVAN (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/03/2004 **Stopped:** 31/03/2004

Laboratory Investigations:

Additional Information:
Patient also taking Rivotril, Xanax and Stilnox.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 198872 **Seq:** 1
Reported: 12/07/2004
Hospitalisation:
Onset Date: 18/06/2004
Outcome: Not yet recovered

Gender: F
Weight: 58.00
Age: 48
DOB: 31/07/1955
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion	Required Visit to Doctor	Excess salivation and mouth ulcers, rapid growth of nails and teeth aching.	
Mouth ulceration	Required Visit to Doctor		
Nail disorder	Required Visit to Doctor		
Toothache	Required Visit to Doctor		

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

20.0 Milligram Daily Oral

Batch: **Started:** 15/06/2004 **Stopped:** 29/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 198879 **Seq:** 1 **Gender:** M
Reported: 12/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 53
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug interaction Amnesia Confusional state Depression Disorientation Disturbance in attention Hyperhidrosis Myoclonus Serotonin syndrome Suicidal ideation		Drug interaction, serotonin syndrome, depression and suicidal ideation.	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction)			**Reason:**	Depression	
Capsule	80.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	Continuing
OLANZAPINE (Interaction)			**Reason:**	Depression	
Tablet	5.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	Continuing
DIAZEPAM (Other drug)			**Reason:**	Otr spec symp psychopathol nec	
	15.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History included recurrent major depressive disorder, generalised anxiety disorder and alcohol dependence in remission.
Chopra P, Ng C, Schweitzer I. Serotonin syndrome associated with fluoxetine and Olanzapine. World Journal of Biological Psychiatry. 2004; 5: 114-115.
Fluexetine was stopped, but he was maintained on Olanzapine and Diazepam due to his agitation. Over a week the disorientation, poor concentration, short-term memory and neurological symptoms resolved. After another week he was recommenced on Fluoxetine 20mg in addition to his other medications. There was no observed recurrence of serotonergic or depressive symptoms

Report Detail

Case Number: 198879 **Seq:** 1 **Gender:** M
Reported: 12/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 53
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction)			**Reason:**	Depression		
Capsule	80.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		Continuing
OLANZAPINE (Interaction)			**Reason:**	Depression		
Tablet	5.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		Continuing
DIAZEPAM (Other drug)			**Reason:**	Otr spec symp psychopathol nec		
	15.0	Milligram	Daily			
Batch:	**Started:**			**Stopped:**		

Laboratory Investigations:

Additional Information:

History included recurrent major depressive disorder, generalised anxiety disorder and alcohol dependence in remission.
Chopra P, Ng C, Schweitzer I. Serotonin syndrome associated with fluoxetine and Olanzapine. World Journal of Biological Psychiatry. 2004; 5: 114-115.
Fluexetine was stopped, but he was maintained on Olanzapine and Diazepam due to his agitation. Over a week the disorientation, poor concentration, short-term memory and neurological symptoms resolved. After another week he was recommenced on Fluoxetine 20mg in addition to his other medications. There was no observed recurrence of serotonergic or depressive symptoms

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 199509 **Seq:** 1 **Gender:** M
Reported: 30/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 45
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Drug withdrawal syndrome Obsessive-compulsive disorder Suicide attempt		Obsessively suicidal and cut his throat.	Prazac ceased.

Medicine Details:

PROZAC (Suspected) **Reason:**

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

A frequently suicidal man who was put on Fluoxetine 10mg while suicidal, increased to 20mg and he became obsessively suicidal and cuti his throat 3/7 dafter Prozac was stopped.

Report Detail

Case Number: 199561 **Seq:** 1 **Gender:** F
Reported: 30/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 23
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation	Added Risperdal.

Medicine Details:

LOVAN (Suspected) **Reason:**
80.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Nearly died from suicidal attempt

Report Detail

Case Number: 199764 **Seq:** 1 **Gender:** F
Reported: 06/08/2004 **Weight:** 0.00
Hospitalisation: **Age:** 80
Onset Date: 01/04/2004 **DOB:** 06/10/1923
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormon		Siadh - nausea and vomiting and increased confusion.	Fluoxetine and Amizide ceased. Fluid restriction to 1L/day. Demeclocycline started

Medicine Details:

ALPRAZOLAM (Other drug) **Reason:**
Tablet 250.0 Microgram As necessary Oral
Batch: **Started:** L TERM **Stopped:**

SALBUTAMOL (Other drug) **Reason:**
Inhalation 100.0 Microgram As necessary Oral Application
Batch: **Started:** L TERM **Stopped:**

SALMETEROL XINAFOATE (Other drug) **Reason:**
Inhalation 300.0 Microgram Daily Oral Application
Batch: **Started:** L TERM **Stopped:**

BECLOMETHASONE DIPROPIONATE (Other drug) **Reason:**
Inhalation 400.0 Microgram Daily Oral Application
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/08/2004	Sodium		01/04/2004	113 mmol/L	
06/08/2004	Sodium		04/04/2004	118 mmol/L	
06/08/2004	Sodium		08/04/2004	135 mmol/L	
06/08/2004	Urine osmolality		01/04/2004	445	

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 199764 **Seq:** 1
Reported: 06/08/2004
Hospitalisation:
Onset Date: 01/04/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 80
DOB: 06/10/1923
Causality: Causality possible

Reaction Detail

Medicine Details:

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

1.0 Millilitre Daily

Batch: **Started:** S TERM **Stopped:**

AMIZIDE (Suspected) **Reason:**

Tablet 1.0 Dose Unspecified Daily Oral

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 199876 **Seq:** 1
Reported: 11/08/2004
Hospitalisation:
Onset Date: 07/07/2004
Outcome: Not yet recovered

Gender: F
Weight: 84.00
Age: 54
DOB: 05/10/1949
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration	Required Visit to Doctor	Patient developed mouth and throat ulceration with increase in dose of Fluoxetine from 20mg to 40mg	
Throat irritation	Required Visit to Doctor		

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 03/07/2004 **Stopped:** 05/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previously taken Fluoxetine for 12/12

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 199943 **Seq:** 1
Reported: 12/08/2004
Hospitalisation: Admitted to hospital
Onset Date: 09/08/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 27
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Swelling face	Caused or prolonged inpatient hospitalisation	Hospitalised at 7:45am with facial swelling, lip swelling and shortness of breath. Felt dizzy and light-headed on getting out of bed. She had been taking Lovan 20mg daily since July 26th but after 3 days noticed "hives" on her back and on the backs of both hands.The "hives" were itchy and "mildly annoying". She phoned the GP who said it could be related to the Lovan and advised she stop taking it (2nd August). She was keen to re-try the Lovan since it had lifted her mood and energy levels whilst she was taking it. The hives responded to stopping the medication and had resolved by 5th August so she started the Lovan again on 5th August, 20mg daily. When she woke on 9th August, her ...	IV adrenaline, steroids and antihistamines

Medicine Details:

LOVAN (Suspected) **Reason:**

20.0 Milligram 1 time Oral

Batch: **Started:** 05/08/2004 **Stopped:** 09/08/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 199943 **Seq:** 1
Reported: 12/08/2004
Hospitalisation: Admitted to hospital
Onset Date: 09/08/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 27
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anaphylactic reaction	Caused or prolonged inpatient hospitalisation	... partner took her to hospital because of the swelling and shortness of breath. She was admitted and treated for angioedema and anaphylaxis and remained in hospital for 1 night.	
Angioedema	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:**

20.0 Milligram 1 time Oral

Batch: **Started:** 05/08/2004 **Stopped:** 09/08/2004 0

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 199943 **Seq:** 1
Reported: 12/08/2004
Hospitalisation: Admitted to hospital
Onset Date: 09/08/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 27
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Lip swelling	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:**

20.0 Milligram 1 time Oral

Batch: **Started:** 05/08/2004 **Stopped:** 09/08/2004 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 199943 **Seq:** 1
Reported: 12/08/2004
Hospitalisation: Admitted to hospital
Onset Date: 09/08/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 27
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus	Caused or prolonged inpatient hospitalisation		
Swelling face	Caused or prolonged inpatient hospitalisation		
Urticaria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram 1 time Oral
Batch: **Started:** 05/08/2004 **Stopped:** 09/08/2004 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 200225 **Seq:** 1
Reported: 23/08/2004
Hospitalisation:
Onset Date: 17/08/2004
Outcome: Not yet recovered

Gender: M
Weight: 46.00
Age: 9
DOB: 26/09/1994
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Panic attack		Panic attacks.	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

20.0 Milligram Daily Oral

Batch: **Started:** 07/08/2004 **Stopped:** 17/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 200328 **Seq:** 1
Reported: 26/08/2004
Hospitalisation: Admitted to hospital
Onset Date: 22/07/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 67Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Serotonin syndrome with confusion, agitation, tremor, impaired mobility, hallucinations, hyper-reflexia, hypertonia, hypertension and fever	Amantadine, Lovan and MS Contin ceased.
Agitation	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

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

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

MS CONTIN (Suspected) **Reason:** Pain
Batch: **Started:** L TERM **Stopped:** 22/07/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 200328 **Seq:** 1
Reported: 26/08/2004
Hospitalisation: Admitted to hospital
Onset Date: 22/07/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 67Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination	Caused or prolonged inpatient hospitalisation		
Hyperreflexia	Caused or prolonged inpatient hospitalisation		
Hypertension	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMANTADINE HYDROCHLORIDE (Suspected) **Reason:** Pain

Capsule 200.0 Milligram Daily Oral

Batch: **Started:** 22/07/2004 **Stopped:** 22/07/2004

LOVAN (Suspected) **Reason:** Depression

40.0 Milligram Daily

Batch: **Started:** 15/04/2003 **Stopped:** 17/08/2004

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 200328 **Seq:** 1
Reported: 26/08/2004
Hospitalisation: Admitted to hospital
Onset Date: 22/07/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 67Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mobility decreased	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

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

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

MS CONTIN (Suspected) **Reason:** Pain
Batch: **Started:** L TERM **Stopped:** 22/07/2004

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 200328 **Seq:** 1
Reported: 26/08/2004
Hospitalisation: Admitted to hospital
Onset Date: 22/07/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 67Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

AMANTADINE HYDROCHLORIDE (Suspected)			**Reason:**	Pain	
Capsule	200.0	Milligram	Daily		Oral
Batch:	**Started:**	22/07/2004		**Stopped:**	22/07/2004
LOVAN (Suspected)			**Reason:**	Depression	
	40.0	Milligram	Daily		
Batch:	**Started:**	15/04/2003		**Stopped:**	17/08/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 200329 **Seq:** 1
Reported: 27/08/2004
Hospitalisation: Admitted to hospital
Onset Date: 27/08/2004
Outcome: Unknown

Gender: F
Weight: 45.00
Age: 97
DOB: 29/04/1907
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation	Acute Confusion	
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatremia	

Medicine Details:

LOVAN (Suspected) **Reason:** Otr spec symp psychopathol nec

20.0 Milligram Daily Oral

Batch: **Started:** 18/08/2004 S TERM **Stopped:** 27/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/08/2004	Chloride				87
27/08/2004	Sodium				Sodium 123

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 201099 **Seq:** 1 **Gender:** F
Reported: 23/09/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 22
Onset Date: 29/08/2004 **DOB:** 04/06/1982
Outcome: Recovered 04/09/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Infantile apnoeic attack	Required Visit to Doctor	Baby born at 36 weeks gestation spontaneous rapture of membranes, prolonged labour induced with syntocinon infusion by normal vaginal delivery. Time to establish respiration 5 min. transient bradycardia associated with decreased temperature.	Required ventilation, ICU
Bradycardia			
Hypothermia			
Premature labour	Required Visit to Doctor		

Medicine Details:

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

Capsule 40.0 Milligram Daily Oral

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

QUETIAPINE (Suspected) **Reason:**

Tablet 25.0 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 201273 **Seq:** 1 **Gender:** M
Reported: 27/09/2004 **Weight:** 77.00
Hospitalisation: **Age:** 45
Onset Date: 14/09/2004 **DOB:** 21/04/1959
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Influenza like illness		When has a flu-like illness gets "electric shock feelings " intermittently from head and down body to feet.	

