



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 118890 **Seq:** 1 **Gender:** F
Reported: 08/07/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention			Dose of luvox

Medicine Details:

INDERAL (Other drug)		Reason: Migraine	
	240.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
EPILIM (Suspected)		Reason: Other&unspecified epilepsy	
	0.0		
Batch:	Started:	L TERM	Stopped:
LUVOX (Suspected)		Reason: Depression	
Tablet	2.0 Dose Unspecified	Daily	Oral
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 118922 **Seq:** 1 **Gender:** M
Reported: 08/07/1997 **Weight:** 80.00
Hospitalisation: **Age:** 49Y
Onset Date: 29/06/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania		Acute drug induced mania (first episode)	Chlorpromazine 200mg daily in divided doses
Affect lability		Elevated mood, religious preoccupation,	
Agitation		Psychomotor agitation, incr energy, reduced	

Medicine Details:

RANITIDINE (Other drug)		Reason:	
	300.0 Milligram	Daily	
Batch:	Started: 01/01/1996	Stopped:	CONTIN
LUVOX (Suspected)		Reason: Depression	
	50.0 Milligram	Daily	
Batch:	Started: 19/06/1997	Stopped:	30/06/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has been treated previously with tricyclic antidepressants, sertraline moclobemide, uneventfully. reaction occurred after changing antidepressant from serzone to luvox. the dosage start date is not accurate but indicates that start occurred sometime during the year.



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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 119911 **Seq:** 1 **Gender:** F
Reported: 13/08/1997 **Weight:** 64.00
Hospitalisation: **Age:** 55Y
Onset Date: 30/07/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Could not be still either standing or sitting	Benztropine 2mg when needed
Choreoathetosis		Some associated athetotic arm movements	

Medicine Details:

MOGADON (Other drug)					Reason:	Specific disorders of sleep	
Tablet	5.0	Milligram	Daily			Oral	
Batch:	Started:	L TERM		Stopped:			
LUVOX (Suspected)					Reason:	Depression	
Tablet	50.0	Milligram	Daily			Oral	
Batch:	Started:	28/07/1997		Stopped:	01/08/1997		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 121078 **Seq:** 1 **Gender:** F
Reported: 25/09/1997 **Weight:** 70.00
Hospitalisation: Admitted to hospital **Age:** 56Y
Onset Date: 21/07/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Coma Coordination abnormal Hyponatraemia		Seizures	Icu, ventilation

Medicine Details:

FLUPHENAZINE DECANOATE (Other drug)	Reason: Depression
2.5 Milligram Daily	
Batch:	Started: L TERM Stopped: 22/07/1997
LITHIUM CARBONATE (Other drug)	Reason: Depression
500.0 Milligram Daily	
Batch:	Started: L TERM Stopped: 22/07/1997
GLIBENCLAMIDE (Other drug)	Reason: Diabetes mellitus
2.5 Milligram Daily	
Batch:	Started: L TERM Stopped: 22/07/1997
FLUVOXAMINE MALEATE (Suspected)	Reason: Depression
100.0 Milligram Daily	
Batch:	Started: 10/07/1997 Stopped: 22/07/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Na 118 lowest.

Additional Information:



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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 121090

Seq: 1

Gender: F

Reported: 25/09/1997

Weight: 60.00

Hospitalisation:

Age: 70Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Breast enlargement			
Hypochloraemia			
Hyponatraemia			
Palpitations			

Medicine Details:

LUVOX (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 15/08/1997
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 121364 **Seq:** 1 **Gender:** F
Reported: 06/09/1997 **Weight:** 99.00
Hospitalisation: **Age:** 28
Onset Date: 31/07/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthma Hypercapnia Hypoventilation Hypoxia Respiratory depression	Severe		

Medicine Details:

METHADONE HYDROCHLORIDE (Interaction)	Reason:
70.0 Milligram Daily	
Batch:	Started: 01/01/1996 Stopped: 07/08/1997
FLUVOXAMINE MALEATE (Interaction)	Reason: Depression
100.0 Milligram Daily	
Batch:	Started: 01/07/1997 Stopped:
DIAZEPAM (Interaction)	Reason: Anxiety neurosis
4.0 Milligram Daily	
Batch:	Started: 01/07/1997 Stopped: 07/08/1997
IPRATROPIUM BROMIDE (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Other data				
17/12/2002	Pharmacokinetics				

Additional Information:

Australian and new zeland journal of psychiatry 1999; 33:99-101. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. Fluvoxamine - Methadone interaction.



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 121364

Seq: 1

Gender: F

Reported: 06/09/1997

Weight: 99.00

Hospitalisation:

Age: 28

Onset Date: 31/07/1997

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

SPIRONOLACTONE (Other drug)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RANITIDINE (Other drug)		Reason:	
	300.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Australian and new zelaand journal of psychiatry 1999; 33:99-101. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. Fluvoxamine - Methadone interaction.



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 121522 **Seq:** 1 **Gender:** F
Reported: 13/10/1997 **Weight:** 66.00
Hospitalisation: **Age:** 48Y
Onset Date: 25/09/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itchy all over, hives on neck & face	
Periorbital oedema		Swelling around eyes	
Malaise			

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Capsule	50.0 Milligram	Daily	Oral
Batch:	Started: 24/09/1997	Stopped:	26/09/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recovered within days without treatment.



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 121637 **Seq:** 1 **Gender:** F
Reported: 17/10/1997 **Weight:** 68.00
Hospitalisation: **Age:** 43Y
Onset Date: 15/08/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Severe		

Medicine Details:

MURELAX (Other drug)		Reason: Specific disorders of sleep
	30.0 Milligram	Daily
Batch:	Started: 01/01/1986	Stopped:
LUVOX (Suspected)		Reason: Depression
Tablet	0.5 Milligram	Daily Oral
Batch:	Started: 28/07/1997	Stopped: 29/09/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient describes pain as much worse than after hysterectomy. the dosage start date is not accurate but indicates that start occurred sometime during the year.



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 122094 **Seq:** 1 **Gender:** F
Reported: 03/11/1997 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 34Y
Onset Date: 01/10/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Increased appetite Insomnia			Ceased luvox and pulmicort

Medicine Details:

PULMICORT TURBUHALER (Interaction)	Reason: Asthma
Inhalation 0.0 Inhalation	
Batch: Started: 30/09/1997 Stopped: 01/10/1997	
LUVOX (Interaction)	Reason: Depression
Tablet 25.0 Milligram Daily Oral	
Batch: Started: 15/09/1997 Stopped: 01/10/1997	
VENTOLIN (Other drug)	Reason: Asthma
0.0	
Batch: Started: 23/09/1997 Stopped:	
DOXYCYCLINE HYDROCHLORIDE (Other drug)	Reason:
0.0	
Batch: Started: 23/09/1997 Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
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Report Detail

Case Number: 122166 **Seq:** 1 **Gender:** M
Reported: 05/11/1997 **Weight:** 76.00
Hospitalisation: **Age:** 49Y
Onset Date: 31/08/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorgasmia			Same reaction to zoloft

Medicine Details:

DAPA-TABS (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
GAVISCON (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
ZOCOR (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
LUVOX (Suspected)	Reason: Depression
Tablet	100.0 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.



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 123300 **Seq:** 1 **Gender:** F
Reported: 11/12/1997 **Weight:** 65.00
Hospitalisation: **Age:** 52Y
Onset Date: 01/11/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorgasmia Constipation Dry mouth Headache Libido decreased Nausea			

Medicine Details:

LUVOX (Suspected)	Reason:	Depression
	50.0 Milligram	Daily
Batch:	Started: 24/10/1997	Stopped: 30/11/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also uses brauer biotherapies for high fever. delayed orgasm with paraxetine.



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 123664 **Seq:** 1 **Gender:** F
Reported: 30/12/1997 **Weight:** 45.00
Hospitalisation: **Age:** 36Y
Onset Date: 14/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia Agitation Hyperhidrosis Insomnia		Muscle jaw spasm	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 12/12/1997	Stopped:	19/12/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Possible earlier similar reaction to sertraline.



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 124459 **Seq:** 1 **Gender:** F
Reported: 28/01/1998 **Weight:** 42.00
Hospitalisation: **Age:** 55Y
Onset Date: 02/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthenia Confusional state Fatigue Hypocalcaemia Pruritus			Ceased luvox

Medicine Details:

LUVOX (Interaction) 20.0 Milligram Daily Batch: Started: 18/11/1997 Stopped: 05/01/1998 Reason: Depression
ROCALTROL (Interaction) Capsule 1.0 Milligram Daily Oral Batch: Started: 01/01/1992 Stopped: Reason: Other specified symptoms nec
OROXINE (Other drug) Tablet 50.0 Microgram Daily Oral Batch: Started: 01/01/1967 Stopped: Reason: Myxedema
PROGYNOVA (Other drug) Tablet 1.0 Milligram Daily Oral Batch: Started: 01/01/1996 Stopped: Reason: Menopausal symptoms

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Interaction between luvox and rocaltrol -> failure to maintain calcium level with rocaltrol in hypothyroidism patient. 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.



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 124785 **Seq:** 1 **Gender:** M
Reported: 06/02/1998 **Weight:** 76.00
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome			
Hallucination			

Medicine Details:

LUVOX (Suspected)	Reason:	Depression
	150.0 Milligram	Daily
Batch:	Started: 30/09/1997	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Luvox quantity gradually reduced from 11/11/97 due to withdrawal.



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 124969

Seq: 1

Gender: F

Reported: 16/02/1998

Weight: 58.00

Hospitalisation:

Age: 43Y

Onset Date: 06/02/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mydriasis			

Medicine Details:

LUVOX (Suspected)		Reason:	Depression
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 05/02/1998	Stopped:	
SERZONE (Suspected)		Reason:	Depression
	300.0 Milligram	Daily	
Batch:	Started: 03/01/1998	Stopped:	04/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 125073 **Seq:** 1 **Gender:** F
Reported: 18/02/1998 **Weight:** 64.00
Hospitalisation: Admitted to hospital **Age:** 37Y
Onset Date: 15/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis		Fluvoxamine-induced hepatitis.	
Dehydration	Severe	Patient significantly dehydrated.	
Diarrhoea	Severe		Patient hospitalised. intravenous rehydration. fluvoxamine ceased
Vomiting			

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 14/01/1998	Stopped:	19/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		15/01/1998	264	
	AST = SGOT		15/01/1998	180	
	Bilirubin		15/01/1998	41	
	GGT = SGGT =		15/01/1997	101	

Additional Information:



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 125091 **Seq:** 1 **Gender:** F
Reported: 18/02/1998 **Weight:**
Hospitalisation: **Age:** 51Y
Onset Date: 31/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Severe		Discontinued luvox.

Medicine Details:

PETHIDINE HYDROCHLORIDE (Other drug)		Reason: Migraine
Injection	100.0 Milligram	As necessary Intravenous
Batch:	Started:	Stopped:
LUVOX (Suspected)		Reason: Depression
Tablet	0.0	Oral
Batch:	Started: 30/01/1998	Stopped: 02/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Possible interaction with pethidine. "serotonin syndrome".



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FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 125917 **Seq:** 1 **Gender:** F
Reported: 18/03/1998 **Weight:** 70.00
Hospitalisation: **Age:** 26Y
Onset Date: 03/03/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Urticarial rash face, arms & legs	Fluvoxamine ceased

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Other drug)		Reason: Otr spec symp psychopathol nec
	60.0 Milligram Daily	
Batch:	Started: S TERM	Stopped: 04/03/1998
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
	50.0 Milligram Daily	
Batch:	Started: 20/02/1998	Stopped: 26/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 126197 **Seq:** 1 **Gender:** M
Reported: 27/03/1998 **Weight:** 75.00
Hospitalisation: **Age:** 43Y
Onset Date: 20/03/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Nausea Palpitations Paraesthesia			Luvox ceased

Medicine Details:

DIAZEPAM (Other drug)	Reason: Lumbalgia
Tablet	5.0 Milligram As necessary Oral
Batch:	Started: 27/02/1998 Stopped:
CODALGIN FORTE (Other drug)	Reason: Lumbalgia
	2.0 Dose Unspecified As necessary
Batch:	Started: 27/02/1998 Stopped:
LUVOX (Suspected)	Reason: Depression
	50.0 Milligram Daily
Batch:	Started: 20/03/1998 Stopped: 24/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 127250 **Seq:** 1 **Gender:** F
Reported: 06/05/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema			

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
FLUVOXAMINE MALEATE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 127465

Seq: 1

Gender: F

Reported: 15/05/1998

Weight: 70.00

Hospitalisation:

Age: 65Y

Onset Date: 31/05/1998

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia		Felt eyes wide open, wide awake	
Headache			
Nausea			
Visual disturbance			

Medicine Details:

LUVOX (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 127650 **Seq:** 1 **Gender:** F
Reported: 20/05/1998 **Weight:** 56.00
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Luvox ceased

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
	250.0 Milligram	Daily	
Batch:	Started: 12/03/1998	Stopped: 14/05/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		24/04/1998	84	Worse 04/05/98 and improving 11/05/98.
	AST = SGOT		24/04/1998	59	Worse 04/05/98 and improving 11/05/98.
	GGT = SGGT =		24/04/1998	121	Worse 04/05/98 and improving 11/05/98.

Additional Information:

Pt is very sensitive to other anti-depression drugs. pt hasn't had abnormal lft's before.



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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 127838 **Seq:** 1 **Gender:** F
Reported: 27/05/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 56Y
Onset Date: 13/04/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage Anaemia Haematemesis Prothrombin level decreased		Gastrointestinal tract bleed	Admitted to icu - transfusion

Medicine Details:

COUMADIN (Interaction)	Reason:
5.0 Milligram Daily	
Batch:	Started: 01/01/1990 Stopped:
LUVOX (Interaction)	Reason: Depression
100.0 Milligram Daily	
Batch:	Started: 16/03/1998 Stopped: 13/04/1998
LARGACTIL (Interaction)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: 16/03/1998 Stopped: 13/04/1998
LASIX (Other drug)	Reason:
40.0 Milligram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haemoglobin International				Haemoglobin 2.6 Inr on admission > 20

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 127838

Seq: 1

Gender: F

Reported: 27/05/1998

Weight:

Hospitalisation: Admitted to hospital

Age: 56Y

Onset Date: 13/04/1998

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

SPAN-K (Other drug)		Reason:	
	1.2 Gram	Daily	
Batch:	Started:	L TERM	Stopped:
LANOXIN (Other drug)		Reason:	
	187.0 Microgram	Daily	
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 128095 **Seq:** 1 **Gender:** M
Reported: 05/06/1998 **Weight:**
Hospitalisation: Hospitalisation prolonged **Age:** 37Y
Onset Date: 24/05/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nystagmus		Unable to keep eyes still	
Dizziness			Luvox dose decreased to 50mg

Medicine Details:

ORUDIS SR (Suspected)		Reason: Pain
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 22/05/1998	Stopped: CONTIN
ENDONE (Suspected)		Reason: Pain
Tablet	30.0 Milligram	Daily Oral
Batch:	Started: 21/05/1998	Stopped: CONTIN
LUVOX (Suspected)		Reason: Depression
Tablet	100.0 Milligram	Daily Oral
Batch:	Started: 21/05/1998	Stopped: 25/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had similar reaction to fluoxetine



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 128250 **Seq:** 1 **Gender:** F
Reported: 10/06/1998 **Weight:** 85.00
Hospitalisation: **Age:** 50Y
Onset Date: 18/04/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope Dizziness Nausea Vomiting		Fainting Light headed	Luvox ceased

Medicine Details:

LUVOX (Suspected)	Reason:	Depression
	50.0 Milligram	Daily
Batch:	Started: 17/04/1998	Stopped: 20/04/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 128285 **Seq:** 1 **Gender:** F
Reported: 11/06/1998 **Weight:** 85.00
Hospitalisation: **Age:** 48Y
Onset Date: 31/01/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperthyroidism			Propyl thiouracil

Medicine Details:

WARFARIN SODIUM (Other drug)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1995	Stopped:	CONTIN
ZESTRIL (Other drug)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1995	Stopped:	CONTIN
AMIODARONE HYDROCHLORIDE (Suspected)		Reason: Prophylaxis	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1996	Stopped:	CONTIN
FLUVOXAMINE MALEATE (Suspected)		Reason: Obsessive compulsive neurosis	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1996	Stopped: 28/02/1998	

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 128610 **Seq:** 1 **Gender:** F
Reported: 23/06/1998 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: 31/05/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Excessive somnolence	Ceased luvox and changed to efexor and felt relief of somnolence within two days.