Medicine Details:

PROZAC (Suspected) **Reason:** Anxiety neurosis

Milligram Daily Oral

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspect drug positive rechallenge - patient claims same symptoms on previous exposure.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 201444 **Seq:** 1 **Gender:** M
Reported: 05/10/2004 **Weight:** 62.00
Hospitalisation: **Age:** 45
Onset Date: 15/04/2004 **DOB:** 16/03/1959
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Acne		Patient developed facial acne.	Lovan ceased

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** 10/03/2004 **Stopped:** 15/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 201899 **Seq:** 1
Reported: 21/10/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 17
DOB: 13/06/1987
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania	Caused or prolonged inpatient hospitalisation	Patient became manic half an hour after commencing antidepressant.	

Medicine Details:

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

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 15/07/2004 **Stopped:** 02/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202111 **Seq:** 1
Reported: 27/10/2004
Hospitalisation: Admitted to hospital
Onset Date: 20/08/2004
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 41Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression	Caused or prolonged inpatient hospitalisation	My brother is suffering from deep depression. Was perscribed Lovan which caused tremors and he was not sleeping.	About a week or 2 later he was put on Diazepam. One at night with a sleeping tablet.
Insomnia	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

60.0 Milligram 3 times Oral

Batch: **Started:** 11/08/2004 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 202907 is the second sequence to this report.
No treatment has has been done as to side effects of tablets. Many tests have been carried out for his loss of balance and tremors. Many blood tests, CT's, MRI's, but they are all clear and they cannot find what is causing his problems for which I believe is due to his medication!

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202143 **Seq:** 1 **Gender:** M
Reported: 28/10/2004 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: 25/10/2004 **DOB:**
Outcome: Recovered 26/10/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Panic attack		Awoke with a panic attack-anxious, felt he could not breath.	

Medicine Details:

GenRx Fluoxetine (Suspected) **Reason:** Depression
Capsule 20.0 Milligram 1 time Oral
Batch: **Started:** 25/10/2004 **Stopped:** 25/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 202666 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Aggression		Patient had suicidal ideation and was	

Medicine Details:

OLANZAPINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202672 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 40
Onset Date: **DOB:** 28/04/1964
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Hallucination, auditory Muscle spasms Tremor		After ceasing Prozac, patient experienced trembling, cramps, heard voices and had suicidal ideation	

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202691 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Homicidal ideation		Suicidal and homicidal ideation.	

Medicine Details:

QUETIAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Capsule Oral
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202721 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Suicide attempt		Suicidal ideation and suicide attempt.	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**

Capsule 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202762 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicide attempt.	Dicharged on 60mg Fluoxetine on 29/08/03.

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Capsule Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202767 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 43
Onset Date: 05/02/2004 **DOB:** 17/07/1960
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia Suicidal ideation Suicide attempt		Patient experienced akathisia, suicidal ideation and suicide attempt.	

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202771 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Aggression		Suicidal violence.	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Capsule Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 202774 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**

Capsule 20.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202777 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Suicide attempt		Suicidal ideation and suicide attempt.	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Capsule Oral
Batch: **Started:** **Stopped:**

RISPERDAL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202784 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: **DOB:** 16/08/1954
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Akathisia Suicide attempt		Suicidal ideation, suicide attempt and	

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202789 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 37
Onset Date: **DOB:** 14/09/1967
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicide attempt.	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**

Capsule 20.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202835 **Seq:** 1 **Gender:** U
Reported: 19/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicidal ideation and suicide attempt.	

Medicine Details:

RISPERDAL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Capsule 80.0 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202836 **Seq:** 1 **Gender:** U
Reported: 19/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt Aggression		Suicide attempt and violent.	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Capsule Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 202844 **Seq:** 1 **Gender:** U
Reported: 19/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Aggression		Suicidal ideation and violent.	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Capsule Oral
Batch: **Started:** **Stopped:**

ZYPREXA (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 203186 **Seq:** 1
Reported: 01/12/2004
Hospitalisation: Admitted to hospital
Onset Date: 15/01/2004
Outcome: Unknown

Gender: M
Weight: 82.00
Age: 60
DOB: 05/03/1943
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Life	The patient developed bad trembling, high anxiety, chills, impaired vision, sweating, depression, bad dreams, headaches, low libido and hallucinations.	Hospitalisation for 3 days.
Anxiety	Life		
Chills	Life		
Depression	Life		
Hallucination	Life		
Headache	Life		
Hyperhidrosis	Life		
Loss of libido	Life		
Nightmare	Life		

Medicine Details:

AROPAX (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

LOVAN (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Lexapro (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

DOTHEP (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 203186 **Seq:** 1
Reported: 01/12/2004
Hospitalisation: Admitted to hospital
Onset Date: 15/01/2004
Outcome: Unknown

Gender: M
Weight: 82.00
Age: 60
DOB: 05/03/1943
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance	Life		

Medicine Details:

VERAPAMIL HYDROCHLORIDE (Suspected) **Reason:** Headache

Tablet 80.0 Milligram Daily Oral

Batch: **Started:** 15/10/2003 **Stopped:**

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

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

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

Capsule 225.0 Milligram Daily Oral

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 203391 **Seq:** 1 **Gender:** F
Reported: 09/12/2004 **Weight:** 60.00
Hospitalisation: **Age:** 15
Onset Date: **DOB:** 09/04/1989
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea		The patient experienced nausea.	Lowered dosage temporarily with some benefit.

Medicine Details:

FISH OIL NOS (Other drug) **Reason:**
1.0 Gram
Batch: **Started:** **Stopped:**

FERROUS SULPHATE (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

SODIUM VALPROATE (Other drug) **Reason:** Unspecifid affective psychosis
1.0 Gram Daily Oral
Batch: **Started:** 15/07/2004 S TERM **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Capsule 40.0 Milligram Daily Oral
Batch: **Started:** 26/10/2004 S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

In the past has had migraines with Citalopram, suicidality since age 4, 2 episodes of mania. Family history of mood disorder.

Report Detail

Case Number: 203503 **Seq:** 1
Reported: 13/12/2004
Hospitalisation: Admitted to hospital
Onset Date: 21/11/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 51
DOB: 16/01/1953
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Caused or prolonged inpatient hospitalisation	Collapse at home, syncope. Complaints of feeling dizzy, anxious and jerking movements. Mild intention tremor.	Prozac and Sinequan ceased.
Anxiety	Caused or prolonged inpatient hospitalisation		
Dizziness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROZAC (Interaction) **Reason:**
240.0 Milligram Daily Oral
Batch: **Started:** 20/10/2004 **Stopped:** 22/11/2004

SINEQUAN (Interaction) **Reason:**
250.0 Milligram Daily Oral
Batch: **Started:** 20/10/2004 **Stopped:** 22/11/2004

MOGADON (Other drug) **Reason:** Specific disorders of sleep
20.0 Milligram Oral
Batch: **Started:** 15/03/2004 **Stopped:** 22/11/2004

TEMAZE (Other drug) **Reason:** Specific disorders of sleep
20.0 Milligram Oral
Batch: **Started:** 15/11/2004 **Stopped:** 22/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 203503 **Seq:** 1
Reported: 13/12/2004
Hospitalisation: Admitted to hospital
Onset Date: 21/11/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 51
DOB: 16/01/1953
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Caused or prolonged inpatient hospitalisation		
Syncope	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ORDINE (Other drug) **Reason:** Headache

200.0 Milligram Daily Oral

Batch: **Started:** 20/10/2004 **Stopped:** 22/11/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 203557 **Seq:** 1 **Gender:** M
Reported: 15/12/2004 **Weight:** 0.00
Hospitalisation: **Age:** 20
Onset Date: **DOB:** 29/04/1984
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Required Visit to Doctor	Patient rapidly developed Serotonin Syndrome, agitation, confusion, vomiting, sweating, dizziness, tremor and inco-ordination	Required a visit to casualty and kept in a few hours. Buprenorphine ceased.
Agitation	Required Visit to Doctor		
Confusional state	Required Visit to Doctor		
Coordination abnormal	Required Visit to Doctor		
Dizziness	Required Visit to Doctor		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Capsule 40.0 Milligram Daily Oral
Batch: **Started:** 13/05/2004 **Stopped:**

BUPRENORPHINE HYDROCHLORIDE (Interaction) **Reason:** Dependence on unspecifid drugs
2.0 Milligram Daily
Batch: **Started:** 15/06/2004 **Stopped:** 22/06/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 203557 **Seq:** 1 **Gender:** M
Reported: 15/12/2004 **Weight:** 0.00
Hospitalisation: **Age:** 20
Onset Date: **DOB:** 29/04/1984
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Required Visit to Doctor		
Tremor	Required Visit to Doctor		
Vomiting	Required Visit to Doctor		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Capsule 40.0 Milligram Daily Oral
Batch: **Started:** 13/05/2004 **Stopped:**

BUPRENORPHINE HYDROCHLORIDE (Interaction) **Reason:** Dependence on unspecifid drugs
2.0 Milligram Daily
Batch: **Started:** 15/06/2004 **Stopped:** 22/06/2004 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 203566 **Seq:** 1 **Gender:** F
Reported: 15/12/2004 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: 23/11/2004 **DOB:** 25/05/1955
Outcome: Recovered 27/11/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Febrile up to 40.1, tachycardic, hypotensive, widespread aches in limbs / stomach / back, 3 days incontinence, dehydrated and some peripheral oedema.	
Blood creatine phosphokinase in	Caused or prolonged inpatient hospitalisation		
Dehydration	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 225.0 Milligram Daily Oral
Batch: **Started:** 08/11/2004 **Stopped:** 23/11/2004

ATORVASTATIN (Suspected) **Reason:** Othr&unspec metabolic diseases
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/11/2004

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/12/2004	Creatine kinase				CK rise to 902
15/12/2004	Other data				serum myoglobin 128
15/12/2004	Troponin				TnI 1.8

Additional Information:

Deranged LFT's for over a year prior to this event --> secondary to statin therapy.

Report Detail

Case Number: 203566 **Seq:** 1 **Gender:** F
Reported: 15/12/2004 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: 23/11/2004 **DOB:** 25/05/1955
Outcome: Recovered 27/11/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation		
Hypotension	Caused or prolonged inpatient hospitalisation		
Myalgia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 225.0 Milligram Daily Oral
Batch: **Started:** 08/11/2004 **Stopped:** 23/11/2004

ATORVASTATIN (Suspected) **Reason:** Othr&unspec metabolic diseases
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/11/2004

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/11/2004

Laboratory Investigations:

Additional Information:

Deranged LFT's for over a year prior to this event --> secondary to statin therapy.

Report Detail

Case Number: 203566 **Seq:** 1 **Gender:** F
Reported: 15/12/2004 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: 23/11/2004 **DOB:** 25/05/1955
Outcome: Recovered 27/11/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 225.0 Milligram Daily Oral
Batch: **Started:** 08/11/2004 **Stopped:** 23/11/2004

ATORVASTATIN (Suspected) **Reason:** Othr&unspec metabolic diseases
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/11/2004

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/11/2004

Laboratory Investigations:

Additional Information:

Deranged LFT's for over a year prior to this event --> secondary to statin therapy.

Report Detail

Case Number: 203566 **Seq:** 1 **Gender:** F
Reported: 15/12/2004 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: 23/11/2004 **DOB:** 25/05/1955
Outcome: Recovered 27/11/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 225.0 Milligram Daily Oral
Batch: **Started:** 08/11/2004 **Stopped:** 23/11/2004

ATORVASTATIN (Suspected) **Reason:** Othr&unspec metabolic diseases
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/11/2004

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/11/2004

Laboratory Investigations:

Additional Information:

Deranged LFT's for over a year prior to this event --> secondary to statin therapy.

Report Detail

Case Number: 204250 **Seq:** 1
Reported: 14/01/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	The patient experienced a neck rigidity.	
Nuchal rigidity	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Capsule Oral
Batch: **Started:** S TERM **Stopped:**

Abilify (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 204850 **Seq:** 1 **Gender:** F
Reported: 03/02/2005 **Weight:** 0.00
Hospitalisation: **Age:** 18Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intentional self-injury Agitation		Deliberate self harm, patient cutting herself, agitation.	Ceased Fluoxetine.

Medicine Details:

LOVAN (Suspected) **Reason:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 205201 **Seq:** 1
Reported: 11/02/2005
Hospitalisation: Admitted to hospital
Onset Date: 11/09/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 32
DOB: 22/09/1971
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation	Patient experienced nausea, vomiting and [illegible]	All medications ceased.
Chills	Caused or prolonged inpatient hospitalisation		
Hot flush	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** 20/07/2004 **Stopped:**

IBILEX (Suspected) **Reason:** Ac upr resp inf,mult,unsp stes
Capsule 2.0 Gram Daily Oral
Batch: **Started:** 09/09/2004 **Stopped:** 0

PANADEINE FORTE (Suspected) **Reason:**
1.0 Dose Unspecified Daily Oral
Batch: **Started:** 09/09/2004 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/02/2005	Other data				LFT's were: ALT 1458 (7-33) and AST 1347 (10-45) on the same day of admission. Negative hepatitis A, B and C serology.

Additional Information:

This was the patient's first exposure to both Lovan and Ibilex. It is medically confirmed since reported by a H.P. She has a previous history of allergy to Maxalon.

Report Detail

Case Number: 205201 **Seq:** 1
Reported: 11/02/2005
Hospitalisation: Admitted to hospital
Onset Date: 11/09/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 32
DOB: 22/09/1971
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Rash	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** 20/07/2004 **Stopped:**

IBILEX (Suspected) **Reason:** Ac upr resp inf,mult,unsp stes
Capsule 2.0 Gram Daily Oral
Batch: **Started:** 09/09/2004 **Stopped:** 0

PANADEINE FORTE (Suspected) **Reason:**
1.0 Dose Unspecified Daily Oral
Batch: **Started:** 09/09/2004 **Stopped:** 0

Laboratory Investigations:

Additional Information:

This was the patient's first exposure to both Lovan and Ibilex. It is medically confirmed since reported by a H.P. She has a previous history of allergy to Maxalon.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 205643 **Seq:** 1
Reported: 01/03/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 53
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Patient experienced serotonin syndrome, confusional state, memory impairment, speech disorder, tremor, hypertidrosis, myoclonus, anxiety disorder, somatic hallucination and disorientation.	Fluoxetine ceased. Recommenced Fluoxetine 20mg/daily.
Anxiety	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression

Capsule 80.0 Milligram Daily Oral

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

OLANZAPINE (Interaction) **Reason:** Depression

Tablet 2.0 Milligram Daily Oral

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

DIAZEPAM (Other drug) **Reason:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Literature report: World J Biol Psychiatry (2004) 5, 114-115: Serotonin Syndrome Associated with Fluoxetine and Olanzapine, Prem Chopra, Chee Ng, Isaac Schweltzer. Patient received a high dose of Fluoxetine previously with no adverse effects, the patient only developed serotonin syndrome after the addition of Olanzapine for three weeks.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 205643 **Seq:** 1
Reported: 01/03/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 53
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disorientation	Caused or prolonged inpatient hospitalisation		
Hallucination	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction)			**Reason:**	Depression	
Capsule	80.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
OLANZAPINE (Interaction)			**Reason:**	Depression	
Tablet	2.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
DIAZEPAM (Other drug)			**Reason:**		
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

Literature report: World J Biol Psychiatry (2004) 5, 114-115: Serotonin Syndrome Associated with Fluoxetine and Olanzapine, Prem Chopra, Chee Ng, Isaac Schweltzer. Patient received a high dose of Fluoxetine previously with no adverse effects, the patient only developed serotonin syndrome after the addition of Olanzapine for three weeks.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 205643 **Seq:** 1
Reported: 01/03/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 53
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Memory impairment	Caused or prolonged inpatient hospitalisation		
Myoclonus	Caused or prolonged inpatient hospitalisation		
Speech disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Capsule 80.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

OLANZAPINE (Interaction) **Reason:** Depression
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

DIAZEPAM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Literature report: World J Biol Psychiatry (2004) 5, 114-115: Serotonin Syndrome Associated with Fluoxetine and Olanzapine, Prem Chopra, Chee Ng, Isaac Schweltzer. Patient received a high dose of Fluoxetine previously with no adverse effects, the patient only developed serotonin syndrome after the addition of Olanzapine for three weeks.

Report Detail

Case Number: 205643 **Seq:** 1
Reported: 01/03/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 53
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction)			**Reason:**	Depression	
Capsule	80.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
OLANZAPINE (Interaction)			**Reason:**	Depression	
Tablet	2.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
DIAZEPAM (Other drug)			**Reason:**		
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

Literature report: World J Biol Psychiatry (2004) 5, 114-115: Serotonin Syndrome Associated with Fluoxetine and Olanzapine, Prem Chopra, Chee Ng, Isaac Schweltzer. Patient received a high dose of Fluoxetine previously with no adverse effects, the patient only developed serotonin syndrome after the addition of Olanzapine for three weeks.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 205733 **Seq:** 1 **Gender:** F
Reported: 03/03/2005 **Weight:** 70.00
Hospitalisation: **Age:** 39
Onset Date: 07/12/2004 **DOB:** 25/08/1965
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus	Required Visit to Doctor	Experienced ringing in ears, dry mouth, over excitement,	Changed to Efexor.
Dry mouth	Required Visit to Doctor		
Euphoric mood	Required Visit to Doctor		

Medicine Details:

LOVAN (Suspected) **Reason:** Anxiety neurosis
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 01/12/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 205832 **Seq:** 1
Reported: 08/03/2005
Hospitalisation:
Onset Date: 15/12/2004
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 17
DOB: 02/04/1987
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug level increased	Required Visit to Doctor	The patient experienced dyskinesia and showed a 'recent' serum level of 800 ng/ml, whilst on Clozaril as part of multiple therapy	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction) **Reason:**
Capsule Oral
Batch: **Started:** **Stopped:**

CLOZARIL (Interaction) **Reason:**
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 14/09/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/03/2005	Serum drug level				(Recently) Clozapine serum level: 800 ng/ml.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 206280 **Seq:** 1
Reported: 28/03/2005
Hospitalisation:
Onset Date: 09/01/2005
Outcome: Recovered with sequelae

Gender: F
Weight: 54.00
Age: 15
DOB: 21/06/1989
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life	Attempt to hang herself with television cord from curtain rail in hospital bedroom. Nurse said she found her at the last moment.	
Drug ineffective	Life		

Medicine Details:

ZYPREXA (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:**
Tablet Milligram Daily Oral
Batch: **Started:** 16/12/2004 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

One patient with ADRs 206280, 206281, 206282 206283

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 206282 **Seq:** 1
Reported: 28/03/2005
Hospitalisation:
Onset Date: 20/12/2004
Outcome: Recovered with sequelae

Gender: F
Weight: 54.00
Age: 15
DOB: 21/06/1989
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life	Suicide attempt. Ingested 40 Panadol tablets. Also frequent self harming	Charcoal and drip of drug to break down the paracetamol.
Drug ineffective	Life		
Self injurious behaviour	Life		

Medicine Details:

PANADOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

OLANZAPINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

PANADEINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 0

PROZAC (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 16/12/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

One patient with ADRs 206280, 206281, 206282 206283

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 206283 **Seq:** 1
Reported: 28/03/2005
Hospitalisation:
Onset Date: 23/03/2005
Outcome: Not yet recovered

Gender: F
Weight: 54.00
Age: 15
DOB: 21/06/1989
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life	Attempted suicide by ingestion of 80 Panadol, 20 Panadeine, 7 Olanzapine (Zyprexa)	Charcoal, drips of various antidotes including one for breaking down paracetamol, ventilator, all monitors, intensive care for 20 hours. She is now having constant convulsions. These started on 26 March 2005 and are continuing. On 26 march they were of long duration and with only breaks of 10 or 20 minutes. On 27 March they were of various duration and sometimes an hour or two apart. Today she has already had some fits today. The hospital cannot work out the