Medicine Details:

OGEN (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
PROVERA (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
RANITIDINE (Other drug)	Reason:
150.0 Milligram Daily	
Batch:	Started: 01/01/1995 Stopped: 28/05/1997
LUVOX (Suspected)	Reason: Depression
1.0 Dose Unspecified Daily	
Batch:	Started: 01/05/1998 Stopped: 28/06/1998 2W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Excessive somnolence with both zoloft and luvox. pt switched to efexor and recovered within two days. - 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 stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 128722 **Seq:** 1 **Gender:** M
Reported: 26/06/1998 **Weight:** 80.00
Hospitalisation: **Age:** 37Y
Onset Date: 26/05/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania			Commenced rivotril and ceased luvox and sandomigran.

Medicine Details:

LUVOX (Suspected)		Reason: Depression
Tablet	100.0 Milligram	Daily Oral
Batch:	Started: 01/06/1997	Stopped: 28/07/1998
SANDOMIGRAN (Suspected)		Reason: Headache
	1.5 Milligram	Daily
Batch:	Started: 02/05/1998	Stopped: 23/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Withdrawal of sandomigran with increase serotonin the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 128765 **Seq:** 1 **Gender:** F
Reported: 29/06/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase in Neuroleptic malignant syndrome			

Medicine Details:

ZYPREXA (Suspected)		Reason:			
Tablet	20.0 Milligram	Daily	Oral		
Batch:	Started: 01/05/1998	Stopped: 28/06/1998	1M		
LUVOX (Suspected)		Reason:			
Tablet	300.0 Milligram	Daily	Oral		
Batch:	Started:	Stopped:			

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 128817 **Seq:** 1 **Gender:** M
Reported: 30/06/1998 **Weight:** 70.00
Hospitalisation: **Age:** 30Y
Onset Date: 31/03/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia Somnolence Dry mouth		Jaw stiff Sleepiness in the afternoon	In march the dose of fluvoxamine was increased to 200mg and the side effects started. fluvoxamine ceased and changed to meclonemide, after two days being drug free

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1998	Stopped: 28/04/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 129061 **Seq:** 1 **Gender:** F
Reported: 09/07/1998 **Weight:** 35.00
Hospitalisation: Admitted to hospital **Age:** 73Y
Onset Date: 30/06/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypothermia Blood creatine phosphokinase in Bradycardia Coma		Temp of 27.2'c	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)	Reason:	Depression
Batch:	Started:	Stopped:
PLENDIL ER (Suspected)	Reason:	Essential benign hypertension
Batch:	Started:	Stopped:
CLONAZEPAM (Suspected)	Reason:	
Batch:	Started:	Stopped:
TEMAZEPAM (Suspected)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Ck rise to 157 (mb 30%)

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 129222 **Seq:** 1 **Gender:** M
Reported: 15/07/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 25Y
Onset Date: 02/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flushing Headache Nausea Tachycardia	Severe		Observation.

Medicine Details:

SERZONE (Suspected)		Reason: Depression
	0.0	
Batch:	Started:	Stopped: 29/06/1998
LUVOX (Suspected)		Reason: Depression
	50.0 Milligram	Total
Batch:	Started: 01/07/1998	Stopped: 01/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt had been taking serzone, but gradually withdrawn and ceased on 29/06/98.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 129312 **Seq:** 1 **Gender:** F
Reported: 20/07/1998 **Weight:** 70.00
Hospitalisation: **Age:** 47Y
Onset Date: 31/10/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea			Ceased luvox. therapy changed to zoloft.

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
	100.0 Milligram	Daily	
Batch:	Started: 01/10/1997	Stopped: 28/04/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 129375

Seq: 1

Gender: M

Reported: 23/07/1998

Weight: 95.00

Hospitalisation:

Age: 24Y

Onset Date: 03/06/1998

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			

Medicine Details:

LUVOX (Suspected)	Reason:
200.0 Milligram	Daily
Batch:	Started: 02/06/1998
	Stopped: 04/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 129711 **Seq:** 1 **Gender:** F
Reported: 30/07/1998 **Weight:**
Hospitalisation: **Age:** 46Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea			Luvox ceased and started cipramil on 22/07/98 see report 129711

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 29/06/1998	Stopped:	16/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 129874 **Seq:** 1 **Gender:** F
Reported: 04/08/1998 **Weight:** 68.00
Hospitalisation: **Age:** 37
Onset Date: 22/07/1998 **DOB:** 17/03/1961
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Required Specialist Consultation	Mild swelling of hands, feet and lower	Luvox ceased.

Medicine Details:

LARGACTIL (Other drug)		Reason: Anxiety neurosis
	100.0 Milligram	1 time
Batch:	Started: 18/07/1998	Stopped: 18/07/1998
ATIVAN (Other drug)		Reason: Anxiety neurosis
Tablet	1.0 Milligram	Daily Oral
Batch:	Started: 18/12/1997	Stopped:
LUVOX (Suspected)		Reason: Depression
Tablet	50.0 Milligram	Daily Oral
Batch:	Started: 17/07/1998	Stopped: 22/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms 5 days after commencing luvox 50mg daily, withdrawn for 2 days and then re-started, so luvox ceased. allergic to sulpha.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 130283 **Seq:** 1 **Gender:** M
Reported: 18/08/1998 **Weight:** 65.00
Hospitalisation: **Age:** 37Y
Onset Date: 08/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Choreoathetosis		Chorea movements of shoulders, muscles.	Haloperidol substituted for

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	1.2 Gram	Daily	Oral
Batch:	Started: 01/01/1994	Stopped:	CONTIN
ZYPREXA (Suspected)		Reason: Schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 31/07/1998	Stopped: 10/08/1998	
LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 31/07/1998	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.



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 130805 **Seq:** 1 **Gender:** F
Reported: 07/09/1998 **Weight:** 50.00
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Widespread limbs and truncal ecchymosis	
Nausea	Severe		Luvox ceased
Vomiting	Severe		

Medicine Details:

XANAX (Other drug)		Reason:	
Tablet	500.0 Microgram	Daily	Oral
Batch:	Started: 01/01/1997	Stopped:	CONTIN
LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 02/08/1998	Stopped: 02/09/1998	

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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 131014 **Seq:** 1 **Gender:** U
Reported: 10/09/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 10/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthenia		Muscle weakness lower limbs	Ceased luvox

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
	5.0 Milligram	As necessary	
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 23/07/1998	Stopped: 24/08/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 131160

Seq: 1

Gender: M

Reported: 14/09/1998

Weight: 72.00

Hospitalisation:

Age: 59Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastrooesophageal reflux disease			

Medicine Details:

LUVOX (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 04/09/1998
	Stopped: 08/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 131195 **Seq:** 1 **Gender:** M
Reported: 17/09/1998 **Weight:**
Hospitalisation: **Age:** 24Y
Onset Date: 31/08/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Increased clozapine level in blood.	

Medicine Details:

CLOZAPINE (Interaction)	Reason:
0.0	
Batch:	Started: Stopped:
LUVOX (Interaction)	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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 131304 **Seq:** 1 **Gender:** F
Reported: 18/09/1998 **Weight:** 90.00
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Spots on face, papules over nose & cheeks	

Medicine Details:

KEFLEX (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
EPILIM (Suspected)	Reason:
1.0 Gram Daily	
Batch:	Started: Stopped:
LUVOX (Suspected)	Reason:
300.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
OLANZAPINE (Suspected)	Reason:
30.0 Milligram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 131775 **Seq:** 1 **Gender:** F
Reported: 02/10/1998 **Weight:**
Hospitalisation: **Age:** 22Y
Onset Date: 28/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain		Jaw pain so severe patient unable to eat	Luvox ceased
Nausea		Severe	

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 26/08/1998	Stopped:	04/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 131886 **Seq:** 1 **Gender:** M
Reported: 01/10/1998 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Disturbance in attention Amnesia Visual disturbance Drug ineffective Depersonalisation		Anxious for 2 - 3 days after one tablet Could not concentrate on conversation for 2-3 days Could not retain information from conversation Experienced lightning flashes in both eyes Generally depressed for 2-3 days after one tablet	

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	1.0	Dose Unspecified 1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Went for a swim about 20 hours after taking one luvox tab and was told he had been staring into the corner of the pool for 15 minutes.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 132274 **Seq:** 1 **Gender:** M
Reported: 20/10/1998 **Weight:** 80.00
Hospitalisation: **Age:** 27Y
Onset Date: 12/10/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills			
Dizziness			

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 01/10/1997	Stopped:	
LITHICARB (Suspected)		Reason:	
Tablet	750.0 Milligram	Daily	Oral
Batch:	Started: 01/12/1997	Stopped:	
NUROFEN (Suspected)		Reason: Pain in joint	
Tablet	2.0 Dose Unspecified	Daily	Oral
Batch:	Started: 11/10/1998	Stopped: 12/10/1998	

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 132737 **Seq:** 1 **Gender:** F
Reported: 02/11/1998 **Weight:** 68.00
Hospitalisation: **Age:** 42Y
Onset Date: 02/10/1998 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia		Numbness of lips and tongue and left arm.	Ceased luvox and changed to zoloft 50mg.

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Capsule	100.0 Milligram	Daily	Oral
Batch:	Started: 01/10/1998	Stopped: 05/10/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms 20 minutes after taking luvox and recurring after next dose. previous anaphylaxis with penicillin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 133200 **Seq:** 1 **Gender:** F
Reported: 16/11/1998 **Weight:** 55.00
Hospitalisation: **Age:** 38
Onset Date: 28/10/1998 **DOB:** 13/02/1960
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Insomnia Nausea Pruritus Rash			

Medicine Details:

LUVOX (Suspected)	Reason: Depression
	1.0 Dose Unspecified Daily
Batch:	Started: 14/09/1998 Stopped: 12/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 133830 **Seq:** 1 **Gender:** M
Reported: 01/12/1998 **Weight:**
Hospitalisation: **Age:** 41Y
Onset Date: 31/10/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Blurred peripheral vision	

Medicine Details:

LISINOPRIL (Other drug)		Reason: Essential benign hypertension
	10.0 Milligram	Daily
Batch:	Started: 01/01/1994	Stopped: CONTIN
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
	150.0 Milligram	Daily
Batch:	Started: 24/09/1998	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Blurred peripheral vision lasting 1 hour after each dose of fluvoxamine. onset when dose increased from 100mg to 150mg. continuing treatment. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 133967 **Seq:** 1 **Gender:** F
Reported: 03/12/1998 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 16/11/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased Galactorrhoea Dry mouth Insomnia		Desire for fatty foods Galactorrhoea	

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 15/10/1998	Stopped:	26/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient stopped breast feeding at age 46.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 134002 **Seq:** 1 **Gender:** F
Reported: 03/12/1998 **Weight:**
Hospitalisation: **Age:** 26Y
Onset Date: 10/10/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nystagmus		Sensation of shaky eyes	Cease medication

Medicine Details:

LUVOX (Suspected)		Reason: Obsessive compulsive neurosis
	100.0 Milligram	Daily
Batch:	Started: 23/09/1998	Stopped: 04/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Assessed by ophthalmologist. diagnosis of oscillopathy which is apparently a cerebellar effect.

Additional Information:

Similar response to prozac several years ago



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 134550 **Seq:** 1 **Gender:** F
Reported: 21/12/1998 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: **DOB:** 12/11/1978
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Prothrombin level decreased			Fluvoxamine discontinued.

Medicine Details:

WARFARIN SODIUM (Interaction)		Reason:	
	0.0		
Batch:	Started:	L TERM	Stopped:
FLUVOXAMINE MALEATE (Interaction)		Reason:	
	3.0 Dose Unspecified Total		
Batch:	Started:		Stopped:
ORAL CONTRACEPTIVE NOS (Other drug)		Reason:	
	0.0		
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	International				Increased to 9.2.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 134762 **Seq:** 1 **Gender:** F
Reported: 05/01/1999 **Weight:** 50.00
Hospitalisation: **Age:** 24Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Excessive bruising	

Medicine Details:

BREVINOR (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 04/11/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 135030 **Seq:** 1

Reported: 12/01/1999

Hospitalisation:

Onset Date: 01/12/1998

Outcome: Recovered

Gender: M

Weight: 69.00

Age: 20Y

DOB:

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Nausea			

Medicine Details:

LUVOX (Suspected)	Reason:	Depression
	100.0 Milligram	Daily
Batch:	Started:	01/12/1998
	Stopped:	04/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 135187 **Seq:** 1
Reported: 15/01/1999
Hospitalisation:
Onset Date:
Outcome: Recovered

Gender: M
Weight:
Age: 72Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue		Lethargic and spent most of the day in bed.	
Disturbance in attention		Lost either the urge or ability to write his	
Drug ineffective		Was not aware of feeling any less	

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
	50.0 Milligram	Daily	
Batch:	Started:	Stopped:	2M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Fluvoxamine on a dose building up from 50mg to 500mg per day.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 135941 **Seq:** 1 **Gender:** F
Reported: 09/02/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence			
Urinary incontinence			

Medicine Details:

DOXEPIN HYDROCHLORIDE (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
FLUVOXAMINE MALEATE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 13/11/1997	Stopped:	3M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 136122 **Seq:** 1 **Gender:** F
Reported: 11/02/1999 **Weight:**
Hospitalisation: **Age:** 43Y
Onset Date: 31/10/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Polydipsia Polyuria Urinary incontinence			Ceased luvox

Medicine Details:

HALDOL DECANOATE (Other drug)	Reason: Unspecified psychosis
Injection 50.0 Milligram Monthly Intramuscular	
Batch: Started: L TERM Stopped: CONTIN	
NORMISON (Other drug)	Reason: Specific disorders of sleep
2.0 Dose Unspecified Daily	
Batch: Started: L TERM Stopped: CONTIN	
VALIUM (Other drug)	Reason: Anxiety neurosis
2.0 Milligram Daily	
Batch: Started: L TERM Stopped: CONTIN	
LUVOX (Suspected)	Reason: Depression
Tablet 150.0 Milligram Daily Oral	
Batch: Started: 01/06/1998 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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 136302 **Seq:** 1 **Gender:** F
Reported: 16/02/1999 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: 29/01/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus Drug withdrawal syndrome Headache Nightmare Paraesthesia		Buzzing in head.	Symptoms settled with fluvoxamine 50mg which was taken on 2 occasions.

Medicine Details:

PERINDOPRIL (Other drug)		Reason: Essential benign hypertension
	0.0	
Batch:	Started:	Stopped: 28/01/1999
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 04/08/1998	Stopped: 28/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Abrupt cessation of fluvoxamine upon diagnosis of pregnancy, resulted in pt suffering symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 136355 **Seq:** 1 **Gender:** M
Reported: 19/02/1999 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: 03/02/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			
Rash maculo-papular			Luvox ceased.