Medicine Details:

ZYPREXA (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

PANADOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

PANADEINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:**
Tablet Milligram Daily Oral
Batch: **Started:** 16/12/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

One patient with ADRs 206280, 206281, 206282 206283. She takes Olanzapine to help her sleep. She is not psychotic (per reporter).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 206283 **Seq:** 1
Reported: 28/03/2005
Hospitalisation:
Onset Date: 23/03/2005
Outcome: Not yet recovered

Gender: F
Weight: 54.00
Age: 15
DOB: 21/06/1989
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Life		
Drug ineffective	Life		

Medicine Details:

ZYPREXA (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

PANADOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

PANADEINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:**
Tablet Milligram Daily Oral
Batch: **Started:** 16/12/2004 **Stopped:**

Laboratory Investigations:

Additional Information:

One patient with ADRs 206280, 206281, 206282 206283. She takes Olanzapine to help her sleep. She is not psychotic (per reporter).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 206601 **Seq:** 1 **Gender:** M
Reported: 04/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 71
Onset Date: 12/11/2004 **DOB:** 11/09/1933
Outcome: Recovered 24/11/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation	Confusion and delirium.	Ceased Lovan, simple analgesia, Serenace prn and narcotics for very strong pain.
Delirium	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CORDARONE X (Other drug) **Reason:**
Tablet 200.0 Milligram Oral
Batch: **Started:** **Stopped:**

ENALAPRIL MALEATE (Other drug) **Reason:**
Tablet 40.0 Milligram Oral
Batch: **Started:** **Stopped:**

SOMAC (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

STEMETIL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 206601 **Seq:** 1 **Gender:** M
Reported: 04/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 71
Onset Date: 12/11/2004 **DOB:** 11/09/1933
Outcome: Recovered 24/11/2004 **Causality:** Causality possible

Reaction Detail

Medicine Details:

CAPADEX (Suspected)			**Reason:** Pain		
Capsule	2.0	Dose Unspecified	As necessary	Oral	
Batch:	**Started:** 21/10/2004			**Stopped:**	
MORPHINE SULPHATE (Suspected)			**Reason:** Pain		
Injection	8.0	Milligram	As necessary	Intravenous	
Batch:	**Started:** 21/10/2004			**Stopped:**	
PETHIDINE HYDROCHLORIDE (Suspected)			**Reason:** Pain		
Injection	75.0	Milligram	As necessary	Intravenous	
Batch:	**Started:** 16/09/2004			**Stopped:**	
LOVAN (Suspected)			**Reason:**		
	20.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:** 17/11/2004	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 206906 **Seq:** 1 **Gender:** F
Reported: 11/04/2005 **Weight:** 50.00
Hospitalisation: Admitted to hospital **Age:** 19Y
Onset Date: 18/02/2005 **DOB:**
Outcome: Recovered 18/02/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient had a seizure "switching off, throwing her head back and twitching her arms all over the place. Her left leg straightened and became stiff. It lasted about 1 minute. Patient was very sleepy and also found to be dehydrated and had a blood glucose of 3 (hypoglycaemia BGL = 3). Withdrawal reaction suspected.	Patient weaned herself off
Dehydration	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** 15/11/2003 **Stopped:** 31/01/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/04/2005	Electroencephalog				Results of EEG Normal (11th March 2005).
11/04/2005	Other data				Ct brain and Lumbar Puncture both of which were normal. Blood tests at the hospital were all normal.

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 206906 **Seq:** 1 **Gender:** F
Reported: 11/04/2005 **Weight:** 50.00
Hospitalisation: Admitted to hospital **Age:** 19Y
Onset Date: 18/02/2005 **DOB:**
Outcome: Recovered 18/02/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		
Hypoglycaemia	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** 15/11/2003 **Stopped:** 31/01/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 207062 **Seq:** 1 **Gender:** M
Reported: 14/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: 15/10/2004 **DOB:** 27/01/1965
Outcome: Death, maybe drug 02/04/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Death Angiocentric lymphoma	Death Death	Diffuse large cell lymphoma. The patient died from lymphoma whilst on Clopine treatment	

Medicine Details:

CLOPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** 30/04/2004 **Stopped:** 02/04/2005 0

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 0

AMISULPRIDE (Suspected) **Reason:** Schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 30/10/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 207514 **Seq:** 1
Reported: 29/04/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 15/10/2004
Outcome: Not yet recovered

Gender: F
Weight: 85.00
Age: 47
DOB: 09/06/1957
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sleep walking Abnormal sleep-related event Eating disorder		Patient experienced sleepwaking and eating while asleep as has no memory of doing so but her daughter has caught her several times	Nil

Medicine Details:

TRAMADOL HYDROCHLORIDE (Other drug)		**Reason:**	Other disturbance of sensation
Batch:	**Started:**		**Stopped:**
VOLTAREN EMULGEL (Other drug)		**Reason:**	Other disturbance of sensation
Batch:	**Started:**		**Stopped:**
AMITRIPTYLINE HYDROCHLORIDE (Other drug)		**Reason:**	Pain
Batch:	**Started:**		**Stopped:**
FLIXOTIDE (Other drug)		**Reason:**	Asthma
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 207514 **Seq:** 1
Reported: 29/04/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 15/10/2004
Outcome: Not yet recovered

Gender: F
Weight: 85.00
Age: 47
DOB: 09/06/1957
Causality: Causality possible

Reaction Detail

Medicine Details:

VENTOLIN CFC-FREE INHALER (Other drug)				**Reason:**	Asthma	
Batch:	**Started:**				**Stopped:**	
STILNOX (Suspected)				**Reason:**	Specific disorders of sleep	
Tablet	10.0	Milligram	Daily		Oral	
Batch:	**Started:**	30/10/2003	L TERM		**Stopped:**	
FLUOXETINE HYDROCHLORIDE (Suspected)				**Reason:**	Depression	
	20.0	Milligram	Daily		Oral	
Batch:	**Started:**	30/10/2003	L TERM		**Stopped:**	15/01/2005

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 207566 **Seq:** 1 **Gender:** M
Reported: 03/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 79
Onset Date: 02/02/2005 **DOB:** 11/08/1925
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatremia. Was not symptomatic and was not the reason for admission. Discovered incidentally in blood test. Doctor asked for Na levels to be monitored. If levels did not normalise Dr recommended ceasing Lovan to see if that resolves low Na levels.	observation

Medicine Details:

ANTENEX (Other drug) **Reason:**
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

SOLPRIN (Other drug) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

LOVAN (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/05/2005	Electrolytes				Serum Na several readings in the 120's (normal value

Additional Information:

Report Detail

Case Number: 207579 **Seq:** 1 **Gender:** F
Reported: 04/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 26
Onset Date: 26/03/2005 **DOB:** 16/01/1979
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug level above therapeutic		Patient's dose was increased from 375mg nocte to 400mg nocte, described as being more than twice the therapeutic level.	

Medicine Details:

PROZAC (Interaction) **Reason:**
Batch: **Started:** **Stopped:** 20/04/2005 0

CLOZARIL (Interaction) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 03/03/2003 **Stopped:** 0

DIAZEPAM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/05/2005	Serum drug level	400-1000	13/10/2004	830	Clozapine serum levels and trough Clozapine serum level.
04/05/2005	Serum drug level	400-1000	26/03/2005	1720	Clozapine serum levels and trough Clozapine serum level.
04/05/2005	Serum drug level	400-1000	29/03/2005	2010	Clozapine serum levels and trough Clozapine serum level.
04/05/2005	Serum drug level	400-1000	19/04/2005	1980	Clozapine serum levels and trough Clozapine serum level.
04/05/2005	Serum drug level	400-1000	04/05/2005	2140.	Clozapine serum levels and trough Clozapine serum level.

Additional Information:

The patient was noted to be a heavy drinker and smoker.Patient was also a polysubstance abuser

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 207619 **Seq:** 1 **Gender:** U
Reported: 05/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 22/11/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pyrexia Anorexia Arthralgia Fatigue Headache Myalgia		Patient developed fever, tiredness, lethargy, joint pain, headche, anorexia and muscle aches	Fluid resus and Bromocriptine

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 17/11/2004 **Stopped:**

OLANZAPINE (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

ATORVASTATIN (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 23/11/2004

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 23/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Nil muscle rigidity.

Report Detail

Case Number: 207619 **Seq:** 1 **Gender:** U
Reported: 05/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 22/11/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

CELEBREX (Suspected)			**Reason:**		
Capsule	20.0	Milligram	Daily	Oral	
Batch:	**Started:**		S TERM	**Stopped:**	

Laboratory Investigations:

Additional Information:
Nil muscle rigidity.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 208041 **Seq:** 1 **Gender:** M
Reported: 20/05/2005 **Weight:** 52.00
Hospitalisation: **Age:** 14Y
Onset Date: 02/05/2005 **DOB:**
Outcome: Recovered 03/05/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination Choreoathetosis Dyskinesia Muscle twitching		The patient developed hallucination, abnormal limb movements, twitching and chorea-athetatic movement.	IM Diazepam.

Medicine Details:

LOVAN (Suspected) **Reason:** Behavior disorders of childhod
20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 02/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 208447 **Seq:** 1 **Gender:** M
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 28
Onset Date: **DOB:** 17/07/1976
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania		The patient developed Seroternergic Syndrome, somewhat manic, like a happy drunk and semi-delirious.	Prozac ceased.

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:** 0

NARCOTIC NOS (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 208451 **Seq:** 1 **Gender:** F
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 28
Onset Date: **DOB:** 27/07/1976
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	The patient developed acute suicidal	Prozac changed back to
Suicide attempt	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 208449 is the first sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 208453 **Seq:** 1 **Gender:** F
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 73
Onset Date: **DOB:** 01/11/1931
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Homicidal ideation	Caused or prolonged inpatient hospitalisation	The patient experienced homicidal ideation and made a suicide attempt.	Prozac ceased. Treated with Chlorpromazine and Valium and needed three ECTs.