Medicine Details:

COGENTIN (Other drug)	Reason: Unspecified schizophrenia
1.0 Milligram Daily	
Batch:	Started: 01/01/1997 Stopped:
LARGACTIL (Other drug)	Reason: Unspecified schizophrenia
200.0 Milligram Daily	
Batch:	Started: 01/01/1997 Stopped:
DIAZEPAM (Other drug)	Reason: Unspecified schizophrenia
5.0 Milligram Daily	
Batch:	Started: 01/01/1997 Stopped:
LUVOX (Suspected)	Reason: Depression
Tablet 100.0 Milligram Daily Oral	
Batch:	Started: 01/08/1998 Stopped: 08/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous rash. resolved after withdrawal of luvox. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 136593 **Seq:** 1 **Gender:** F
Reported: 24/02/1999 **Weight:** 55.00
Hospitalisation: **Age:** 36Y
Onset Date: 30/01/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia Depersonalisation Nausea Tremor		Abdominal and jaw muscles spasm Feel.of watchi.herself & ot people from a	

Medicine Details:

NORIMIN (Other drug)		Reason: Contraception	
Tablet	1.0 Dose Unspecified Daily	Oral	
Batch:	Started:	Stopped:	CONTIN
LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram 1 time	Oral	
Batch:	Started: 30/01/1999	Stopped:	30/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergic to iodine and septrim.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 136630 **Seq:** 1 **Gender:** M
Reported: 24/02/1999 **Weight:**
Hospitalisation: **Age:** 28Y
Onset Date: 30/01/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Muscular spasm in jaw and top of arms.	

Medicine Details:

LUVOX (Suspected)		Reason: Depression
Tablet	100.0 Milligram	Daily Oral
Batch:	Started: 28/01/1999	Stopped: CONTIN
ALDAZINE (Suspected)		Reason: Otr spec symp psychopathol nec
Tablet	50.0 Milligram	Daily Oral
Batch:	Started: 27/01/1999	Stopped: 17/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 136952 **Seq:** 1 **Gender:** F
Reported: 05/03/1999 **Weight:** 85.00
Hospitalisation: **Age:** 28Y
Onset Date: 30/11/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia Bronchospasm Generalised oedema		Aches & pains.	

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 17/11/1998	Stopped:	22/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 137312

Seq: 1

Gender: M

Reported: 16/03/1999

Weight: 70.00

Hospitalisation:

Age: 62Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Prothrombin level decreased			

Medicine Details:

LUVOX (Suspected)	Reason:
0.0	
Batch:	Started: 03/02/1999
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	International		02/03/1999	5.8	

Additional Information:

Patient stable on warfarin 5mg for years with inr between 2-3 for aortic stenosis. see original report for other drugs - zocor, aspirin, prazosin, & warfarin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 138842 **Seq:** 1 **Gender:** F
Reported: 28/04/1999 **Weight:** 60.00
Hospitalisation: **Age:** 30Y
Onset Date: 04/04/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills Neurosis Affect lability Dry mouth Hyperkinesia Serotonin syndrome Tachycardia		Hot and cold feelings Intrusive tune in head, dysinhibition Uncontrolled laughing intermittently, some	

Medicine Details:

LUVOX (Suspected)	Reason: Depression
100.0 Milligram	2 times
Batch:	Started: 03/04/1999 Stopped: 04/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous exposure to luvox and other antidepressants. bromocriptine had caused syncope in the past. reaction occurred in response to 1 x 100mg luvox. took one more before medication was stopped. taking no other medications and no illicit drugs, no herbal remedies, was not using alcohol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 139294 **Seq:** 1 **Gender:** F
Reported: 07/05/1999 **Weight:** 55.00
Hospitalisation: **Age:** 29Y
Onset Date: 01/04/1999 **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania		Became increasingly manic, couldn't sleep	
Hallucination		Eventually described visual hallucinations	

Medicine Details:

LUVOX (Suspected)		Reason: Depression
	100.0 Milligram	Daily
Batch:	Started: 22/03/1999	Stopped: 06/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae: financial and social re behaviour during manic phase. see original report for details of other drugs - alprazolam, aloecin, bricanyl, pulmicort, microgynon.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 139965 **Seq:** 1 **Gender:** M
Reported: 27/05/1999 **Weight:**
Hospitalisation: **Age:** 46Y
Onset Date: 31/01/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			Luvox ceased. was changed onto zoloft.

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 16/12/1998	Stopped:	09/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recurrent multiple tender lumps in both axillae - similar to hydradenitis. did not respond to multiple courses of antibiotics. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 140404 **Seq:** 1 **Gender:** F
Reported: 10/06/1999 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 27Y
Onset Date: 11/05/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression		Became very depressed about extreme	
Cushing's syndrome		Patient developed cushingoid syndrome on	
Purpura		Pink/purple striae on axillae & lower	
Hypertension			
Obesity			

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia
Tablet	10.0 Milligram	Daily Oral
Batch:	Started: 01/01/1999	Stopped: 07/05/1999
LARGACTIL (Suspected)		Reason: Unspecified schizophrenia
Tablet	150.0 Milligram	Daily Oral
Batch:	Started: 01/01/1999	Stopped: 07/05/1999
LUVOX (Suspected)		Reason: Unspecified schizophrenia
Tablet	100.0 Milligram	Daily Oral
Batch:	Started: 01/01/1999	Stopped: 07/05/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Fasting cortisol 370 (125-695)nmol/l.

Additional Information:

See original report for other drug details - coversyl. stopped all psychotropic tablets 4 days prior to admission. patient came in with significant paracetamol overdose. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 140650 **Seq:** 1 **Gender:** F
Reported: 18/06/1999 **Weight:** 60.00
Hospitalisation: **Age:** 51Y
Onset Date: 07/01/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gingivitis			

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
	50.0 Milligram	Daily	
Batch:	Started: 26/12/1998	Stopped:	26/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 140704 **Seq:** 1 **Gender:** M
Reported: 21/06/1999 **Weight:** 70.00
Hospitalisation: **Age:** 35Y
Onset Date: 21/05/1999 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain Gastrooesophageal reflux disease			Failed to respond to antacid, ranitidine 150mg bd. also given omeprazole, xylocaine viscous, maxolon.

Medicine Details:

LUVOX (Suspected)	Reason:	Depression
	50.0 Milligram	Daily
Batch:	Started: 18/05/1999	Stopped: 22/05/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No past history of GORD. rechallenge on 26/5 with single dose of 50mg gave recurrence of nocturnal symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 141190 **Seq:** 1 **Gender:** M
Reported: 05/07/1999 **Weight:** 84.00
Hospitalisation: **Age:** 62Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Astigmatism	

Medicine Details:

LUVOX (Suspected)	Reason:	Depression
	100.0 Milligram	Daily
Batch:	Started:	30/04/1999
	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details: panadeine, loperamide, & normison.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 141385 **Seq:** 1 **Gender:** F
Reported: 12/07/1999 **Weight:** 45.00
Hospitalisation: **Age:** 28Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Leg spasms	Ceased luvox
Hyperkinesia			

Medicine Details:

LUVOX (Suspected)		Reason: Depression
Tablet	100.0 Milligram	Daily Oral
Batch:	Started: 28/04/1999	Stopped: 09/06/1999
METHADONE HYDROCHLORIDE (Suspected)		Reason: Dependence on unspecified drugs
Oral application	40.0 Milligram	Daily Oral
Batch:	Started: 02/06/1999	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 141544 **Seq:** 1 **Gender:** F
Reported: 02/07/1999 **Weight:** 53.00
Hospitalisation: **Age:** 41Y
Onset Date: 27/06/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Somnolence			

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 26/06/1999	Stopped:	27/06/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 141555

Seq: 1

Gender: F

Reported: 14/07/1999

Weight: 68.00

Hospitalisation:

Age: 25Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased Anorgasmia		Also decreased arousal	

Medicine Details:

LUVOX (Suspected)	Reason:
Batch:	Started: 0.0 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reactions improved with increased dose. see original report for details of other drug - verapamil.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 141768 **Seq:** 1 **Gender:** F
Reported: 21/07/1999 **Weight:**
Hospitalisation: **Age:** 24Y
Onset Date: 02/07/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason:	
Oral application	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	01/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details: zyprexa & roxithromycin.



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 142771 **Seq:** 1 **Gender:** F
Reported: 19/08/1999 **Weight:** 70.00
Hospitalisation: **Age:** 49Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Choreoathetosis		Jerky movements right arm and shoulder	

Medicine Details:

LUVOX (Suspected)	Reason:	Depression
	300.0 Milligram	Daily
Batch:	Started:	03/03/1999
	Stopped:	23/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 142854 **Seq:** 1 **Gender:** F
Reported: 23/08/1999 **Weight:** 62.00
Hospitalisation: **Age:** 18Y
Onset Date: 01/07/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia	Severe	Muscle rigidity, expecially on her right side.	
Visual disturbance		Patient experienced increased visual	
Flushing		Patient experienced severe hot flushes.	
Nausea		Patient experienced severe nausea.	
Polyuria		Pt experienced increased diuresis.	
Insomnia			

Medicine Details:

LUVOX (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 12/06/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous exposure to any drugs or antidepressants. no past history of reaction to any otc medications or antibiotics. no past history of any prescription med other than antibiotics. patient has very mild milk-allergy with resp symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 143425 **Seq:** 1 **Gender:** M
Reported: 03/09/1999 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 12/08/1999 **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypokalaemia Prothrombin level decreased			Plasma and potassium.

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/07/1999	Stopped: 12/08/1999	3W
NATRILIX (Suspected)		Reason: Essential benign hypertension	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started:	Stopped: 12/08/1999	
COUMADIN (Suspected)		Reason: Prophylaxis	
Tablet	6.5 Milligram	Daily	Oral
Batch:	Started: 01/01/1992	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	International		15/07/1999	2.8	Previous result 3-4 weeks before admission into hospital & on day of reactoin.
	International		12/08/1999	12.3	Previous result 3-4 weeks before admission into hospital & on day of reactoin.
	Potassium		12/08/1999	2.3	

Additional Information:

Sequelae: arrythmia precipitated by hypokalaemia. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 144166 **Seq:** 1 **Gender:** F
Reported: 29/09/1999 **Weight:** 74.00
Hospitalisation: **Age:** 20Y
Onset Date: 20/09/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Polyhydramnios		Polyhydramnios discovered at 37 weeks.	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason:	Obsessive compulsive neurosis	
Tablet	100.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/1999	Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

First pregnancy not on luvox, no polyhydramnios. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 145358 **Seq:** 1 **Gender:** U
Reported: 05/11/1999 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapeutic response unexpecte		Resolution of raynaud's phenomenon	

Medicine Details:

LUVOX (Suspected)	Reason:		
	150.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 145571

Seq: 1

Gender: M

Reported: 09/11/1999

Weight: 65.00

Hospitalisation:

Age: 33Y

Onset Date: 04/10/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			

Medicine Details:

MELLERIL (Suspected)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
LUVOX (Suspected)		Reason: Depression	
	100.0 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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 146563 **Seq:** 1 **Gender:** F
Reported: 06/12/1999 **Weight:** 48.00
Hospitalisation: **Age:** 33Y
Onset Date: 28/10/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Glossitis		Sensation of burning tongue looks cracked	Fluvoxamine ceased. recovered within 2 days.

Medicine Details:

OXAZEPAM (Other drug)		Reason:	Specific disorders of sleep	
Oral application	30.0 Milligram	Daily	Oral	
Batch:	Started: 15/10/1999	Stopped:	CONTIN	
FLUVOXAMINE MALEATE (Suspected)		Reason:	Depression	
Tablet	100.0 Milligram	Daily	Oral	
Batch:	Started: 27/10/1999	Stopped:	18/11/1999	
PAROXETINE HYDROCHLORIDE (Suspected)		Reason:	Depression	
Tablet	20.0 Milligram	Daily	Oral	
Batch:	Started: 13/10/1999	Stopped:	26/10/1999	
SODIUM VALPROATE (Suspected)		Reason:	Otr spec symp psychopathol nec	
Tablet	600.0 Milligram	Daily	Oral	
Batch:	Started: 20/10/1999	Stopped:	26/10/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 147206 **Seq:** 1 **Gender:** M
Reported: 20/12/1999 **Weight:**
Hospitalisation: **Age:** 55
Onset Date: **DOB:** 25/03/1944
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia Drug level increased		Pt developed a lean to one side	Fluvoxamine reduced to 100mg daily

Medicine Details:

CLOZARIL (Suspected)	Reason:
Tablet 300.0 Milligram Daily Oral	
Batch:	Started: L TERM Stopped: CONTIN
FLUVOXAMINE MALEATE (Suspected)	Reason:
200.0 Milligram Daily	
Batch:	Started: Stopped: CONTIN
SODIUM VALPROATE (Suspected)	Reason:
500.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level		30/12/1999	1.92	Clozaril level was 3.8.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 147866 **Seq:** 1 **Gender:** M
Reported: 10/01/2000 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 15/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug level increased			

Medicine Details:

LUVOX (Interaction)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level		15/12/1999	7	Clozaril level (units not specified).

Additional Information:

The patient's previous two clozaril serum levels were 2 (units not specified). after receiving luvox briefly, the patient's level increased to 7 (units not specified).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 149502 **Seq:** 1 **Gender:** F
Reported: 21/02/2000 **Weight:** 55.00
Hospitalisation: **Age:** 36
Onset Date: 05/11/1999 **DOB:** 10/05/1963
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			Required a visit to doctor.

Medicine Details:

LUVOX (Suspected)		Reason: Depression
	150.0 Milligram	Daily
Batch:	Started: 01/02/1999	Stopped: 28/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin		05/11/1999	1707	Increased prolactin

Additional Information:

Prolactin levels reverted to normal 6 weeks after ceasing antidepressant. date of recovery: 12/2/2000. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 150263 **Seq:** 1 **Gender:** M
Reported: 10/03/2000 **Weight:** 115.00
Hospitalisation: **Age:** 47Y
Onset Date: 28/02/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia	Severe	Severe facial & neck spasm, mild (r) finger	

Medicine Details:

LUVOX (Suspected)		Reason: Depression
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 01/01/1998	Stopped: 02/03/2000
ISOPTIN (Suspected)		Reason: Migraine
	160.0 Milligram	Daily
Batch:	Started: 20/01/1999	Stopped: 02/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking monopril and dapa tabs. spasm was lasting upto 30 seconds every minute. on gogentin initially 4mg no 2mg daily. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 150437 **Seq:** 1 **Gender:** F
Reported: 16/03/2000 **Weight:** 60.00
Hospitalisation: **Age:** 44Y
Onset Date: 11/03/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting		Patient vomited once.	
Nausea		Sensation of nausea.	
Flushing		Still experienced flushing after 2 days.	
Hyperhidrosis			
Paraesthesia			
Tremor			

Medicine Details:

LUVOX (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 06/03/2000 Stopped: 10/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 150551 **Seq:** 1 **Gender:** M
Reported: 21/03/2000 **Weight:**
Hospitalisation: **Age:** 19
Onset Date: **DOB:** 12/03/1981
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope		Transient loss of consciousness.	Zyprexa therapy ceased.

Medicine Details:

ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 14/12/1999	Stopped:	10/02/2000
LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 14/12/1999	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a medical history of depression, family conflict, behavioural disturbances. the patient was found later by his parents unconscious on the bathroom floor with a minor graze to the head.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 150801 **Seq:** 1 **Gender:** M
Reported: 24/03/2000 **Weight:** 52.00
Hospitalisation: **Age:** 81Y
Onset Date: 06/02/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Welts & rash right and left forearms.	Phenergan 25mg, hydrocortisone 100mg.

Medicine Details:

SLOW-K (Suspected)		Reason:	
	0.0		
Batch:	Started: 30/01/2000	Stopped:	
MAGMIN (Suspected)		Reason:	
	0.0		
Batch:	Started: 01/02/2000	Stopped:	
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Oral application	50.0 Milligram	Daily	Oral
Batch:	Started: 29/01/2000	Stopped:	
CILOXAN (Suspected)		Reason:	
Ear Drops	12.0 Dose Unspecified	Daily	Topical
Batch:	Started: 04/02/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt also taking sorbolene, elocon, qv bath oil coversyl, indapamide, pulmicort, oxazepam, ventolin, temazepam. history of widespread patch eczema and allergy to penicillin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 150801

Seq: 1

Gender: M

Reported: 24/03/2000

Weight: 52.00

Hospitalisation:

Age: 81Y

Onset Date: 06/02/2000

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

CEFTRIAZONE (Suspected)		Reason:	
Injection	2.0 Gram	Daily	Intravenous
Batch:	Started: 01/02/2000	Stopped: 04/02/2000	
METRONIDAZOLE (Suspected)		Reason:	
Oral application	1.2 Gram	Daily	Oral
Batch:	Started: 01/02/2000	Stopped: 03/02/2000	
FLAGYL (Suspected)		Reason:	
Injection	1.5 Gram	Daily	Intravenous
Batch:	Started: 03/02/2000	Stopped:	
CEFTAZIDIME (Suspected)		Reason:	
Injection	3.0 Gram	Daily	Intravenous
Batch:	Started: 04/02/2000	Stopped: 06/02/2000	

Laboratory Investigations:

Additional Information:

Pt also taking sorbolene, elocon, qv bath oil coversyl, indapamide, pulmicort, oxazepam, ventolin, temazepam. history of widespread patch eczema and allergy to penicillin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 151250 **Seq:** 1 **Gender:** F
Reported: 05/04/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: 02/04/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching Diarrhoea Headache Tremor		Flickering of eyes.	

Medicine Details:

LUVOX (Suspected)		Reason: Depression
Tablet	100.0 Milligram	Daily Oral
Batch:	Started: 30/03/2000	Stopped: 03/04/2000
FERRO-GRADUMET (Suspected)		Reason:
	1.0 Dose Unspecified	Daily
Batch:	Started: 30/03/2000	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 151258 **Seq:** 1 **Gender:** M
Reported: 05/04/2000 **Weight:** 65.00
Hospitalisation: **Age:** 30
Onset Date: 02/04/2000 **DOB:** 30/09/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction-jaw spasms	Relieved by im cogentin 1.5ml followed half hour later by 2ml, followed with oral cogentin.
Bruxism		Left to right grinding	

Medicine Details:

LUVOX (Suspected)	Reason: Specific disorders of sleep
100.0 Milligram	Daily
Batch:	Started: 31/03/2000 Stopped: 02/04/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 151802 **Seq:** 1 **Gender:** F
Reported: 17/04/2000 **Weight:**
Hospitalisation: **Age:** 48Y
Onset Date: 16/02/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Elevated liver enzymes.	Zyprexa ceased.

Medicine Details:

ZYPREXA (Suspected)	Reason: Otr spec symp psychopathol nec
Tablet	10.0 Milligram Daily Oral
Batch:	Started: Stopped: 28/02/2000 12M
AURORIX (Suspected)	Reason:
	600.0 Milligram Daily
Batch:	Started: Stopped:
CAPTOPRIL (Suspected)	Reason:
	100.0 Milligram Daily
Batch:	Started: Stopped:
LUVOX (Suspected)	Reason:
	100.0 Milligram Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		16/02/2000	79	
	ALT = SGPT		13/03/2000	61	
	AST = SGOT		16/02/2000	82	
	AST = SGOT		13/03/2000	58	
	GGT = SGGT =		16/02/2000	493	
	GGT = SGGT =		13/03/2000	409	
	SAP = ALP		16/02/2000	175	

Additional Information:

Patient has just been diagnosed with diabetes and the doctor now believes this is the cause of the elevated lft's.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 151802 **Seq:** 1 **Gender:** F
Reported: 17/04/2000 **Weight:**
Hospitalisation: **Age:** 48Y
Onset Date: 16/02/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

ZYPREXA (Suspected)		Reason:		Otr spec symp psychopathol nec	
Tablet	10.0 Milligram	Daily	Oral		
Batch:	Started:		Stopped:	28/02/2000	12M
AURORIX (Suspected)		Reason:			
	600.0 Milligram	Daily			
Batch:	Started:		Stopped:		
CAPTOPRIL (Suspected)		Reason:			
	100.0 Milligram	Daily			
Batch:	Started:		Stopped:		
LUVOX (Suspected)		Reason:			
	100.0 Milligram	Daily			
Batch:	Started:		Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		13/03/2000	155	

Additional Information:

Patient has just been diagnosed with diabetes and the doctor now believes this is the cause of the elevated lft's.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 152428 **Seq:** 1 **Gender:** F
Reported: 05/05/2000 **Weight:**
Hospitalisation: **Age:** 52
Onset Date: 19/04/2000 **DOB:** 12/02/1948
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Coordination abnormal Affect lability Dyskinesia Sensory disturbance		Electric shock sensation Unsteady on feet.	

Medicine Details:

LUVOX (Suspected)	Reason:
100.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Withdrawal reaction to ceasing luvox 100mg daily despite gradual reduction 50mg one week, alternate day for next week before ceasing.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 152625 **Seq:** 1 **Gender:** F
Reported: 15/05/2000 **Weight:** 80.00
Hospitalisation: **Age:** 54Y
Onset Date: 01/05/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypersensitivity	Severe	Severe allergic reaction	

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 01/05/2000	Stopped: 03/05/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 153471 **Seq:** 1 **Gender:** M
Reported: 05/06/2000 **Weight:**
Hospitalisation: **Age:** 63
Onset Date: 15/05/2000 **DOB:** 11/03/1937
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest			The patient was successfully resuscitated but due to the patient's mental status he was not resuscitated a second time.
Sudden death			

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 01/08/1997	Stopped: 06/04/2000	
LUVOX (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This patient experienced a cardiac arrest and died on the 15/05/2000, two and a half years after commencing clozaril therapy. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 154072 **Seq:** 1 **Gender:** M
Reported: 26/06/2000 **Weight:** 30.00
Hospitalisation: **Age:** 10Y
Onset Date: 28/04/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations Pallor Nausea Anxiety Tremor		Heart racing Pale Unsuccessful attempt at vomiting. Very distressed	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 27/04/2000	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred after 2nd dose of an increased dose of fluvoxamine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 154088 **Seq:** 1 **Gender:** F
Reported: 27/06/2000 **Weight:** 60.00
Hospitalisation: Admitted to hospital **Age:** 38
Onset Date: 08/04/2000 **DOB:** 12/09/1961
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bipolar disorder		Manic depressive	
Psychotic disorder			

Medicine Details:

MURELAX (Other drug)	Reason: Specific disorders of sleep
15.0 Milligram Daily Oral	
Batch: Started: 07/04/2000 Stopped:	
AUGMENTIN DUO FORTE (Suspected)	Reason: Ac upr resp inf,mult,unsp stes
2.0 Dose Unspecified Daily Oral	
Batch: Started: 07/04/2000 Stopped: 08/04/2000	
LUVOX (Suspected)	Reason: Anxiety neurosis
200.0 Milligram Daily Oral	
Batch: Started: 07/04/2000 Stopped: 08/04/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Psychotic episode after increased dose of Luvox 100 to 300mg/d (on first day of 300mg)



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 154783 **Seq:** 1 **Gender:** F
Reported: 14/07/2000 **Weight:** 72.00
Hospitalisation: **Age:** 51
Onset Date: 31/03/2000 **DOB:** 01/12/1948
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Electrical impulses all over the scalp.	

Medicine Details:

LUVOX (Suspected)	Reason:	Depression
	100.0 Milligram	Daily
Batch:	Started: 25/12/1999	Stopped: 22/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Luvox was used for 3 months with similar, though not quite so bad reaction as efexor. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 154858 **Seq:** 1 **Gender:** F
Reported: 17/07/2000 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: 01/04/2000 **DOB:** 13/10/1946
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pollakiuria		Increased frequency of urination.	

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 30/03/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 155298 **Seq:** 1 **Gender:** F
Reported: 21/07/2000 **Weight:** 107.00
Hospitalisation: **Age:** 38Y
Onset Date: 10/07/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dermatitis bullous		On right lateral leg, dorsum, l. foot, l.	Luvox ceased.

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
	100.0 Milligram	Daily	
Batch:	Started: 10/05/2000	Stopped: 14/07/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Lesion resembled blister secondary superficial partial thickness, burn.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 156007 **Seq:** 1 **Gender:** F
Reported: 09/08/2000 **Weight:** 107.00
Hospitalisation: **Age:** 38
Onset Date: 10/07/2000 **DOB:** 20/10/1961
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dermatitis bullous		Bullous skin reaction on right lateral lower	Conservative. required a visit to doctor.

Medicine Details:

LUVOX (Suspected)	Reason:	Depression
	100.0 Milligram	Daily
Batch:	Started: 10/05/2000	Stopped: 17/07/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Histology				Bullous drug reaction confirmed by histological examination of

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 158166 **Seq:** 1 **Gender:** F
Reported: 21/09/2000 **Weight:** 50.00
Hospitalisation: **Age:** 58Y
Onset Date: 31/05/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Diarrhoea Hyperhidrosis Nausea			

Medicine Details:

HYPERICUM-ST JOHN'S WORT (Interaction)		Reason:	
Tablet	1.0 Dose Unspecified 1 time	Oral	
Batch:	Started:	Stopped:	
LUVOX (Interaction)		Reason: Depression	
	100.0 Milligram Daily		
Batch:	Started: 07/04/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Inadvertantly took 1 tablet of st john's wort while taking luvox. st john's wort had ceased 1 month previously and luvox commenced 2 weeks before incident. patient also taking oroxine, kiogest. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 159547 **Seq:** 1 **Gender:** M
Reported: 27/11/2000 **Weight:**
Hospitalisation: **Age:** 64
Onset Date: 16/11/2000 **DOB:** 30/10/1936
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Daytime somnolence	
Insomnia		Night insomnia	
Sleep disorder			Date of recovery 19/11/00.

Medicine Details:

LUVOX (Suspected)	Reason: Anxiety neurosis
50.0 Milligram	Daily
Batch:	Started: 16/11/2000 Stopped: 18/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking bi-quinate, lipitor.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 159566 **Seq:** 1 **Gender:** F
Reported: 28/11/2000 **Weight:** 60.00
Hospitalisation: **Age:** 16Y
Onset Date: 31/10/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia			Conservative/observation. required a visit to doctor.

Medicine Details:

NORDETTE NOS (Other drug)		Reason: Contraception
Tablet	1.0 Dose Unspecified Daily	Oral
Batch:	Started:	Stopped:
LUVOX (Suspected)		Reason: Depression
	100.0 Milligram Daily	
Batch:	Started: 01/03/1999	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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 159766 **Seq:** 1 **Gender:** F
Reported: 07/12/2000 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: **DOB:** 02/02/1947
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			

Medicine Details:

LUVOX (Suspected)	Reason:	Depression
	100.0 Milligram	Daily
Batch:	Started: 27/11/2000	Stopped: 27/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 159951 **Seq:** 1 **Gender:** F
Reported: 13/12/2000 **Weight:**
Hospitalisation: **Age:** 72
Onset Date: 11/11/2000 **DOB:** 04/03/1928
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state		Siadh confusion.	
Hyponatraemia			Cease fluvoxamine.

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started:	Stopped:	11/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrolytes				Lowest serum sodium was 114

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 161382 **Seq:** 1 **Gender:** F
Reported: 12/02/2001 **Weight:** 110.00
Hospitalisation: **Age:** 49
Onset Date: 15/01/2001 **DOB:** 23/07/1951
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching	Severe	Severe twitching of arm, legs, body.	Zyban dose reduced to 150mg. date of recovery 05/02/01.

Medicine Details:

ZYBAN SR (Interaction)	Reason:
0.0	
Batch:	Started: 08/01/2001 Stopped:
LUVOX (Interaction)	Reason: Depression
200.0 Milligram Daily	
Batch:	Started: 01/01/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking luvox, natrilix, slow k, trisequens, temtabs. the dose start date of luvox is not accurate but indicates that the drug was started sometime in the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 161761 **Seq:** 1 **Gender:** F
Reported: 20/02/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 57
Onset Date: 13/07/2000 **DOB:** 03/12/1942
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness			Luvox dose reduced to 50mg

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 13/07/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Involved in minor mva. brought to hospital by ambulance, stayed overnight, discharged next afternoon. patient also taking monotard, actrapid, paracetamol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 161857 **Seq:** 1 **Gender:** F
Reported: 23/02/2001 **Weight:** 50.00
Hospitalisation: **Age:** 68
Onset Date: 13/01/2001 **DOB:** 02/03/1932
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Patient was already in hospital. given cogentin 1mg daily, reduced fluvoxamine from 200 mg daily to 100mg daily.
Gait disturbance			
Hypertonia			

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
	200.0 Milligram	Daily
Batch:	Started: 09/01/2001	Stopped: 15/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Parkinson-like symptoms of shuffling gait, wide based gait when turning, mild cog-wheel rigidity ul (l) & (r). patient recovered 20/1/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 163234 **Seq:** 1 **Gender:** M
Reported: 02/03/2001 **Weight:**
Hospitalisation: **Age:** 54
Onset Date: 12/02/2001 **DOB:** 14/11/1946
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Eczema	Severe	Severe eczematous reaction.	Systemic steroids required to settle reaction.
Urticaria	Severe	Severe urticarial reaction.	

Medicine Details:

LUVOX (Suspected)	Reason:		
	0.0		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 163650 **Seq:** 1 **Gender:** F
Reported: 12/04/2001 **Weight:** 61.00
Hospitalisation: **Age:** 52
Onset Date: 17/03/2001 **DOB:** 29/06/1948
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal Confusional state Coordination abnormal Dysarthria Somnolence		Perseveration, amnesic periods.	Required a visit to neurologist, had mri, stop fluvoxamine.