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 208458 **Seq:** 1 **Gender:** F
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 59
Onset Date: **DOB:** 04/09/1945
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation	The patient experienced suicidal ideation, suicide attempt and homicidal ideation - she attempted to kill her parents.	
Homicidal ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 208464 **Seq:** 1 **Gender:** U
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 69
Onset Date: **DOB:** 07/11/1935
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation	The patient experienced suicidal ideation and was very anxious.	Fluoxetine ceased, changed to Reboxetine.
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
150.0 Milligram Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 208486 **Seq:** 1
Reported: 03/06/2005
Hospitalisation: Required a specialist consultation
Onset Date: 15/12/2004
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 66Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Life	Patient developed agranulocytosis, neutropenia and fever, weight loss, malaise, sore throat, oral thrush. Have been neutropenic for 6 months and was hospitalised on 4/05/2005	Treated with colony stimulating factor. Nexium was discontinued
Malaise	Life		
Neutropenia	Life		
Oral candidiasis	Life		
Pharyngolaryngeal pain	Life		
Pyrexia	Life		
Weight decreased	Life		

Medicine Details:

NEXIUM (Suspected) **Reason:** Other diseases of esophagus

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 15/01/2003 **Stopped:** 11/05/2005 0

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

40.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/06/2005	Neutrophils				0.0
03/06/2005	White blood cells				18

Additional Information:

Fluoxetine added as a suspect drug. It was started in March 2005. History: Osteoarthritis.

Report Detail

Case Number: 208666 **Seq:** 1 **Gender:** F
Reported: 10/06/2005 **Weight:** 54.00
Hospitalisation: **Age:** 15
Onset Date: 08/06/2005 **DOB:** 21/06/1989
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life	Suicide Attempt, strangling herself with the iPod cord in the bathroom of the hospital. Agitation, She ran around crying and banging her fists of the walls and windows begging to be let out...it lasted about 10 minutes before I could settle her...and they gave her extra Olanzapine then too. Withdrawal reaction, when Olanzapine is wearing off, they give her extra Olanzapine	Agitation, Withdrawal reaction, Akathisia -> given extra Olanzapine
Akathisia	Life		
Drug withdrawal syndrome	Life		

Medicine Details:

OLANZAPINE (Suspected) **Reason:**
10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

One patient with ADRs 206280, 206281, 206282, 206283, 208666. She takes Olanzapine to help her sleep. She is not psychotic (per reporter).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 208943 **Seq:** 1 **Gender:** F
Reported: 22/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hair texture abnormal Hair colour changes Hypersensitivity Loss of consciousness Skin odour abnormal		The patient developed a serious skin allergy, whereby her pores opened up excessively and she could not put make up on. She also experienced a change in her hair texture, it became straw-like and darkened. She experienced excessive body odour and blackouts.	Patient is progressively decreasing her dose of Prozac.

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
80.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 208947 **Seq:** 1 **Gender:** F
Reported: 22/06/2005 **Weight:** 56.00
Hospitalisation: **Age:** 14Y
Onset Date: 18/10/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pancreatitis		Pancreatitis suspected.	

Medicine Details:

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

Capsule 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 209532 **Seq:** 1
Reported: 06/07/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation	Efexor exacerbated her symptoms of depression (hyper-vigilance, sleeplessness, dysphoria and panic). After one particularly nasty episode of panic I "took a fistful of sleeping pills" (suicide	
Condition aggravated	Caused or prolonged inpatient hospitalisation		
Dysphoria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

PROZAC (Suspected) **Reason:** Depression
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 209532 **Seq:** 1
Reported: 06/07/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypervigilance	Caused or prolonged inpatient hospitalisation		
Insomnia	Caused or prolonged inpatient hospitalisation		
Panic attack	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

PROZAC (Suspected) **Reason:** Depression
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 210039 **Seq:** 1
Reported: 21/07/2005
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 100.00
Age: 75
DOB: 20/10/1929
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Incapacity/disability	tremor	ceased tramadol

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction) **Reason:**

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

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:**

Capsule 150.0 Milligram 2 times Oral

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 210603 **Seq:** 1
Reported: 11/08/2005
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 68.00
Age: 51
DOB: 16/12/1953
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia	Incapacity/disability	The patient experienced short term	

Medicine Details:

EFEXOR-XR (Other drug) **Reason:** Depression
Batch: **Started:** **Stopped:**

CALCIUM NOS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

EVENING PRIMROSE OIL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

FISH OIL NOS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 210603 **Seq:** 1
Reported: 11/08/2005
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 68.00
Age: 51
DOB: 16/12/1953
Causality: Causality possible

Reaction Detail

Medicine Details:

PROZAC (Suspected) **Reason:** Depression

Oral

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 210779 **Seq:** 1 **Gender:** M
Reported: 16/08/2005 **Weight:** 75.00
Hospitalisation: **Age:** 53
Onset Date: 01/06/2005 **DOB:** 10/06/1951
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash pruritic	Incapacity/disability	Pruritic rash on torso and limbs	aristocort, then medication

Medicine Details:

LOVAN (Suspected) **Reason:**
Tablet 1 time Oral
Batch: unknown **Started:** 23/03/2005 **Stopped:** 12/08/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 211231 **Seq:** 1
Reported: 31/08/2005
Hospitalisation:
Onset Date: 01/02/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 35Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Amnesia		Patient experienced profuse sweating when tramadol started, already on Lovan 40mg, sweating decreased when Lovan dose was reduced to 20mg but increased as Lovan was steadily increased, also experienced memory loss, cloudiness of	Recommendation in progress notes to decrease tramadol with view to ceasing eventually.

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Pain
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

LOVAN (Interaction) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

P/H Itchiness with morphine.

Report Detail

Case Number: 211297 **Seq:** 1 **Gender:** M
Reported: 01/09/2005 **Weight:** 40.00
Hospitalisation: **Age:** 10
Onset Date: 02/10/2004 **DOB:** 23/12/1993
Outcome: Recovered 17/10/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia Dyskinesia Loss of consciousness Nausea		The child experienced loss of consciousness while riding his bike and took two minutes to recover. He had a few days of rhythmic shaking, eg when he put pressure on his foot. He had dystonic contraction of his arms, nausea and was	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** 02/09/2004 **Stopped:** 15/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Relevant history: Aspergers disorder and asthma.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 211391 **Seq:** 1
Reported: 06/09/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 26/07/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 79
DOB: 08/12/1925
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal Abdominal pain upper Nausea		The patient experienced abnormal liver function with nausea and epigastric pain whilst on Lovan.	Lovan ceased.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
10.0 Milligram Daily Oral
Batch: **Started:** 01/07/2005 **Stopped:** 09/08/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/09/2005	ALT = SGPT				635
06/09/2005	AST = SGOT				500
06/09/2005	GGT = SGGT =				715
06/09/2005	SAP = ALP				402

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 212434 **Seq:** 1 **Gender:** F
Reported: 12/10/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 19/09/2005 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		The patient experienced a seizure whilst taking Edronax.	

Medicine Details:

EDRONAX (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

AVANZA (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had a fit 10 years prior to reporting; has been controlled until 19 September 2005. Also taking antihypertensives.

Report Detail

Case Number: 212666 **Seq:** 1
Reported: 18/10/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 15/09/2005
Outcome: Unknown

Gender: F
Weight: 70.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased		The patient experienced decreased libido.	

Medicine Details:

IMPLANON IMPLANT (Other drug) **Reason:** Contraception
Implant Subcutaneous
Batch: **Started:** S TERM **Stopped:**

AVANZA (Other drug) **Reason:**
30.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** 15/09/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Avanza was stopped due to sedation and Lovan was then started.

Report Detail

Case Number: 213887 **Seq:** 1
Reported: 29/11/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 20/11/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 51
DOB: 20/07/1954
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Pityriasis		The patient developed a rash, then exacerbation of pityriasis lichenoides or onset of guttate psoriasis	Creams and Advantin.

Medicine Details:

IMPLANON IMPLANT (Other drug) **Reason:**
Implant Subcutaneous
Batch: **Started:** 09/11/2004 **Stopped:** 0

NORMISON (Other drug) **Reason:**
Oral
Batch: **Started:** **Stopped:** 0

TEARS PLUS (Other drug) **Reason:**
Batch: **Started:** L TERM **Stopped:** 0

LOVAN (Suspected) **Reason:**
30.0 Milligram Daily Oral
Batch: **Started:** 01/11/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also using Retrieve cream.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 214540 **Seq:** 1 **Gender:** F
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 46
Onset Date: **DOB:** 01/04/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restlessness Agitation Dyspnoea Insomnia Palpitations		The patient became restless, had some difficulty breathing, had some palpitations, was agitated and she could not sleep.	

Medicine Details:

DIABEX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

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

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

DOLOBID (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 214540 **Seq:** 1 **Gender:** F
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 46
Onset Date: **DOB:** 01/04/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

TRAMAL (Suspected)			**Reason:**	
Batch:	**Started:** 29/11/2003			**Stopped:**
PROZAC (Suspected)			**Reason:**	
				Oral
Batch:	**Started:** 15/05/2005			**Stopped:**
AVAPRO (Suspected)			**Reason:**	
Tablet				Oral
Batch:	**Started:**			**Stopped:**
ENDEP (Suspected)			**Reason:**	
Tablet	50.0 Milligram		Daily	Oral
Batch:	**Started:** 15/03/2003			**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 214543 **Seq:** 1 **Gender:** M
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 11/09/1970
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Homicidal ideation Dissociation		He had also experienced suicidal thoughts. The patient experienced dissociation and murdered his wife whilst on Prozac.	

Medicine Details:

PROZAC (Suspected) **Reason:**
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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 214576 **Seq:** 1 **Gender:** M
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 23
Onset Date: **DOB:** 07/09/1982
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Suicide attempt		The patient became violent, slept badly and woke at night, lost twenty kg in three weeks, was agitated and suicidal.	

Medicine Details:

LOVAN (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

SEREPAX (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

ALCOHOL (Suspected) **Reason:**
Oral Liquid Oral
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 214704 **Seq:** 1 **Gender:** M
Reported: 09/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 29Y
Onset Date: 06/12/2005 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation	Pateint experienced acute anxiety, abdominal pain, and social isolation, he also experienced weight loss over the last few months, the patient attempted suicide by cutting his wrists.	Risperdal Consta was ceased.
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

LOVAN (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Risperdal Consta (Suspected) **Reason:**
Injection 25.0 Milligram Fortnightly Intramuscular
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

DRUG ADDICT, ALCOHOL

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 214704 **Seq:** 1 **Gender:** M
Reported: 09/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 29Y
Onset Date: 06/12/2005 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

LOVAN (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Risperdal Consta (Suspected) **Reason:**
Injection 25.0 Milligram Fortnightly Intramuscular
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

DRUG ADDICT, ALCOHOL

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 214804 **Seq:** 1 **Gender:** M
Reported: 10/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 43Y
Onset Date: 06/12/2005 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bleeding time prolonged Hypotension Melaena Syncope		The patient experienced prolonged bleeding, dizziness, fainted, had low blood pressure and melaena after a tooth extraction whilst receiving Lovan.	Saline drip. Fluoxetine ceased temporarily.