Medicine Details:

HALOPERIDOL (Other drug)	Reason: Otr spec symp psychopathol nec
0.5 Milligram As necessary	
Batch:	Started: Stopped:
DIAZEPAM (Other drug)	Reason: Otr spec symp psychopathol nec
2.0 Milligram As necessary	
Batch:	Started: Stopped:
THYROXINE SODIUM (Other drug)	Reason: Thyroiditis
100.0 Microgram Daily	
Batch:	Started: Stopped:
LIPEX (Other drug)	Reason:
20.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae: recovered but ataxia started again.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 163650 Seq: 1

Gender: F

Reported: 12/04/2001

Weight: 61.00

Hospitalisation:

Age: 52

Onset Date: 17/03/2001

DOB: 29/06/1948

Outcome: Recovered with sequelae

Causality: Causality possible

Reaction Detail

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason:	Depression
	100.0 Milligram	Daily	
Batch:	Started: 21/02/2001	Stopped: 03/04/2001	
LITHIUM CARBONATE (Suspected)		Reason:	Unspecifid affective psychosis
	900.0 Milligram	Daily	
Batch:	Started: 24/08/1999	Stopped:	

Laboratory Investigations:

Additional Information:

Sequelae: recovered but ataxia started again.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 163754 **Seq:** 1 **Gender:** F
Reported: 17/04/2001 **Weight:** 55.00
Hospitalisation: **Age:** 36Y
Onset Date: 22/03/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination		Lasted several hours	

Medicine Details:

STILNOX (Interaction)		Reason: Specific disorders of sleep
1.0 Dose Unspecified As necessary		
Batch:	Started: 01/03/2001	Stopped: 22/03/2001
LUVOX (Interaction)		Reason: Depression
25.0 Milligram Daily		
Batch:	Started: 22/03/2001	Stopped: 08/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt on prn stilnox 1 nocte. started on luvox 100mg. took 25mg the first dose with stilnox and had hallucinations that lasted for several hours. the dose start date of stilnox is not necessarily accurate but indicates that the drug was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 163898 **Seq:** 1 **Gender:** F
Reported: 23/04/2001 **Weight:** 70.00
Hospitalisation: **Age:** 75
Onset Date: 02/04/2001 **DOB:** 26/08/1925
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthenia			Required visit to doctor

Medicine Details:

ZYBAN SR (Interaction)	Reason: Smoker
300.0 Milligram Daily	
Batch:	Started: 02/04/2001 Stopped:
FLUVOXAMINE MALEATE (Interaction)	Reason: Depression
100.0 Milligram Daily	
Batch:	Started: Stopped:
AMITRIPTYLINE HYDROCHLORIDE (Other drug)	Reason: Pain
20.0 Milligram Daily	
Batch:	Started: Stopped:
SANDOMIGRAN (Other drug)	Reason: Migraine
2.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recovery date 17/4/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 163898

Seq: 1

Gender: F

Reported: 23/04/2001

Weight: 70.00

Hospitalisation:

Age: 75

Onset Date: 02/04/2001

DOB: 26/08/1925

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

FAMOTIDINE (Other drug)	80.0 Milligram	Daily	Reason: Other diseases of esophagus
Batch:	Started:	Stopped:	
OXYCONTIN (Other drug)	80.0 Milligram	Daily	Reason:
Batch:	Started:	Stopped:	
QUINATE (Other drug)	300.0 Milligram	Daily	Reason:
Batch:	Started:	Stopped:	
ASPIRIN (Other drug)	150.0 Milligram	Daily	Reason:
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Recovery date 17/4/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 164776

Seq: 1

Gender: M

Reported: 21/05/2001

Weight: 90.00

Hospitalisation:

Age: 29

Onset Date:

DOB: 06/01/1972

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			Required a visit to doctor.

Medicine Details:

LUVOX (Suspected)	Reason:
200.0 Milligram	Daily
Batch:	Started: 12/02/2001
	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 164940 **Seq:** 1 **Gender:** M
Reported: 28/05/2001 **Weight:** 86.00
Hospitalisation: **Age:** 39
Onset Date: 06/04/2001 **DOB:** 30/06/1961
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bruxism		Bruxism/ache in jaw.	Required a visit to doctor.

Medicine Details:

FAVERIN (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 05/04/2001	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 165483 **Seq:** 1 **Gender:** F
Reported: 18/06/2001 **Weight:** 58.00
Hospitalisation: **Age:** 43
Onset Date: 09/05/2001 **DOB:** 24/03/1958
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Tonic clonic convulsions	Required visit to doctor
Urinary incontinence			

Medicine Details:

CELEBREX (Other drug)	Reason: Pain in joint
200.0 Milligram Daily	
Batch:	Started: 22/11/2000 Stopped:
INDERAL (Other drug)	Reason: Peptic ulcer nos w/o ment perf
20.0 Milligram Daily	
Batch:	Started: 01/08/2000 Stopped:
LUVOX (Suspected)	Reason: Depression
100.0 Milligram Daily	
Batch:	Started: 28/02/2001 Stopped: 27/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electroencephalog				Eeg on 25/5/01 nad.

Additional Information:

Epilepsy as a child



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 168028 **Seq:** 1 **Gender:** F
Reported: 30/08/2001 **Weight:** 50.00
Hospitalisation: **Age:** 37
Onset Date: 21/08/2001 **DOB:** 27/03/1964
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular Somnolence Nervousness Tremor		Generalised heavy papular rash Profoundly sleepy	Patient required to visit a

Medicine Details:

FEFOL (Other drug)		Reason: Unspecified anemia	
1.0 Dose Unspecified Daily			
Batch:	Started:	L TERM	Stopped:
LUVOX (Suspected)		Reason:	
200.0 Milligram Daily			
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 168164 **Seq:** 1 **Gender:** F
Reported: 05/09/2001 **Weight:** 62.00
Hospitalisation: **Age:** A2
Onset Date: 28/08/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight increase of 10kg.	Required a visit to doctor.
Headache			

Medicine Details:

LUVOX (Suspected)	Reason:	Depression
	0.0	
Batch:	Started: 20/08/2001	Stopped: 26/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 169231 **Seq:** 1 **Gender:** F
Reported: 18/10/2001 **Weight:** 55.00
Hospitalisation: **Age:** 75
Onset Date: 01/09/2001 **DOB:** 12/09/1925
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia			Luvox discontinued.
Tetany			

Medicine Details:

GELUSIL (Other drug)	Reason:
Solution 80.0 Millilitre As necessary Oral	
Batch:	Started: Stopped:
PANAMAX (Other drug)	Reason:
Tablet 500.0 Milligram As necessary Oral	
Batch:	Started: Stopped:
PROCTOSEDYL (Other drug)	Reason:
Ointment 0.0 As necessary Topical	
Batch:	Started: Stopped:
CYCLOPHOSPHAMIDE (Other drug)	Reason:
Injection 500.0 Milligram Monthly Intravenous	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Carpal tunnel releases x 2 (first sign of mctd). connective tissue disorder (mixed). fibrosing alveolitis (bilateral). scleroderma
oesophagus tinnitus? sec. to presbycusis or plaquenil?? upper gi=>mild oesophagitis, barrett's mucosa depression.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 169231
Reported: 18/10/2001
Hospitalisation:
Onset Date: 01/09/2001
Outcome: Recovered

Seq: 1

Gender: F
Weight: 55.00
Age: 75
DOB: 12/09/1925
Causality: Causality possible

Reaction Detail

Medicine Details:

TEARS PLUS (Other drug)		Reason:	
Eye Drops	2.0 Dose Unspecified	Fortnightly	Ophthalmic
Batch:	Started:	Stopped:	
ARISTOCORT (Other drug)		Reason:	
Ointment	0.0	Daily	Topical
Batch:	Started:	Stopped:	
NOVASONE (Other drug)		Reason:	
Ointment	0.0	Daily	Topical
Batch:	Started:	Stopped:	
PREDNISOLONE (Other drug)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Carpal tunnel releases x 2 (first sign of mctd). connective tissue disorder (mixed). fibrosing alveolitis (bilateral). scleroderma oesophagus tinnitus? sec. to presbycusis or plaquenil?? upper gi=>mild oesophagitis, barrett's mucosa depression.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 169231
Reported: 18/10/2001
Hospitalisation:
Onset Date: 01/09/2001
Outcome: Recovered

Seq: 1

Gender: F
Weight: 55.00
Age: 75
DOB: 12/09/1925
Causality: Causality possible

Reaction Detail

Medicine Details:

TEMAZE (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
VIOXX (Other drug)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ZOTON (Other drug)		Reason:	
Capsule	60.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Carpal tunnel releases x 2 (first sign of mctd). connective tissue disorder (mixed). fibrosing alveolitis (bilateral). scleroderma
oesophagus tinnitus? sec. to presbycusis or plaquenil?? upper gi=>mild oesophagitis, barrett's mucosa depression.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 170378 **Seq:** 1 **Gender:** F
Reported: 27/11/2001 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: 02/11/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			
Syncope			

Medicine Details:

DEPO-PROVERA (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
ALCOHOL (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
LUVOX (Suspected)	Reason: Depression
100.0 Milligram Daily	
Batch:	Started: 01/10/2001 Stopped: 12/11/2001
ZYPREXA (Suspected)	Reason:
10.0 Milligram Daily	
Batch:	Started: 01/10/2001 Stopped: 02/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start dates for luvox and zyprexa are not necessarily accurate but indicates the drugs were started sometime in the month. no patient history of seizures.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 170600 **Seq:** 1 **Gender:** M
Reported: 29/11/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 49Y
Onset Date: 27/05/2001 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oculogyration			Patient was hospitalised and required medical attention, treated with cogentin 2mg im, 2mg x 2 diazeapm 5mg x 6, midazolam

Medicine Details:

DIAZEPAM (Other drug)		Reason: Depression
Oral application	5.0 Milligram	As necessary Oral
Batch:	Started: 25/05/2001	Stopped:
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
Tablet	50.0 Milligram	Daily Oral
Batch:	Started: 27/05/2001	Stopped: 28/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pateint had two doses of fluvoxamine and reaction with same symptoms on both occasions.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 171508 **Seq:** 1 **Gender:** M
Reported: 02/01/2002 **Weight:** 81.00
Hospitalisation: **Age:** 20
Onset Date: 16/10/2001 **DOB:** 30/07/1981
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis			Withdrawal of fluvoxamine. date of recovery 29/10/2001. required a visit to doctor.

Medicine Details:

THIAMINE (Other drug)	Reason:
100.0 Milligram Daily	
Batch: Started: Stopped:	
DIAZEPAM (Other drug)	Reason:
15.0 Milligram Daily	
Batch: Started: Stopped:	
FLUVOXAMINE MALEATE (Suspected)	Reason: Essential benign hypertension
100.0 Milligram Daily	
Batch: Started: Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 171654 **Seq:** 1 **Gender:** F
Reported: 04/01/2002 **Weight:** 66.00
Hospitalisation: **Age:** 16
Onset Date: 11/08/2001 **DOB:** 12/07/1985
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia		Stiff neck.	Treated with benztropine. date of recovery 16.8.01.
Visual disturbance			

Medicine Details:

PERICYAZINE (Suspected)		Reason: Unspecified psychosis
	2.5 Milligram	As necessary
Batch:	Started: 04/08/2001	Stopped: 11/08/2001
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
	50.0 Milligram	Daily
Batch:	Started: 03/08/2001	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 171880 **Seq:** 1 **Gender:** F
Reported: 07/01/2002 **Weight:** 83.00
Hospitalisation: **Age:** 58
Onset Date: **DOB:** 05/12/1943
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fixed eruption		Developed slowly over months.	Required a visit to doctor. stop

Medicine Details:

LASIX (Other drug)	Reason: Polyuria
40.0 Milligram	As necessary
Batch:	Started: L TERM Stopped:
RHINOCORT AQUEOUS NASAL SPRAY (Other drug)	Reason: Hay fever
2.0 Dose Unspecified	As necessary
Batch:	Started: L TERM Stopped:
LUVOX (Suspected)	Reason: Depression
200.0 Milligram	Daily
Batch:	Started: 01/09/1999 Stopped: 28/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 172435 **Seq:** 1 **Gender:** M
Reported: 06/02/2002 **Weight:** 68.00
Hospitalisation: **Age:** 17
Onset Date: 04/12/2001 **DOB:** 30/05/1984
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Dizziness over past few days when stands	
Dysphagia			Required a visit to doctor.

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
	100.0 Milligram	Daily
Batch:	Started: 29/11/2001	Stopped:
RISPERIDONE (Suspected)		Reason: Depression
	0.5 Milligram	Daily
Batch:	Started: 29/11/2001	Stopped: 04/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 172602 **Seq:** 1 **Gender:** F
Reported: 11/02/2002 **Weight:**
Hospitalisation: **Age:** 35
Onset Date: 05/02/2002 **DOB:** 13/05/1966
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			Required a visit to doctor.

Medicine Details:

FAVERIN (Suspected)		Reason: Depression
	100.0 Milligram	Daily
Batch:	Started: 21/01/2002	Stopped: 06/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 173171 **Seq:** 1 **Gender:** F
Reported: 27/02/2002 **Weight:**
Hospitalisation: **Age:** 86
Onset Date: 29/01/2002 **DOB:** 03/01/1916
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			Seizure treatment. therapy changed to mirtazapine.

Medicine Details:

TEMAZEPAM (Other drug)	Reason:
10.0 Milligram	As necessary
Batch:	Started: Stopped:
ASPIRIN (Other drug)	Reason: Chron isch heart dis no hyper
150.0 Milligram	Daily
Batch:	Started: Stopped:
FLUVOXAMINE MALEATE (Suspected)	Reason: Depression
150.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae: acute brain syndrome.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 173393 **Seq:** 1 **Gender:** F
Reported: 06/03/2002 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: 05/01/2002 **DOB:** 26/12/1954
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Rash on face and upper trunk.	Required a visit to doctor.

Medicine Details:

LUVOX (Suspected)		Reason: Depression
	100.0 Milligram	Daily
Batch:	Started:	Stopped:
ZYPREXA (Suspected)		Reason: Depression
	10.0 Milligram	Daily
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 173800 **Seq:** 1 **Gender:** M
Reported: 22/03/2002 **Weight:** 105.00
Hospitalisation: **Age:** 54
Onset Date: 09/03/2002 **DOB:** 13/04/1947
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Vomiting Shock	Severe	Extremely disoriented. Severe vomiting.	Date of recovery 13/03/2002. required a visit to doctor.

Medicine Details:

FAVERIN (Suspected)		Reason: Depression
	100.0 Milligram	Daily
Batch:	Started: 06/03/2002	Stopped: 08/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on faverin 50mg/day for the first day.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 173969 **Seq:** 1 **Gender:** M
Reported: 14/03/2002 **Weight:** 74.00
Hospitalisation: **Age:** 51
Onset Date: 28/08/2001 **DOB:** 04/07/1950
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia			
Hypoaesthesia			
Myalgia			

Medicine Details:

STILNOX (Other drug)	Reason: Specific disorders of sleep
10.0 Milligram Daily	
Batch:	Started: 01/04/2001 Stopped:
LUVOX (Suspected)	Reason: Depression
0.0	
Batch:	Started: 01/08/2001 Stopped: 28/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start and stop date is not necessarily accurate but indicates luvox was started and stopped sometime in the month. 175142 is a duplicate of 173969. patient was also taking allegron(unspecified).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 174036 **Seq:** 1 **Gender:** F
Reported: 28/03/2002 **Weight:** 62.00
Hospitalisation: **Age:** 35
Onset Date: 23/03/2002 **DOB:** 27/07/1966
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Racing heart beat (>100).	Required a visit to doctor. ceased cipramil and luvox.

Medicine Details:

STILNOX (Other drug)	Reason: Specific disorders of sleep
10.0 Milligram	As necessary
Batch:	Started: Stopped:
MERSYNDOL (Other drug)	Reason: Headache
1.0 Dose Unspecified	As necessary
Batch:	Started: Stopped:
UNISOM SLEEPGELS (Other drug)	Reason: Specific disorders of sleep
1.0 Dose Unspecified	As necessary
Batch:	Started: Stopped:
CIPRAMIL (Suspected)	Reason: Depression
20.0 Milligram	Daily
Batch:	Started: 01/09/2001 Stopped: 18/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for cipramil is not necessarily accurate but indicates cipramil was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 174036

Seq: 1

Gender: F

Reported: 28/03/2002

Weight: 62.00

Hospitalisation:

Age: 35

Onset Date: 23/03/2002

DOB: 27/07/1966

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

LUVOX (Suspected)

Reason: Depression

100.0 Milligram

Daily

Batch:

Started: 22/03/2002

Stopped: 25/03/2002

Laboratory Investigations:

Additional Information:

The dose start date for cipramil is not necessarily accurate but indicates cipramil was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 174149 **Seq:** 1 **Gender:** M
Reported: 02/04/2002 **Weight:** 77.00
Hospitalisation: **Age:** 20
Onset Date: 22/02/2002 **DOB:** 22/09/1981
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia Ejaculation failure		No feeling in his penis.	Required a visit to doctor. date of recovery 23.3.02.

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 19/02/2002	Stopped:	20/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Similar problem with citalopram and paroxetine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 175333 **Seq:** 1 **Gender:** M
Reported: 08/05/2002 **Weight:**
Hospitalisation: **Age:** 82
Onset Date: **DOB:** 29/05/1919
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety		Acute anxiety attack.	Date of recovery 24.4.02.

Medicine Details:

MICARDIS (Other drug)	Reason: Essential benign hypertension
40.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
MURELAX (Other drug)	Reason: Specific disorders of sleep
15.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
CELEBREX (Other drug)	Reason: Osteoarthritis
200.0 Milligram Daily	
Batch:	Started: 06/12/2001 Stopped:
LOSEC (Other drug)	Reason: Other diseases of esophagus
20.0 Milligram Daily	
Batch:	Started: 02/12/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 175333

Seq: 1

Gender: M

Reported: 08/05/2002

Weight:

Hospitalisation:

Age: 82

Onset Date:

DOB: 29/05/1919

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

LUVOX (Suspected)

Reason: Depression

100.0 Milligram

Daily

Batch:

Started: 17/04/2002

Stopped: 20/04/2002

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 175392 **Seq:** 1 **Gender:** F
Reported: 13/05/2002 **Weight:** 55.00
Hospitalisation: **Age:** 88Y
Onset Date: 25/03/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypokalaemia			Ceased avapro hct.

Medicine Details:

CELECOXIB (Other drug)		Reason: Osteoarthritis	
	0.0		
Batch:	Started: 25/03/2002	Stopped:	
FAMOTIDINE (Other drug)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started: 25/03/2002	Stopped:	
AVAPRO HCT 300/12.5 (Suspected)		Reason: Essential benign hypertension	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started: 25/03/2002	Stopped: 26/03/2002	
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Capsule	50.0 Milligram	Daily	Oral
Batch:	Started: 25/03/2002	Stopped: 26/03/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium		25/03/2002	3.0	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 175644 **Seq:** 1 **Gender:** F
Reported: 23/05/2002 **Weight:** 79.00
Hospitalisation: Admitted to hospital **Age:** 41
Onset Date: 08/04/2002 **DOB:** 20/09/1960
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myocarditis C-reactive protein increased Cardiac failure Cough		Patient experienced a Clozapine-related myocarditis, complained of feeling generally unwell and fluey, dyspnoea and/or chest pain, febrile (38.4), tachycardic. There was evidence of heart failure and small pleural effusions. Her echo demonstrated a reduced ejection fraction and evidence of elevated EST and elevations in C-reactive protein. There was also an increase in the eosinophil count.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
300.0 Milligram Daily Oral	
Batch:	Started: 20/03/2002 Stopped: 08/04/2002
LUVOX (Suspected)	Reason: Schizophrenia
300.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/05/2002	C-Reactive Protein				CRP: 246 (11/04/2002)
23/05/2002	Chest X-ray				07/04/2002: Heart size normal limits. Small left basal pleural effusion and some linear markings at both lung bases consistent with small areas of scarring or subsequent collapse.
23/05/2002	Echocardiogram				09/04/2002: LV wall thickness mildly increased, global reduction in systolic functioning (EF: 48%). Valves were normal.
23/05/2002	Electrocardiograph				08/04/2002: ECG: ST segment straightening septal leads and non-specific T wave globally.

Additional Information:

Clozapine started 12.5mg up to 300mg/day. Eventually published in Australian and New Zealand Journal of Psychiatry. Reinders J, Pasonage W, Lange D, Potter JM, Plevier S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropolitan psychiatric service Volume:38 Year:2004 pages:915-922.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 175644 **Seq:** 1 **Gender:** F
Reported: 23/05/2002 **Weight:** 79.00
Hospitalisation: Admitted to hospital **Age:** 41
Onset Date: 08/04/2002 **DOB:** 20/09/1960
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Ejection fraction decreased Electrocardiogram abnormal Eosinophil count increased Fatigue Hepatic function abnormal Hypotension Leukocytosis Pleural effusion Productive cough Pyrexia			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
300.0 Milligram Daily Oral	
Batch:	Started: 20/03/2002 Stopped: 08/04/2002
LUVOX (Suspected)	Reason: Schizophrenia
300.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Erythrocyte		02/09/2003	110	
17/12/2002	Neutrophils		02/09/2003	11.07	
17/12/2002	White blood cells		02/09/2003	18.8	

Additional Information:

Clozapine started 12.5mg up to 300mg/day. Eventually published in Australian and New Zealand Journal of Psychiatry. Reinders J, Pasonage W, Lange D, Potter JM, Plevier S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropolitan psychiatric service Volume:38 Year:2004 pages:915-922.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 175644 **Seq:** 1 **Gender:** F
Reported: 23/05/2002 **Weight:** 79.00
Hospitalisation: Admitted to hospital **Age:** 41
Onset Date: 08/04/2002 **DOB:** 20/09/1960
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Red blood cell sedimentation rate			
Tachycardia			
Troponin increased			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
300.0 Milligram	Daily Oral
Batch:	Started: 20/03/2002 Stopped: 08/04/2002
LUVOX (Suspected)	Reason: Schizophrenia
300.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

Clozapine started 12.5mg up to 300mg/day. Eventually published in Australian and New Zealand Journal of Psychiatry. Reinders J, Pasonage W, Lange D, Potter JM, Plevier S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropolitan psychiatric service Volume:38 Year:2004 pages:915-922.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 175672 **Seq:** 1 **Gender:** F
Reported: 27/05/2002 **Weight:** 95.00
Hospitalisation: **Age:** 42
Onset Date: 14/05/2002 **DOB:** 19/01/1960
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia Palpitations Paraesthesia Tremor Visual disturbance Vomiting			Required a visit to doctor. ceased luvox. patient now taking avanza. date of recovery: 18/05/2002

Medicine Details:

STILNOX (Suspected)	Reason: Specific disorders of sleep
10.0 Milligram	As necessary
Batch:	Started: 14/05/2002 Stopped:
LUVOX (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 14/05/2002 Stopped: 14/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 175806 **Seq:** 1 **Gender:** M
Reported: 30/05/2002 **Weight:** 86.00
Hospitalisation: **Age:** 55
Onset Date: 01/05/2002 **DOB:** 09/04/1947
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia			Patient required a visit to doctor. date of 07/05/02

Medicine Details:

LUVOX (Suspected)	Reason:
100.0 Milligram	Daily
Batch:	Started: 30/04/2002 Stopped: 04/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 176065 **Seq:** 1 **Gender:** F
Reported: 07/06/2002 **Weight:** 60.00
Hospitalisation: **Age:** 44
Onset Date: 11/05/2002 **DOB:** 30/05/1957
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Neurosis Nausea Vertigo		Dysentry. Phobias out of the ordinary	

Medicine Details:

LUVOX (Suspected)		Reason:	
	50.0 Milligram	Daily	
Batch: 310667	Started: 11/05/2002	Stopped: 13/05/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Luvox batch no 310667 patient recovered 17/5/02.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 176273 **Seq:** 1 **Gender:** M
Reported: 18/06/2002 **Weight:**
Hospitalisation: **Age:** 6
Onset Date: 30/04/2002 **DOB:** 10/11/1995
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Dyskinesia arms, mouth, tongue.	Required a doctor's visit.

Medicine Details:

LUVOX (Suspected)		Reason:	
	12.5 Milligram	Daily	
Batch:	Started: 01/08/2001	Stopped: 09/05/2002	
DEXAMPHETAMINE SULPHATE (Suspected)		Reason:	
	12.5 Milligram	Daily	
Batch:	Started: 01/01/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for luvox and dexamphetamine is not necessarily accurate but indicates the drugs were started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 176336 **Seq:** 1 **Gender:** F
Reported: 17/06/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 72Y
Onset Date: 19/02/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Anxiety Drug withdrawal syndrome Insomnia Tachycardia			Patient was hospitalised. alprazolam and faverin ceased.

Medicine Details:

ALPRAZOLAM (Suspected)	Reason:
0.0	
Batch:	Started: L TERM Stopped:
FAVERIN (Suspected)	Reason: Anxiety neurosis
100.0 Milligram Daily	
Batch: Started: 01/11/2001 Stopped: 19/02/2002	
KALMA (Suspected)	Reason: Anxiety neurosis
4.0 Milligram Daily	
Batch: Started: L TERM Stopped: 28/11/2001	
TRAMAL (Suspected)	Reason: Anxiety neurosis
100.0 Milligram Daily	
Batch: Started: Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 178633 **Seq:** 1 **Gender:** F
Reported: 02/09/2002 **Weight:** 63.00
Hospitalisation: **Age:** 63
Onset Date: 27/04/2002 **DOB:** 04/11/1938
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Drug level increased Somnolence			Dose of phenytoin reduced to 200mg daily. patient recovered 06/11/02

Medicine Details:

DILANTIN (Interaction)	Reason: Other&unspecified epilepsy
500.0 Milligram Daily	
Batch: Started: Stopped:	
LUVOX (Interaction)	Reason: Depression
Tablet 100.0 Milligram Daily Oral	
Batch: Started: 10/04/2002 Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level	PHENYTOIN	06/04/2002	38	
	Serum drug level	PHENYTOIN	27/04/2002	134	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 178733 **Seq:** 1 **Gender:** F
Reported: 05/09/2002 **Weight:**
Hospitalisation: **Age:** 51
Onset Date: 28/06/2001 **DOB:** 04/10/1949
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Delusion Psychotic disorder Suicide attempt			Mental health unit, haloperidol.

Medicine Details:

FAVERIN (Suspected)	Reason: Depression
0.0	
Batch:	Started: 01/05/2001 Stopped: 28/06/2001
SEREPAX (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

178733 is a seq of 178734.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 179058 **Seq:** 1 **Gender:** M
Reported: 16/09/2002 **Weight:** 0.00
Hospitalisation: **Age:** 36
Onset Date: 12/08/2002 **DOB:** 06/02/1966
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Myoclonic jerks.	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 01/08/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 179698 **Seq:** 1 **Gender:** F
Reported: 15/10/2002 **Weight:**
Hospitalisation: **Age:** 71
Onset Date: 26/09/2002 **DOB:** 07/07/1931
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscular weakness Diarrhoea Urinary incontinence		Legs weak	Ceased luvox. recovered 24/10/02

Medicine Details:

REPLENS (Other drug)		Reason:	
Gel	0.0	Vaginal	
Batch:	Started:	Stopped:	
DYMADON P (Other drug)		Reason:	
Tablet	500.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	
FELDENE (Other drug)		Reason:	
Tablet	20.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	
BETALOC (Other drug)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 179698

Seq: 1

Gender: F

Reported: 15/10/2002

Weight:

Hospitalisation:

Age: 71

Onset Date: 26/09/2002

DOB: 07/07/1931

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

CALTRATE (Other drug)		Reason:	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started:	Stopped:	
DIPROSONE (Other drug)		Reason:	
Ointment	2.0 Dose Unspecified	Daily	Topical
Batch:	Started:	Stopped:	
LIQUIFILM TEARS (Other drug)		Reason:	
Eye Drops	3.0 Dose Unspecified	Daily	Ophthalmic
Batch:	Started:	Stopped:	
NOVASONE (Other drug)		Reason:	
Ointment	1.0 Dose Unspecified	Daily	Topical
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 179698

Seq: 1

Gender: F

Reported: 15/10/2002

Weight:

Hospitalisation:

Age: 71

Onset Date: 26/09/2002

DOB: 07/07/1931

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

OGEN (Other drug)		Reason:	
Tablet	625.0 Microgram	Daily	Oral
Batch:	Started:	Stopped:	
OROXINE (Other drug)		Reason:	
Tablet	500.0 Microgram	Daily	Oral
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 179777 **Seq:** 1 **Gender:** F
Reported: 09/10/2002 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 27/07/2002 **DOB:** 05/04/1962
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression	Life		
Neurosis	Life		Date of recovery 12/8/02. luvox ceased. required a visit to doctor
Psychotic disorder	Life		

Medicine Details:

SINEQUAN (Other drug)		Reason:	
Oral application	0.0		Oral
Batch:	Started: 01/08/2002	Stopped:	02/08/2002
EPILIM (Other drug)		Reason: Cervicalgia	
Oral application	200.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	
LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 23/07/2002	Stopped:	02/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug positive rechallenge. event reappeared after drug was reintroduced started within a few days of starting luvox, and the same thing had happened about 8 months previously. she was subsequently prescribed luvox again by another doctor and the same thing happened.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 180216 **Seq:** 1 **Gender:** F
Reported: 29/10/2002 **Weight:** 65.00
Hospitalisation: **Age:** 82
Onset Date: 30/08/2002 **DOB:** 08/11/1919
Outcome: Recovered 07/09/2002 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination, auditory		Singing voices in ears, chanting	Luvox ceased
Hallucination			Date of recovery: 7/9/02.

Medicine Details:

CAPTOPRIL (Other drug)	Reason:
12.5 Milligram Daily	
Batch:	Started: Stopped:
OROXINE (Other drug)	Reason:
50.0 Microgram Daily	
Batch:	Started: L TERM Stopped:
LOSEC (Other drug)	Reason:
20.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
PROVERA (Other drug)	Reason:
5.0 Milligram Daily	
Batch:	Started: 01/04/1997 L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

180216 is the sequence of 180215.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 180216

Seq: 1

Gender: F

Reported: 29/10/2002

Weight: 65.00

Hospitalisation:

Age: 82

Onset Date: 30/08/2002

DOB: 08/11/1919

Outcome: Recovered

07/09/2002

Causality: Causality probable

Reaction Detail

Medicine Details:

CLIMARA (Other drug)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
LIPEX (Other drug)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
LUVOX (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 09/08/2002	Stopped:	

Laboratory Investigations:

Additional Information:

180216 is the sequence of 180215.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 180715

Seq: 1

Gender: F

Reported: 17/12/2002

Weight: 71.00

Hospitalisation:

Age: 31Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain: 61 to 71 kg over 12 months	required a visit to doctor.