Medicine Details:

IBILEX (Other drug) **Reason:**
Tablet 1.0 Gram Daily Oral
Batch: **Started:** 04/12/2005 **Stopped:** 0

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/01/2006	Other data				He had a FBC (full blood count), PPT (partial thrombolastin time) and APPT (activated partial thrombolastin time) which were all within normal limits

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 214807 **Seq:** 1
Reported: 10/01/2006
Hospitalisation:
Onset Date:
Outcome: Recovered

Gender: M
Weight: 100.00
Age: 62
DOB: 30/01/1943
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash generalised Drug ineffective		Patient experienced generalised rash from feet to hands following change from Lovan to Zactin (after 4 days), stopping within 4 days after ceasing Zactin. OK now back on Lovan. Zactin also was associated with perceived lack of benefit.	Zactin ceased.

Medicine Details:

ZACTIN (Suspected) **Reason:** Depression
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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 215306 **Seq:** 1 **Gender:** M
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 34
Onset Date: **DOB:** 19/09/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia Anxiety Panic reaction		The patient is restless, has difficulty sitting still, fidgets and gets up and down. He has had an increase in anxiety with panic and ventilation. Sometimes he is sick in the stomach, sometimes short of breath, with palpitations and says that he cannot breathe and this lasts for half an hour.	

Medicine Details:

LOVAN (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 215319 **Seq:** 1 **Gender:** M
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 15
Onset Date: **DOB:** 12/01/1991
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Anger		The patient felt angry and wanted to fight.	

Medicine Details:

LOVAN (Suspected) **Reason:**
Capsule Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 215332 **Seq:** 1 **Gender:** F
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 27/04/2000 **DOB:**
Outcome: Death, maybe drug 11/09/2000 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Death	The patient became seriously depressed, complained of headaches and clenching jaw, was unable to sleep and started to self-harm. She began to have suicidal thoughts, was hyperventilating, agoraphobic, had five suicide attempts, was confused, tearful, phobic, aggressive, experienced akathisia and suspected serotonin syndrome. She experienced weird dreams, was impulsive, light headed, had numbness and tingling limbs and committed suicide by hanging on 11 September 2000 on the second attempt.	
Agoraphobia	Death		
Akathisia	Death		

Medicine Details:

AROPAX (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily Oral
Batch: **Started:** 21/03/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 215330 is the first sequence to this report.

Report Detail

Case Number: 215332 **Seq:** 1 **Gender:** F
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 27/04/2000 **DOB:**
Outcome: Death, maybe drug 11/09/2000 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Completed suicide	Death		
Self injurious behaviour	Death		
Serotonin syndrome	Death		
Suicide attempt	Death		

Medicine Details:

AROPAX (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily Oral
Batch: **Started:** 21/03/2000 **Stopped:**

Laboratory Investigations:

Additional Information:

Report 215330 is the first sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 215346 **Seq:** 1 **Gender:** F
Reported: 27/01/2006 **Weight:** 80.00
Hospitalisation: **Age:** 50
Onset Date: **DOB:** 11/11/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia		She experienced 'transient global amnesia'	
Depression		The patient became more depressed whilst taking Prozac. She wanted to throw herself off a train or bus, had difficulty sleeping, was pacing and restless, had voice hallucinations, would look in the mirror and see a different person, had murderous thoughts, stiff legs, was hot a lot, felt she was in a delirium, could not concentrate, was angry, had numbness in her hands and pins and needles a lot in her body, which occurs in akathisia	Ceased Prozac.
Akathisia			
Confusional state			

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 215346 **Seq:** 1 **Gender:** F
Reported: 27/01/2006 **Weight:** 80.00
Hospitalisation: **Age:** 50
Onset Date: **DOB:** 11/11/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium			
Hallucination, auditory			
Homicidal ideation			
Hypoaesthesia			
Insomnia			
Panic disorder			
Pyrexia			
Suicide attempt			

Medicine Details:

PROZAC (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 215352 **Seq:** 1 **Gender:** F
Reported: 30/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 46
Onset Date: **DOB:** 25/05/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation	The patient became confused. She experienced vomiting and was unable to keep anything down, was dehydrated, weak and shaking, had problems breathing, shallow palpitations, was in a delirium, hearing things and seeing things. The nurse's summary diagnoses were hypomanic episode, schizophreniform psychosis, acute brain syndrome/behaviour disturbance in context of substance abuse.	Ducene to counteract side effects of Prozac and Phenergan for allergy. Also treated with Chlorpromazine
Delirium	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADEINE FORTE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
ENDONE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
VIOXX (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
MS CONTIN (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 215352 **Seq:** 1 **Gender:** F
Reported: 30/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 46
Onset Date: **DOB:** 25/05/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination, auditory	Caused or prolonged inpatient hospitalisation		
Hypomania	Caused or prolonged inpatient hospitalisation		
Psychotic disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROZAC (Suspected) **Reason:**
60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 215353 **Seq:** 1 **Gender:** F
Reported: 30/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 04/03/1976
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Stress Irritability Nausea Personality change		The patient experienced stress, had a personality change, complained of nausea and irritability.	Now on Faverin.

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 215464 **Seq:** 1 **Gender:** M
Reported: 01/02/2006 **Weight:** 0.00
Hospitalisation: **Age:** 80
Onset Date: **DOB:** 11/08/1925
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		hyponatraemia	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 20.0 Milligram 1 time Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 216001 **Seq:** 1
Reported: 20/02/2006
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Unknown

Gender: F
Weight: 80.00
Age: 57Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Apathy		The patient experienced a loss of creativity and emotions and a feeling of numbness	Lovan ceased, switched to

Medicine Details:

TEMAZE (Other drug) **Reason:** Specific disorders of sleep
10.0 Milligram As necessary Oral
Batch: **Started:** L TERM **Stopped:** 0

PARIET (Other drug) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

STILNOX (Other drug) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

LOVAN (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 216388 **Seq:** 1 **Gender:** M
Reported: 10/03/2006 **Weight:** 0.00
Hospitalisation: **Age:** 8Y
Onset Date: 14/09/2005 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced a seizure whilst he	
Convulsion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:**
1.5 Litre Daily Oral
Batch: **Started:** 14/08/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 216399 **Seq:** 1 **Gender:** M
Reported: 10/03/2006 **Weight:** 0.00
Hospitalisation: **Age:** 19
Onset Date: **DOB:** 09/10/1986
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Aggression Akathisia Anxiety Euphoric mood		Patient had thoughts about killing himself which made him violent, tried to hit someone else, tried to hit a security guard with feelings of killing and tried to do physical damage. Tried to hurt himself and had thoughts of hurting other people. He was walking faster than normal. Experienced aggression, insomnia and was feeling high on Prozac. Also felt anxious and put on more than 20kg	

Medicine Details:

ZYPREXA (Suspected) **Reason:**
Batch: **Started:** 19/02/2004 **Stopped:** 19/01/2006

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 216399 **Seq:** 1 **Gender:** M
Reported: 10/03/2006 **Weight:** 0.00
Hospitalisation: **Age:** 19
Onset Date: **DOB:** 09/10/1986
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Intentional self-injury Weight increased			

Medicine Details:

ZYPREXA (Suspected) **Reason:**
Batch: **Started:** 19/02/2004 **Stopped:** 19/01/2006

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 217041 **Seq:** 1 **Gender:** U
Reported: 05/04/2006 **Weight:** 70.00
Hospitalisation: **Age:** 54
Onset Date: 21/02/2006 **DOB:** 23/09/1951
Outcome: Recovered 28/02/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Balance disorder Fall		Disturbance of equilibrium with repeated falls, including rolling repeatedly after falling on a slope	Fluoxetine reduced and then

Medicine Details:

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Glucosamine Nos (Other drug) **Reason:** Pain in joint
2.0 Gram Daily
Batch: **Started:** **Stopped:** 0

LOVAN (Suspected) **Reason:** Depression
Tablet 80.0 Milligram Daily Oral
Batch: **Started:** 21/02/2006 **Stopped:** 04/03/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 217086 **Seq:** 1
Reported: 06/04/2006
Hospitalisation: Admitted to hospital
Onset Date: 01/01/2002
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 33
DOB: 24/05/1968
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Feeling abnormal	Caused or prolonged inpatient hospitalisation	Patient felt indifferent and felt frustrated. Slept all day/night, anxious, did not sleep, confused	Ceased medication. Returned to hospital for medication adjustment. Patient now on Abilify, Seroquel and Lithium.
Anxiety	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LITHIUM CARBONATE (Suspected) **Reason:** Unspecified schizophrenia
Tablet Oral
Batch: **Started:** L TERM **Stopped:**

VALIUM (Suspected) **Reason:** Anxiety neurosis
Batch: **Started:** **Stopped:**

RISPERDAL (Suspected) **Reason:** Unspecified schizophrenia
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 217086 **Seq:** 1
Reported: 06/04/2006
Hospitalisation: Admitted to hospital
Onset Date: 01/01/2002
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 33
DOB: 24/05/1968
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Frustration	Caused or prolonged inpatient hospitalisation		
Insomnia	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROZAC (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

LARGACTIL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 217919 **Seq:** 1
Reported: 02/05/2006
Hospitalisation:
Onset Date: 14/03/2006
Outcome: Not yet recovered

Gender: F
Weight: 51.00
Age: 9Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination, auditory Therapy regimen changed		Patient experienced progressive auditory hallucinations on increasing to 1.5 (30mg) Prozac/day, on cutting dose to 1 Prozac/day symptoms started to ease over a few days.	