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 23/06/2002	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 181457 **Seq:** 1 **Gender:** F
Reported: 13/01/2003 **Weight:** 60.00
Hospitalisation: **Age:** 78
Onset Date: 11/12/2002 **DOB:** 14/05/1924
Outcome: Recovered 11/12/2002 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Required Visit to Doctor	Sudden onset severe Headache, Nausea, Palpitations, Sweating, Unilateral Tremor (left arm and leg), sleeplessness, Dyspnoea on Exertion and pre-syncope.	
Circulatory collapse	Required Visit to Doctor		
Dyspnoea	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		
Insomnia	Required Visit to Doctor		

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs - Coloxyl with Senna, Diltiazem hcl, Delivery, Irbesartan, Lanoxin, Lasix and Warfarin Sodium. Medical history - known allergies to - Atenolol, Fluvoxamine and Sertraline.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 181457 **Seq:** 1 **Gender:** F
Reported: 13/01/2003 **Weight:** 60.00
Hospitalisation: **Age:** 78
Onset Date: 11/12/2002 **DOB:** 14/05/1924
Outcome: Recovered 11/12/2002 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Required Visit to Doctor		
Palpitations	Required Visit to Doctor		
Tremor	Required Visit to Doctor		

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Other drugs - Coloxyl with Senna, Diltiazem hcl, Delivery, Irbesartan, Lanoxin, Lasix and Warfarin Sodium. Medical history - known allergies to - Atenolol, Fluvoxamine and Sertraline.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 181633 **Seq:** 1 **Gender:** M
Reported: 15/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 9
Onset Date: 01/10/2002 **DOB:** 19/06/1993
Outcome: Recovered 30/11/2002 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Contusion	Required Visit to Doctor	Bruising, minor secondary to minor trauma.	Stopped luvox
Platelet disorder	Required Visit to Doctor	Purpura and Platelets Abnormal	Stopped luvox

Medicine Details:

ATTENTA (Other drug)		Reason:	Behavior disorders of childhood	
Tablet	20.0 Milligram		Oral	
Batch:	Started:	Stopped:	contin	
LUVOX (Suspected)		Reason:	Anxiety neurosis	
Tablet	50.0 Milligram	Daily	Oral	
Batch:	Started: 09/09/2002	Stopped:	25/11/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 182035 **Seq:** 1 **Gender:** F
Reported: 24/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 34
Onset Date: 25/10/2002 **DOB:** 19/04/1968
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Lactation - Non-Puerperal	

Medicine Details:

EPILIM (Suspected)		Reason: Unspecified schizophrenia
Batch:	2.0 Gram	Daily
Started:		Stopped: Contin
SEROQUEL (Suspected)		Reason: Unspecified schizophrenia
Tablet	300.0 Milligram	Daily Oral
Batch:	Started:	Stopped: Contin
SOLIAN (Suspected)		Reason: Unspecified schizophrenia
Tablet	200.0 Milligram	Daily Oral
Batch:	Started:	Stopped: Contin
LUVOX (Suspected)		Reason: Unspecified schizophrenia
Tablet	100.0 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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 182262 **Seq:** 1 **Gender:** F
Reported: 03/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 78
Onset Date: 02/01/2003 **DOB:** 23/05/1924
Outcome: Recovered 09/01/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Required Visit to Doctor	Mild serotonin syndrome. Sweaty, nausea, restlessness and diarrhoea, drowsiness and disorientation	Stopped faverin
Akathisia	Required Visit to Doctor		
Diarrhoea	Required Visit to Doctor		
Disorientation	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		

Medicine Details:

FAVERIN (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 31/12/2002 Stopped: 02/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking acimax, noten, uremide, temazepam, warfarin, celebrex, monodur, panamax, avapro hct, citrical.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 182262 **Seq:** 1 **Gender:** F
Reported: 03/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 78
Onset Date: 02/01/2003 **DOB:** 23/05/1924
Outcome: Recovered 09/01/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Required Visit to Doctor		
Somnolence	Required Visit to Doctor		

Medicine Details:

FAVERIN (Suspected)		Reason: Depression
	50.0 Milligram	Daily
Batch:	Started: 31/12/2002	Stopped: 02/01/2003

Laboratory Investigations:

Additional Information:

Patient also taking acimax, noten, uremide, temazepam, warfarin, celebrex, monodur, panamax, avapro hct, citrical.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 182870

Seq: 1

Gender: M

Reported: 14/02/2003

Weight: 0.00

Hospitalisation:

Age: 61

Onset Date: 22/07/2002

DOB: 29/09/1940

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Encephalopathy	Caused or prolonged inpatient hospitalisation	Liver failure on presentation ->	
Hepatic failure	Caused or prolonged inpatient hospitalisation	Liver failure on presentation ->	

Medicine Details:

NITRAZEPAM (Other drug)		Reason:
Batch:	5.0 Milligram	Daily
Started:		Stopped:
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
Batch:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/02/2003	ALT = SGPT		22/07/2002	1963	
14/02/2003	AST = SGOT		22/07/2002	3870	
14/02/2003	Bilirubin		22/07/2002	347	
14/02/2003	GGT = SGGT =		22/07/2002	423	

Additional Information:

Past alcohol abuse. There were no general anaesthetics, blood transfusions, augmentin or flucloxacillin in the months prior to the liver problems in any of these patients. The most likely cause was the drug in question, largely because all other possible liver disease was excluded.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 182872

Seq: 1

Gender: U

Reported: 14/02/2003

Weight: 80.00

Hospitalisation:

Age: 23

Onset Date: 11/12/2002

DOB: 31/03/1979

Outcome: Recovered

29/01/2003

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis	Required Visit to Doctor	Hepatitis.	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/02/2003	ALT = SGPT		11/12/2002	247	
14/02/2003	ALT = SGPT		04/06/2002	397	
14/02/2003	ALT = SGPT		20/06/2002	236	
14/02/2003	Albumin		04/06/2002	40	
14/02/2003	Albumin				
14/02/2003	Albumin		20/06/2002	46	
14/02/2003	Biochemistry				

Additional Information:

Patient diagnosed to have schizophreniform disorder with mild depression. He also has a past history of abusing illicit substances. The most likely cause was the drug in question, largely because all other possible liver disease was excluded.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 182872

Seq: 1

Gender: U

Reported: 14/02/2003

Weight: 80.00

Hospitalisation:

Age: 23

Onset Date: 11/12/2002

DOB: 31/03/1979

Outcome: Recovered

29/01/2003

Causality: Causality possible

Reaction Detail

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)

Reason: Depression

Batch:

Started:

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/02/2003	GGT = SGGT =		04/06/2002	243	
14/02/2003	GGT = SGGT =		20/06/2002	219	
14/02/2003	Protein		04/06/2002	72	
14/02/2003	Protein		20/06/2002	79	
14/02/2003	SAP = ALP		04/04/2002	116	
14/02/2003	SAP = ALP		20/06/2002	154	

Additional Information:

Patient diagnosed to have schizophreniform disorder with mild depression. He also has a past history of abusing illicit substances. The most likely cause was the drug in question, largely because all other possible liver disease was excluded.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 183070 **Seq:** 1 **Gender:** F
Reported: 19/02/2003 **Weight:** 52.00
Hospitalisation: **Age:** 77
Onset Date: 25/01/2003 **DOB:** 27/02/1925
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	Agitation and Insomnia.	
Insomnia	Required Visit to Doctor	Agitation and Insomnia.	

Medicine Details:

FLECAINIDE ACETATE (Other drug)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
KARVEZIDE 150/12.5 (Other drug)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started:	L TERM	Stopped:
GLIBENCLAMIDE (Other drug)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
LUVOX (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 12/01/2003	Stopped:	03/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 183479

Seq: 1

Gender: M

Reported: 27/02/2003

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 25/02/2003

DOB: 16/11/1960

Outcome: Recovered

26/02/2003

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Required Visit to Doctor	Serotonin syndrome, profuse sweating, very cold, swollen tongue, unable to speak, high as a kite, tears.	Patient taken to hospital, monitored, diuretic to flush system
Dysarthria	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		
Lacrimonal disorder	Required Visit to Doctor		
Mania	Required Visit to Doctor		

Medicine Details:

LUVOX (Interaction)		Reason: Depression	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started: 29/01/2003	Stopped:	
TRAMAL SR (Interaction)		Reason: Pain	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 25/02/2003	Stopped: 25/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 183479 **Seq:** 1 **Gender:** M
Reported: 27/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 42
Onset Date: 25/02/2003 **DOB:** 16/11/1960
Outcome: Recovered 26/02/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nasopharyngitis	Required Visit to Doctor		
Tongue oedema	Required Visit to Doctor		

Medicine Details:

LUVOX (Interaction)		Reason: Depression
Tablet	1.0 Dose Unspecified Daily	Oral
Batch:	Started: 29/01/2003	Stopped:
TRAMAL SR (Interaction)		Reason: Pain
Tablet	300.0 Milligram Daily	Oral
Batch:	Started: 25/02/2003	Stopped: 25/02/2003

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 183645 **Seq:** 1 **Gender:** F
Reported: 03/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 19
Onset Date: 01/03/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures, whole body and 'violent'.	Luvox ceased.

Medicine Details:

LUVOX (Suspected)	Reason: Depression		
	100.0 Milligram	Daily	Oral
Batch:	Started: 28/02/2003	Stopped:	01/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 184258 **Seq:** 1 **Gender:** M
Reported: 21/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 38
Onset Date: 30/01/2002 **DOB:** 09/07/1963
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Homicidal ideation	Life	Within a week of ceasing/withdrawing Luvox, he attempted to murder both his parents with a butcher knife on 30/01/02.	
Drug withdrawal syndrome	Life		

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 25/06/2001	L TERM	Stopped: 23/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Also taking - Mogadon, Xanax, Oxycontin and Alcohol. History - Chronic back pain and depression. Patient was abusing hypnotics and tranquillizers at time of event. Had also consumed alcohol. I'm not certain if he was still on a rapid withdrawal regime or had actually ceased his Luvox. He was asked to withdraw/cease it on 23/01/02.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 184480

Seq: 1

Gender: F

Reported: 28/03/2003

Weight: 69.00

Hospitalisation:

Age: 52

Onset Date: 19/03/2003

DOB: 25/12/1950

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Required Visit to Doctor	Confused and weak	Reduced dose
Constipation	Required Visit to Doctor	Constipated and sleeping alot.	
Anorexia	Required Visit to Doctor	Unable to eat	
Disturbance in attention	Required Visit to Doctor	Unable to function at work or to drive	
Asthenia	Required Visit to Doctor		

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 18/03/2003	Stopped:	21/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Dose related.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 184792 **Seq:** 1 **Gender:** F
Reported: 08/04/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 57
Onset Date: 18/03/2003 **DOB:** 30/05/1945
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Severe	Hyponatraemia, fitting.	ICU admission. Fluvoxamine
Convulsion	Severe		

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/04/2003	Sodium		18/03/2003	112	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 185123 **Seq:** 1 **Gender:** M
Reported: 17/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: 12/02/2003 **DOB:** 27/05/1967
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Required Visit to Doctor	First fit - Seizure.	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 13/12/2002	Stopped:	31/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/04/2003	LDH				

Additional Information:

History: No past history of fits and no past exposure to drug - has used other SSRIS in past.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 185442 **Seq:** 1 **Gender:** F
Reported: 30/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 26
Onset Date: **DOB:** 27/11/1976
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous		Miscarriage, drug exposure during	
Drug exposure during pregnancy		Miscarriage, drug exposure during	

Medicine Details:

TOPAMAX (Suspected)	Reason: Epilepsy
Oral application	Dose Unspecified
Batch:	Stopped:
ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Suspected)	Reason:
Batch:	Stopped:
FLUVOXAMINE MALEATE (Suspected)	Reason:
Batch:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of Epilepsy. Other drugs: Esomeprazole, Magnesium, Fluvoxamine and Maleate. Physician does not feel the event was related to Topiramate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 185975 **Seq:** 1 **Gender:** M
Reported: 16/05/2003 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 25
Onset Date: 02/05/2003 **DOB:** 09/02/1978
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug interaction		Slurred speech, drowsiness, high clozaril level, drug interaction	
Drug toxicity		Slurred speech, drowsiness, high clozaril level, drug interaction	
Dysarthria		Slurred speech, drowsiness, high clozaril level, drug interaction	
Somnolence		Slurred speech, drowsiness, high clozaril level, drug interaction	

Medicine Details:

LUVOX (Interaction)		Reason:	
Tablet	Dose Unspecified	Oral	
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason: Schizophrenia	
Tablet	300.0 Milligram Daily	Oral	
Batch:	Started: 10/04/2003	Stopped: Contin	
LITHIUM CARBONATE (Other drug)		Reason:	
Tablet	Dose Unspecified	Oral	
Batch:	Started:	Stopped:	
RANITIDINE (Other drug)		Reason:	
Oral application	Dose Unspecified	Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/05/2003	LDH				

Additional Information:

Suspected drug toxicity, high Clozaril level and drug interaction between Clozaril and Luvox.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 186007 **Seq:** 1 **Gender:** F
Reported: 16/05/2003 **Weight:** 58.50
Hospitalisation: **Age:** 67
Onset Date: **DOB:** 14/06/1935
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Worsening LFTs	

Medicine Details:

TEVETEN (Other drug)					Reason:	Essential benign hypertension	
Tablet		800.0	Milligram	Daily	Oral		
Batch:		Started:		Stopped:			
HYDRALAZINE HYDROCHLORIDE (Other drug)					Reason:	Essential benign hypertension	
Tablet		200.0	Milligram	Daily	Oral		
Batch:		Started:		Stopped:			
LUVOX (Suspected)					Reason:	Depression	
Tablet		100.0	Milligram	Daily	Oral		
Batch:		Started:		Stopped:			
		29/11/2002		27/02/2003			

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/05/2003	ALT = SGPT		27/02/2003	44	
16/05/2003	ALT = SGPT		14/03/2003	42	
16/05/2003	AST = SGOT		27/02/2003	41	
16/05/2003	AST = SGOT		14/03/2003	44	
16/05/2003	Bilirubin		27/02/2003	7	
16/05/2003	Bilirubin		14/03/2003	10	
16/05/2003	GGT = SGGT =		27/02/2003	130	

Additional Information:

History of hypertension, depression with anxiety, poliomyelitis, hyponatraemia with thiazide diuretics.
Presumably pre-existing abnormal LFTs secondary to enzymes from polio.
Symptoms occurred in November 2002.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 186007
Reported: 16/05/2003
Hospitalisation:
Onset Date:
Outcome: Unknown

Seq: 1

Gender: F
Weight: 58.50
Age: 67
DOB: 14/06/1935
Causality: Causality possible

Reaction Detail

Medicine Details:

TEVETEN (Other drug)		Reason: Essential benign hypertension	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
HYDRALAZINE HYDROCHLORIDE (Other drug)		Reason: Essential benign hypertension	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 29/11/2002	Stopped: 27/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/05/2003	GGT = SGGT =		14/03/2003	88	
16/05/2003	LDH		27/02/2003	284	
16/05/2003	LDH		14/03/2003	320	
16/05/2003	Other data				
16/05/2003	SAP = ALP		27/02/2003	95	
16/05/2003	SAP = ALP		14/03/2003	95	

Additional Information:

History of hypertension, depression with anxiety, poliomyelitis, hyponatraemia with thiazide diuretics.
Presumably pre-existing abnormal LFTs secondary to enzymes from polio.
Symptoms occurred in November 2002.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 186300 **Seq:** 1 **Gender:** F
Reported: 28/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 44
Onset Date: 10/12/2002 **DOB:** 06/07/1958
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation		Serotonin syndrome, nausea, very agitated, unwell, tremor and scratching.	Ceased Luvox and regular maintenance
Akathisia		Serotonin syndrome, nausea, very agitated, unwell, tremor and scratching.	
Malaise		Serotonin syndrome, nausea, very agitated, unwell, tremor and scratching.	
Pruritus		Serotonin syndrome, nausea, very agitated, unwell, tremor and scratching.	
Serotonin syndrome		Serotonin syndrome, nausea, very agitated, unwell, tremor and scratching.	
Tremor		Serotonin syndrome, nausea, very agitated, unwell, tremor and scratching.	

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking risperidone, Sodium Valproate, Lipitor,Vioxx and Diazepam.
Known allergies: Tegretol, Lithium and Cipramil.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 186770 **Seq:** 1 **Gender:** M
Reported: 10/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 43
Onset Date: 24/02/2003 **DOB:** 13/09/1959
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		Hyperglycaemia	Ceased Olanzapine.
Hyperlipidaemia		Hyperglycaemia	Ceased Olanzapine.