Medicine Details:

PROZAC (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 24/02/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pre-existing severe Asperger's.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 218047 **Seq:** 1 **Gender:** F
Reported: 05/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: 04/05/2006 **DOB:** 06/05/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal Diarrhoea Fatigue Myalgia Vomiting		Called back to Emergency Department re pathology results. ALT 5280, AST 5850, GGT 49, ALP 83, LDH 3470, ck 835 (2/5/06) now 4/5/06 ALT 1770, AST 304, LDH 171, CK 114 ... see comments	Cease all meds

Medicine Details:

HERBAL MEDICINES (Suspected) **Reason:**
Batch: **Started:** 04/04/2006 **Stopped:** 04/05/2006 0

LINSEED OIL (Suspected) **Reason:**
Batch: **Started:** 04/04/2006 **Stopped:** 04/05/2006

Brindle Berry (Suspected) **Reason:**
Tablet 3 times Oral
Batch: **Started:** 03/04/2006 **Stopped:** 04/05/2006 0

CHROMIUM PICOLINATE (Suspected) **Reason:**
6.2 Microgram 3 times
Batch: **Started:** 04/04/2006 **Stopped:** 03/05/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/05/2006	ALT = SGPT		02/05/2006	5280	
05/05/2006	ALT = SGPT		04/05/2006	1770	
05/05/2006	AST = SGOT		02/05/2006	5850	
05/05/2006	AST = SGOT		04/05/2006	340	
05/05/2006	Creatine		02/05/2006	835	
05/05/2006	Creatine		04/05/2006	114	
05/05/2006	GGT = SGGT =		02/05/2006	49	

Additional Information:

herbal medicine also includes: cinnamon oil, rosemary oil,

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 218047 **Seq:** 1 **Gender:** F
Reported: 05/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: 04/05/2006 **DOB:** 06/05/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

KELP (Suspected)			**Reason:**	Obesity othr than endoc origin	
			3 times		
Batch:	**Started:**	04/04/2006		**Stopped:** 04/05/2006	0
FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
Capsule	40.0	Milligram	Daily	Oral	
Batch:	**Started:**	12/04/2006		**Stopped:** 03/05/2006	0
MICROGYNON 50 (Suspected)			**Reason:**		
Tablet	1.0		Daily	Oral	
Batch:	**Started:**	04/04/2006		**Stopped:** 04/05/2006	0
TYROSINE (Suspected)			**Reason:**	Obesity othr than endoc origin	
	300.0	Milligram	Daily		
Batch:	**Started:**	04/04/2006		**Stopped:** 04/05/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/05/2006	LDH		02/05/2006	3470	
05/05/2006	LDH		04/05/2006	171	
05/05/2006	SAP = ALP		02/05/2006	83	

Additional Information:

herbal medicine also includes: cinnamon oil, rosemary oil,

Report Detail

Case Number: 218047 **Seq:** 1
Reported: 05/05/2006
Hospitalisation:
Onset Date: 04/05/2006
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 31
DOB: 06/05/1974
Causality: Causality possible

Reaction Detail

Medicine Details:

SELENIUM SULPHIDE (Suspected) **Reason:**
Tablet Daily Oral
Batch: **Started:** 03/04/2006 **Stopped:** 04/05/2006 0

Laboratory Investigations:

Additional Information:
herbal medicine also includes: cinnamon oil, rosemary oil,

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 218498 **Seq:** 1 **Gender:** M
Reported: 19/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed		The patient has returned 2 packets of GenRex Fluosetine as he feels that the product is less effective than the Innovator brand which he had been previously taking.	

Medicine Details:

GenRx Fluoxetine (Suspected) **Reason:**
Capsule Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 219147 **Seq:** 1
Reported: 14/06/2006
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 44Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Caused or prolonged inpatient hospitalisation	Experienced hot sweats, stabbing pins and needles, weakness, fatigue/exhaustion, shallowing breathing and loss of appetitie.	
Anorexia	Caused or prolonged inpatient hospitalisation		
Asthenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PONSTAN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

LEVLEN ED (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 15/04/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 219147 **Seq:** 1
Reported: 14/06/2006
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 44Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue	Caused or prolonged inpatient hospitalisation		
Hypoventilation	Caused or prolonged inpatient hospitalisation		
Paraesthesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PONSTAN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

LEVLEN ED (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 15/04/2006 **Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 219170 **Seq:** 1
Reported: 15/06/2006
Hospitalisation: Admitted to hospital
Onset Date: 07/05/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 61
DOB: 01/01/1945
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cholestasis	Caused or prolonged inpatient hospitalisation	Patient experienced cholestatsis and increased bilirubin.	Decrease dose of Lovan and then ceased
Blood bilirubin increased	Caused or prolonged inpatient hospitalisation		
Jaundice	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 03/06/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/06/2006	Bilirubin				Cholestatic LFT's mainly hyperbilirubinaemia (up to 364 umol/L); gamma GT and alk phos marginally raised. Bili levels fluctuating during admission

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 219170 **Seq:** 1
Reported: 15/06/2006
Hospitalisation: Admitted to hospital
Onset Date: 07/05/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 61
DOB: 01/01/1945
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 03/06/2006 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 219281 **Seq:** 1
Reported: 20/06/2006
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 61
DOB: 01/01/1945
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Jaundice cholestatic	Caused or prolonged inpatient hospitalisation	Patient presented to the emergency department with jaundice and general feeling unwell, was then admitted to hospital with painless cholestatic jaundice of unknown cause.	Ceased Lovan
Cholelithiasis	Caused or prolonged inpatient hospitalisation		
Malaise	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Cholestais probably related to the gallstones.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 219803 **Seq:** 1
Reported: 09/07/2006
Hospitalisation:
Onset Date: 01/07/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression	Incapacity/disability	Tremors, worsening symptoms of depression, anxiety and agitation	Urgent referral to GP
Agitation	Incapacity/disability		
Anxiety	Incapacity/disability		
Tremor	Incapacity/disability		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 19/09/2000 **Stopped:** 01/06/2006 0

ATORVASTATIN (Other drug) **Reason:** Othr&unspec metabolic diseases
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Capsule 20.0 Milligram Daily Oral
Batch: unknown **Started:** 11/06/2006 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 219806 **Seq:** 1 **Gender:** F
Reported: 10/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 16/06/2006 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Serotonin syndrome Feeling cold Nausea Thinking abnormal Tremor		Patient experienced anxiety, nausea, shakiness, "cotton wool in head" and feeling cold suspected. Venlafaxine ceased and lovan started on the same day without wash out period.	

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Suspected) **Reason:**

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

LOVAN (Suspected) **Reason:**

20.0 Milligram Daily

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 219850 **Seq:** 1 **Gender:** F
Reported: 11/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Upper limb deformity Drug exposure during pregnancy		short arm	

Medicine Details:

ZACTIN (Suspected) **Reason:**

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 220028 **Seq:** 1 **Gender:** M
Reported: 14/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 79Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Fall in sodium level.	Lovan was ceased. Tolvaon 40mg daily and Zyprexa 2.5mg daily were commenced. Given salt tablets 1800mg/bd.

Medicine Details:

DEPTRAN (Other drug) **Reason:**
50.0 Milligram Oral
Batch: **Started:** **Stopped:**

NORMISON (Other drug) **Reason:**
10.0 Milligram Oral
Batch: **Started:** **Stopped:**

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/07/2006	Sodium		13/02/2006	122	
14/07/2006	Sodium		21/02/2006	128	
14/07/2006	Sodium		13/03/2006	134	

Additional Information:

Report 220030 is the second sequence to this report.
Suspect drug certain rechallenge.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 220377 **Seq:** 1 **Gender:** M
Reported: 25/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 37
Onset Date: 26/06/2006 **DOB:** 03/07/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	seizure at induction and again in recovery	

Medicine Details:

MIDAZOLAM (Suspected) **Reason:** Other disturbance of sensation
Injection 3.0 Milligram 1 time Intravenous
Batch: **Started:** **Stopped:** 0

FENTANYL (Suspected) **Reason:** Other disturbance of sensation
Injection 50.0 Microgram 1 time Intravenous
Batch: **Started:** **Stopped:** 0

PROPOFOL (Suspected) **Reason:** Other disturbance of sensation
Injection 150.0 Milligram 1 time Intravenous
Batch: **Started:** **Stopped:**

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Capsule 40.0 Milligram Daily Oral
Batch: **Started:** 01/03/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 220797 **Seq:** 1 **Gender:** F
Reported: 15/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 41Y
Onset Date: 28/07/2006 **DOB:**
Outcome: Recovered 29/07/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed		changed from Lovan to Zactin and experienced symptoms.	
Nausea		she experienced nausea, hot and cold flushes, weakness on the left hand side, difficulty in thinking and headache.	
Asthenia			
Feeling hot and cold			
Flushing			
Headache			
Hemiparesis			
Mental impairment			

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SERETIDE ACCUHALER NOS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZACTIN (Suspected) **Reason:**
Capsule 20.0 Milligram 1 time Oral
Batch: **Started:** 28/07/2006 **Stopped:** 28/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Restarted taking Lovan without recurrence of symptoms, all have resolved except for mild headache

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 220797 **Seq:** 1 **Gender:** F
Reported: 15/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 41Y
Onset Date: 28/07/2006 **DOB:**
Outcome: Recovered 29/07/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal Tremor			

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SERETIDE ACCUHALER NOS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZACTIN (Suspected) **Reason:**
Capsule 20.0 Milligram 1 time Oral
Batch: **Started:** 28/07/2006 **Stopped:** 28/07/2006

Laboratory Investigations:

Additional Information:
Restarted taking Lovan without recurrence of symptoms, all have resolved except for mild headache

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 221486 **Seq:** 1 **Gender:** U
Reported: 07/09/2006 **Weight:** 62.00
Hospitalisation: **Age:** 17
Onset Date: 04/08/2006 **DOB:** 09/08/1988
Outcome: Recovered 04/08/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion Grand mal convulsion		Seizure: Grand mal seizure, tonic clonic x 2 in the space of 4-6 hours.	Supporting therapy, IVT, Neuro

Medicine Details:

OLANZAPINE (Suspected) **Reason:** Unspecified psychosis
5.0 Milligram Daily
Batch: **Started:** 20/07/2006 **Stopped:** 05/08/2006

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 15/07/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 221961 **Seq:** 1
Reported: 26/09/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 25/08/2006
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99U
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash papular		Papular rash on limbs.	Ceased Fluoxetine

Medicine Details:

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

20.0 Milligram Daily Oral

Batch: **Started:** 20/07/2006 **Stopped:** 03/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 223085 **Seq:** 1 **Gender:** F
Reported: 14/11/2006 **Weight:** 0.00
Hospitalisation: **Age:** 29Y
Onset Date: 12/09/2006 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia Abortion spontaneous Drug exposure during pregnancy Insomnia		Hyperactivity, difficulty sleeping, drug exposure during pregnancy and miscarriage with Lovan	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression

Capsule 20.0 Milligram Daily Oral

Batch: **Started:** 12/09/2006 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 223112 **Seq:** 1
Reported: 14/11/2006
Hospitalisation: Admitted to hospital
Onset Date: 21/08/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 16
DOB: 12/07/1990
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life	Patient made 2 suicide attempts since starting drug, nil previous.	Drug ceased.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 19/08/2006 **Stopped:** 23/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

1st time on SSRI.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 223185 **Seq:** 1 **Gender:** F
Reported: 15/11/2006 **Weight:** 50.00
Hospitalisation: **Age:** 16
Onset Date: 31/08/2006 **DOB:** 07/02/1990
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia Agitation Headache Mood swings Nausea Poor quality sleep Restlessness		Loss of appetite, poor sleep, agitation, restlessness, fluctuations in mood, low grade headache and nausea.	Fluoxetine discontinued. Review by psychiatrist regularly

Medicine Details:

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

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 23/08/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previously treated with sertraline without these effects.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 223366 **Seq:** 1 **Gender:** F
Reported: 21/11/2006 **Weight:** 106.00
Hospitalisation: **Age:** 49
Onset Date: 15/08/2006 **DOB:** 05/01/1957
Outcome: Recovered 28/09/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido increased		Marked increase libido.	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 15/05/2005 **Stopped:** 19/08/2006

EDRONAX (Suspected) **Reason:** Depression
Tablet 4.0 Milligram Daily Oral
Batch: **Started:** 15/07/2005 **Stopped:** 21/09/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 223582 **Seq:** 1
Reported: 28/11/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 28/04/2006
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99u
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Abnormal behaviour Change in sustained attention Coordination abnormal Disorientation Sedation Somnolence		Fatigue, disorientation, abnormal behaviour, drowsy, like a "zombie".	

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
Liquid, multipurpose 20.0 Milligram Daily
Batch: **Started:** 27/03/2006 **Stopped:** 15/06/2006 0

LOVAN (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient suspects that there is something wrong with this product but with 4 separate batches (A132260, A132396, A103702 and A162335) there is no batch problem.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 223958 **Seq:** 1
Reported: 11/12/2006
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 54Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium	Caused or prolonged inpatient hospitalisation	"Acute Brain Syndrome" with Lovan	
Delirium	Caused or prolonged inpatient hospitalisation		
Urinary incontinence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LOVAN (Suspected) **Reason:** Unspecified psychosis
100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

EDRONAX (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 224202 **Seq:** 1
Reported: 19/12/2006
Hospitalisation: Admitted to hospital
Onset Date: 26/09/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 82
DOB: 04/09/1924
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ventricular tachycardia	Caused or prolonged inpatient hospitalisation	Tachycardia ventricular and QT interval	Ceased amitriptyline and
Electrocardiogram QT prolonged	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ENDEP (Interaction) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

LOVAN (Interaction) **Reason:**
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

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

INDAPAMIDE HEMIHYDRATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 224202 **Seq:** 1
Reported: 19/12/2006
Hospitalisation: Admitted to hospital
Onset Date: 26/09/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 82
DOB: 04/09/1924
Causality: Causality possible

Reaction Detail

Medicine Details:

PANTOPRAZOLE (Other drug)		**Reason:**	
Batch:	**Started:**	**Stopped:**	
LISINOPRIL (Other drug)		**Reason:**	
Batch:	**Started:**	**Stopped:**	0
DIAZEPAM (Other drug)		**Reason:**	
Batch:	**Started:**	**Stopped:**	
GRAPEFRUIT JUICE (Other drug)		**Reason:**	
Batch:	**Started:**	**Stopped:**	

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 225614 **Seq:** 1 **Gender:** F
Reported: 09/02/2007 **Weight:** 0.00
Hospitalisation: **Age:** 34
Onset Date: **DOB:** 12/05/1972
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Foetal growth retardation Drug exposure during pregnancy		Intrauterine growth retardation - birth weight 2.49 kg at 38 weeks with no other problems; Apgar 9,9	

Medicine Details:

STILNOX (Suspected) **Reason:**
10.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:** 0

EDRONAX (Suspected) **Reason:**
4.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:** 0

PHENERGAN (Suspected) **Reason:**
25.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:** 0

LOVAN (Suspected) **Reason:** Depression
60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 226425 **Seq:** 1 **Gender:** M
Reported: 07/03/2007 **Weight:** 0.00
Hospitalisation: **Age:** 70
Onset Date: 06/03/2007 **DOB:** 30/11/1936
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abnormal sleep-related event		abnormal behaviour during sleep- opened windows, re-arranged furniture and felt he had nightmares all night. He also was still quite agitated in the morning	reviewed medications, medical investigation
Agitation		experienced the next morning	
Therapy regimen changed		the dose of Lovan increased from 10mg to 20mg daily on 5/3/2006	
Nightmare			

Medicine Details:

PRAMIN (Other drug) **Reason:**
Tablet 10.0 Milligram 3 times Oral
Batch: **Started:** L TERM **Stopped:** 0

COLOXYL WITH SENNA (Other drug) **Reason:**
Tablet 3 times Oral
Batch: **Started:** L TERM **Stopped:** 0

MS CONTIN (Other drug) **Reason:**
Tablet 30.0 Milligram 2 times Oral
Batch: **Started:** L TERM **Stopped:** 0

DERALIN (Other drug) **Reason:**
Tablet 10.0 Milligram 2 times Oral
Batch: **Started:** L TERM **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 226425 **Seq:** 1
Reported: 07/03/2007
Hospitalisation:
Onset Date: 06/03/2007
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 70
DOB: 30/11/1936
Causality: Causality possible

Reaction Detail

Medicine Details:

Nidem (Other drug)			**Reason:**		
Tablet	80.0	Milligram	1 time	Oral	
Batch:	**Started:**			**Stopped:**	
ENOXAPARIN (Other drug)			**Reason:**		
Injection	100.0	Milligram	1 time	Subcutaneous	
Batch:	**Started:**			**Stopped:**	
SOMAC (Other drug)			**Reason:**		
Tablet	20.0	Milligram	1 time	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	0
SERENACE (Other drug)			**Reason:**		
Tablet	500.0	Microgram	1 time	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	0

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 226425 **Seq:** 1
Reported: 07/03/2007
Hospitalisation:
Onset Date: 06/03/2007
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 70
DOB: 30/11/1936
Causality: Causality possible

Reaction Detail

Medicine Details:

AVAPRO (Other drug)			**Reason:**		
Tablet	150.0	Milligram	1 time	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	0
LACTULOSE (Other drug)			**Reason:**		
Oral Liquid		Dose Unspecified	As necessary	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	0
PANAMAX (Other drug)			**Reason:**		
Tablet	1000.0	Milligram	As necessary	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	0
STILNOX (Suspected)			**Reason:**		
Tablet	10.0	Milligram	1 time	Oral	
Batch:	**Started:**			**Stopped:**	0

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 226425 **Seq:** 1
Reported: 07/03/2007
Hospitalisation:
Onset Date: 06/03/2007
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 70
DOB: 30/11/1936
Causality: Causality possible

Reaction Detail

Medicine Details:

LOVAN (Suspected)			**Reason:**	
Tablet	20.0 Milligram	1 time	Oral	
Batch:	**Started:** 14/02/2007		**Stopped:**	0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 226901 **Seq:** 1
Reported: 22/03/2007
Hospitalisation:
Onset Date: 03/12/2006
Outcome: Not yet recovered

Gender: F
Weight: 59.00
Age: 27Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bruxism		Bruxism commenced one month after commencement of flucoxetine, continued despite reduction to 30mg.	Reduction of flucoxetine.

Medicine Details:

BUPRENORPHINE HYDROCHLORIDE (Other drug) **Reason:**
31.2 Milligram Daily
Batch: **Started:** **Stopped:** Ongoing.

ECHINACEA (Other drug) **Reason:** Unspec vitamin deficien states
3.0 Gram Daily Oral
Batch: **Started:** **Stopped:**

Fluohexal (Suspected) **Reason:** Anxiety neurosis
Capsule 40.0 Milligram Daily Oral
Batch: **Started:** 24/11/2006 **Stopped:** 12/12/2006

LOVAN (Suspected) **Reason:** Anxiety neurosis
Tablet 30.0 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 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 227470 **Seq:** 1 **Gender:** M
Reported: 11/04/2007 **Weight:** 80.00
Hospitalisation: **Age:** 34
Onset Date: 28/02/2007 **DOB:** 28/05/1972
Outcome: Recovered 05/03/2007 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged		QT prolongation	cease Lovan

Medicine Details:

THIAMINE (Other drug) **Reason:**
100.0 Milligram
Batch: **Started:** **Stopped:**

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

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram 1 time Oral
Batch: **Started:** 12/02/2007 S TERM **Stopped:** 05/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/04/2007	QT interval		28/02/2007	481 ms	
11/04/2007	QT interval		05/03/2007	400 ms	

Additional Information:

medical history includes anxiety, depression and alcohol use

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 228425 **Seq:** 1
Reported: 11/05/2007
Hospitalisation:
Onset Date: 28/03/2007
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 32Y
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intentional overdose	Caused or prolonged inpatient hospitalisation	Intentional overdosed on olanzapine 300mg and fluoxetine 600mg and experienced drowsiness	
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**
600.0 Milligram As necessary Oral
Batch: **Started:** 28/03/2007 **Stopped:** 28/03/2007

ZYPREXA (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 28/03/2007 **Stopped:** 28/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

? interaction

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 229267 **Seq:** 1 **Gender:** F
Reported: 04/06/2007 **Weight:** 125.00
Hospitalisation: **Age:** 27
Onset Date: 15/03/2006 **DOB:** 02/11/1978
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache		Headache	Changed drug.

Medicine Details:

LOVAN (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/03/2006 **Stopped:** 22/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 229513 **Seq:** 1 **Gender:** M
Reported: 07/06/2007 **Weight:** 94.00
Hospitalisation: **Age:** 45
Onset Date: **DOB:** 04/08/1961
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Involuntary motor spasms. Multiple generalised seizures over 24 hours	Lovan ceased. Clozapine temporarily ceased

Medicine Details:

ATIVAN (Other drug) **Reason:**
Tablet 2.5 Milligram As necessary Oral
Batch: **Started:** 19/12/2006 **Stopped:** 26/12/2006

CLOZARIL (Other drug) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 20/05/2006 **Stopped:** 26/12/2006

LOVAN (Suspected) **Reason:**
Tablet 180.0 Milligram Daily Oral
Batch: **Started:** 22/06/2006 **Stopped:** 26/12/2006

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 20/05/2006 **Stopped:** 26/12/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/06/2007	Serum drug level				15/11/07 - clozapine 970 ug/L, norclozapine 400ug/L 26/11/07 - clozapine 1050 ug/L, norclozapine 820 ug/L

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 229964 **Seq:** 1 **Gender:** M
Reported: 20/06/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cognitive disorder Depression suicidal		Experienced severe depression ,cognitive impairment and was acutely suicidal. The patient presented to the AE department at hosp, but was not admitted.	Treated with Fluoxetine

Medicine Details:

FRUSEMIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

IRBESARTAN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PARIET (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

SIMVASTATIN (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Depression is not a listed term for rabeprazole, although it appears on both European and US labels.

Date Range: 1 Jan 1996 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Auscap,EROCAP,FLUOXETINE HYDROCHLORIDE,Fluohexal,GenRx Fluoxetine,LOVAN,PROZAC,PROZAC LIQUID,ZACTIN

Report Detail

Case Number: 229964 **Seq:** 1 **Gender:** M
Reported: 20/06/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected) **Reason:**

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

Laboratory Investigations:

Additional Information:

Depression is not a listed term for rabeprazole, although it appears on both European and US labels.