Medicine Details:

FLUVOXAMINE MALEATE (Interaction)		Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Interaction)		Reason: Depression	
	10.0 Milligram	Daily	
Batch:	Started:	S TERM	Stopped: 27/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/06/2003	Serum glucose		24/02/2003	38.1	

Additional Information:

Patient was also taking Sodium Valproate, Accdactone, Luvox, Mycrogynon ED.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 186858 **Seq:** 1 **Gender:** M
Reported: 10/06/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 84Y
Onset Date: 15/04/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Cardiac failure congestive Cardiomyopathy Renal failure chronic		SOB, CHF and cardiomyopathy, chronic renal failure.	Lasix IV, then Lasix 80mg/bd po. Ramipril and Carvedilol added

Medicine Details:

CELEBREX (Suspected)		Reason:	
Capsule	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 16/04/2003	
FLUVOXAMINE MALEATE (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 16/04/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/06/2003	Creatinine				

Additional Information:

Admitted to cardiac ward. Other drugs: Simvastatin, Frusemide, Clopidogrel and Omeprazole.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 188425 **Seq:** 1 **Gender:** F
Reported: 11/07/2003 **Weight:** 0.00
Hospitalisation: **Age:** 32
Onset Date: **DOB:** 09/01/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence Aura Drug interaction Drug level increased		Somnolence, aura for 4 days, clozaril blood level increased	Clozaril was reduced.

Medicine Details:

CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 25/07/2000	Stopped:	
FLUVOXAMINE MALEATE (Interaction)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/07/2003	Serum drug level		15/05/2003	2738 ng/ml	
11/07/2003	Serum drug level		06/06/2003	2600 ng/ml	
11/07/2003	Serum drug level		26/06/2003	3292 ng/ml	
11/07/2003	Serum drug level		09/07/2003	2945 ng/ml	
11/07/2003	Serum drug level		28/07/2003	2040 ng/ml	

Additional Information:

Doctor had increased the dose of clozaril from 300mg to 500mg gradually then the symptoms occurred.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 188428 **Seq:** 1 **Gender:** M
Reported: 11/07/2003 **Weight:** 0.00
Hospitalisation: **Age:** 37
Onset Date: 02/05/2003 **DOB:** 04/02/1966
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug toxicity		Drug level nos increased high clozaril blood levels, constipation, drug toxicity Clozaril toxicity.	Ceased Clozaril.
Constipation			Coloxy with senna
Drug level increased			

Medicine Details:

CLOZARIL (Interaction)	Reason: Unspecified schizophrenia
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 20/09/2000 Stopped: 27/05/2003
LUVOX (Interaction)	Reason:
	150.0 Milligram Daily
Batch:	Started: Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/07/2003	Pharmacokinetics				

Additional Information:

Concomitant Luvox had elevated the clozapine serum levels.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 188616 **Seq:** 1 **Gender:** F
Reported: 18/07/2003 **Weight:** 65.00
Hospitalisation: **Age:** 51
Onset Date: **DOB:** 07/11/1951
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diabetes insipidus	Required Specialist Consultation	Diabetes insipidus.	Given Minirin.

Medicine Details:

PROVERA (Other drug)		Reason: Menopausal symptoms	
	5.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: Contin
ZANTAC (Other drug)		Reason: Heartburn	
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 24/05/2002	Stopped:	
LUVOX (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 09/05/2002	Stopped:	22/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset date: 10/2002 - 11/2002.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 188732 **Seq:** 1 **Gender:** M
Reported: 22/07/2003 **Weight:** 0.00
Hospitalisation: **Age:** 32
Onset Date: 13/06/2003 **DOB:** 03/01/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Convulsions nos, lethargy, asthenia, somnolence, tremor.	Luvox was ceased.
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	Extrapyramidal disorder, incontinence, drug level nos increased, drug interaction nos.	
Asthenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Interaction)		Reason:	
Tablet	900.0 Milligram	Daily	Oral
Batch:	Started: 13/03/1997	Stopped:	Contin
LUVOX (Interaction)		Reason: Obsessive compulsive neurosis	
	100.0 Milligram	Daily	
Batch:	Started: 13/06/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/07/2003	Computerised				
22/07/2003	Pharmacokinetics	(0.6-1)	07/07/2003	1.48	

Additional Information:

History of intellectual disability, autism (diagnosed 7 years ago) and bipolar disorder (diagnosed 7 years ago).
Patient was also taking Epilim, Lithium,Largactil.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 188732 **Seq:** 1 **Gender:** M
Reported: 22/07/2003 **Weight:** 0.00
Hospitalisation: **Age:** 32
Onset Date: 13/06/2003 **DOB:** 03/01/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug interaction	Caused or prolonged inpatient hospitalisation		
Drug level increased	Caused or prolonged inpatient hospitalisation		
Lethargy	Caused or prolonged inpatient hospitalisation		Luvox was ceased.

Medicine Details:

CLOZARIL (Interaction)		Reason:	
Tablet	900.0 Milligram	Daily	Oral
Batch:	Started: 13/03/1997	Stopped:	Contin
LUVOX (Interaction)		Reason: Obsessive compulsive neurosis	
	100.0 Milligram	Daily	
Batch:	Started: 13/06/2003	Stopped:	

Laboratory Investigations:

Additional Information:

History of intellectual disability, autism (diagnosed 7 years ago) and bipolar disorder (diagnosed 7 years ago).
Patient was also taking Epilim, Lithium,Largactil.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 188732 **Seq:** 1 **Gender:** M
Reported: 22/07/2003 **Weight:** 0.00
Hospitalisation: **Age:** 32
Onset Date: 13/06/2003 **DOB:** 03/01/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		
Urinary incontinence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Interaction)		Reason:	
Tablet	900.0 Milligram	Daily	Oral
Batch:	Started: 13/03/1997	Stopped:	Contin
LUVOX (Interaction)		Reason: Obsessive compulsive neurosis	
	100.0 Milligram	Daily	
Batch:	Started: 13/06/2003	Stopped:	

Laboratory Investigations:

Additional Information:

History of intellectual disability, autism (diagnosed 7 years ago) and bipolar disorder (diagnosed 7 years ago).
Patient was also taking Epilim, Lithium,Largactil.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 189010 **Seq:** 1 **Gender:** M
Reported: 29/07/2003 **Weight:** 0.00
Hospitalisation: **Age:** 34
Onset Date: 21/05/2003 **DOB:** 01/09/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination, visual Confusional state		Hallucination, visual Misperceptions and altered sense of time. The events lasted 2 hours.	

Medicine Details:

STILNOX (Suspected)		Reason:	Specific disorders of sleep	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started: 21/05/2003	Stopped:		
LUVOX (Suspected)		Reason:	Depression	
Tablet	50.0 Milligram	Daily	Oral	
Batch:	Started:	Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

HIV history. Other drugs: Lamivudine, Abacavin and Efavirenz.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 189263 **Seq:** 1 **Gender:** F
Reported: 07/08/2003 **Weight:** 50.00
Hospitalisation: **Age:** 48
Onset Date: 31/07/2003 **DOB:** 12/09/1954
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash	Severe	Severe skin eruption	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
Tablet	50.0 Milligram	Daily Oral
Batch:	Started: 02/07/2003	Stopped: 28/07/2003
OLANZAPINE (Suspected)		Reason: Depression
Tablet	5.0 Milligram	Daily Oral
Batch:	Started: 09/07/2003	Stopped: 28/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 189347 **Seq:** 1 **Gender:** M
Reported: 11/08/2003 **Weight:** 71.00
Hospitalisation: Required a visit to the doctor **Age:** 79
Onset Date: **DOB:** 01/05/1924
Outcome: Recovered 20/07/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Reflux oesophagitis		Heart burn.	
Insomnia	Required Visit to Doctor	Inability to stay asleep.	Luvox stopped.

Medicine Details:

LUVOX (Suspected)	Reason:
Oral application	50.0 Milligram Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Coversyl. Panamax, Norvail, Asprin. Onset date. January 2003



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 189868 **Seq:** 1 **Gender:** F
Reported: 26/08/2003 **Weight:** 73.50
Hospitalisation: **Age:** 99
Onset Date: 15/03/2003 **DOB:** 31/10/1903
Outcome: Recovered 21/08/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ecchymosis	Required Visit to Doctor	Ecchymosis on shins and arms.	

Medicine Details:

BRUFEN (Other drug)		Reason:	
Tablet	1.0 Dose Unspecified	As necessary	Oral
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 190789 **Seq:** 1 **Gender:** F
Reported: 23/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 72
Onset Date: 18/08/2003 **DOB:** 18/03/1931
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia	Required Visit to Doctor	Nausea, anorexia, weight loss, nightmares, insomnia, suicidal, worsening of DED.	
Insomnia	Required Visit to Doctor	Nausea, anorexia, weight loss, nightmares, insomnia, suicidal, worsening of DED.	
Nightmare	Required Visit to Doctor	Nausea, anorexia, weight loss, nightmares, insomnia, suicidal, worsening of DED.	
Suicidal ideation	Required Visit to Doctor	Nausea, anorexia, weight loss, nightmares, insomnia, suicidal, worsening of DED.	

Medicine Details:

Movox (Suspected)	Reason: Depression
200.0 Milligram	Daily
Batch:	Started: 18/08/2003 Stopped: 18/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 190789 **Seq:** 1 **Gender:** F
Reported: 23/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 72
Onset Date: 18/08/2003 **DOB:** 18/03/1931
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight decreased	Required Visit to Doctor	Nausea, anorexia, weight loss, nightmares, insomnia, suicidal, worsening of DED.	
Nausea	Required Visit to Doctor	Nausea, anorexia, weight loss, nightmares, insomnia, suicidal, worsening of OCD.	
Obsessive-compulsive disorder	Required Visit to Doctor	Nausea, anorexia, weight loss, nightmares, insomnia, suicidal, worsening of OCD.	

Medicine Details:

Movox (Suspected)		Reason: Depression
	200.0 Milligram	Daily
Batch:	Started: 18/08/2003	Stopped: 18/09/2003

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 191277 **Seq:** 1 **Gender:** M
Reported: 14/10/2003 **Weight:** 90.00
Hospitalisation: **Age:** 29
Onset Date: 25/09/2003 **DOB:** 17/03/1974
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema	Required Visit to Doctor	Angioedema:- periorbital oedema, facial swelling, tongue swelling.	Ceased Risperidone.
Skin disorder	Required Visit to Doctor	Dry cracking skin on face and hands.	
Erythema	Required Visit to Doctor	Red hands	
Periorbital oedema	Required Visit to Doctor		
Swelling face	Required Visit to Doctor		
Tongue oedema	Required Visit to Doctor		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia
Tablet	2.0 Milligram	Daily Oral
Batch:	Started: 25/09/2003	Stopped: 25/09/2003
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
Tablet	100.0 Milligram	Daily Oral
Batch:	Started: 23/09/2003	Stopped: 01/10/2003
CLOZAPINE (Suspected)		Reason: Unspecified schizophrenia
Tablet	50.0 Milligram	Daily Oral
Batch:	Started: 24/09/2003	Stopped: 24/09/2003
Zolpidem Sandoz (Suspected)		Reason:
Tablet	100.0 Milligram	Daily Oral
Batch:	Started: 23/09/2003	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 191277 Seq: 1

Gender: M

Reported: 14/10/2003

Weight: 90.00

Hospitalisation:

Age: 29

Onset Date: 25/09/2003

DOB: 17/03/1974

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ATENOLOL (Suspected)

Reason:

Tablet

25.0 Milligram

Daily

Oral

Batch:

Started: 23/09/2003

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 191505 **Seq:** 1 **Gender:** U
Reported: 22/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 22
Onset Date: 10/10/2003 **DOB:** 29/06/1981
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus non-insulin-dep		DEVELOPMENT OF DIABETES	

Medicine Details:

FLUVOXAMINE MALEATE (Interaction)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 16/07/2002	Stopped: 05/02/2003	
CLOZAPINE (Interaction)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 16/07/2002	Stopped: 05/02/2003	
AMISULPRIDE (Other drug)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 16/07/2002	Stopped: 05/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/10/2003	Other data				

Additional Information:

? impact of Fluvoxamine causing increased level.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 192271 **Seq:** 1 **Gender:** F
Reported: 17/11/2003 **Weight:** 57.00
Hospitalisation: **Age:** 50
Onset Date: 07/10/2003 **DOB:** 30/01/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Skin reaction		Skin reaction with luvox, settled on cessation. Similar skin reaction with efexor	Luvox stopped

Medicine Details:

LUVOX (Suspected)	Reason:	Depression
	50.0 Milligram	Daily
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction has settled within one week on cessation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 192464 **Seq:** 1 **Gender:** F
Reported: 24/11/2003 **Weight:** 65.00
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Contusion		Patient noticed an increase in spontaneous bruising (no trauma).	

Medicine Details:

LUVOX (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Has had trials of various SSRI'S. Each time noticed increased spontaneous bruising



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 193209 **Seq:** 1 **Gender:** F
Reported: 16/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 61
Onset Date: 17/10/2003 **DOB:** 27/05/1942
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia.	Fluvoxamine ceased, fluid restrictions resulting in normalisation of sodium levels

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 10/10/2003	Stopped:	17/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/12/2003	Sodium		15/10/2003	129	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 194390 **Seq:** 1 **Gender:** F
Reported: 06/02/2004 **Weight:** 56.00
Hospitalisation: **Age:** 38
Onset Date: 01/02/2004 **DOB:** 29/08/1965
Outcome: Recovered 04/02/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia	Required Visit to Doctor	Myalgia, angio oedema, nausea, diarrhoea, tremulousness of muscles.	
Angioedema	Required Visit to Doctor		
Diarrhoea	Required Visit to Doctor		
Nausea	Required Visit to Doctor		
Tremor	Required Visit to Doctor		

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	
Batch:	Started: 20/01/2004	Stopped: 02/02/2004	
MAXOLON (Suspected)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started: 01/02/2004	Stopped: 01/02/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 196024 **Seq:** 1 **Gender:** M
Reported: 29/03/2004 **Weight:** 93.00
Hospitalisation: **Age:** 50
Onset Date: 25/03/2004 **DOB:** 09/10/1953
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain	Required Visit to Doctor	Pains, restlessness, sensory changes, nausea, dry throat, headache, drowsiness.	Ceased Luvox, Stilnox, Zoton. Given Diazepam.
Dry throat	Required Visit to Doctor		
Headache	Required Visit to Doctor		
Nausea	Required Visit to Doctor		
Restlessness	Required Visit to Doctor		
Sensory disturbance	Required Visit to Doctor		

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 24/03/2004	Stopped: 25/03/2004	
STILNOX (Suspected)		Reason: Disturbance of sleep	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 24/03/2004	Stopped: 25/03/2004	
ZOTON (Suspected)		Reason: Other diseases of esophagus	
Capsule	30.0 Milligram	Daily	Oral
Batch:	Started: 24/03/2004	Stopped: 25/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 196024 **Seq:** 1 **Gender:** M
Reported: 29/03/2004 **Weight:** 93.00
Hospitalisation: **Age:** 50
Onset Date: 25/03/2004 **DOB:** 09/10/1953
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence	Required Visit to Doctor		

Medicine Details:

LUVOX (Suspected)		Reason: Depression
Tablet	20.0 Milligram	Daily Oral
Batch:	Started: 24/03/2004	Stopped: 25/03/2004
STILNOX (Suspected)		Reason: Disturbance of sleep
Tablet	10.0 Milligram	Daily Oral
Batch:	Started: 24/03/2004	Stopped: 25/03/2004
ZOTON (Suspected)		Reason: Other diseases of esophagus
Capsule	30.0 Milligram	Daily Oral
Batch:	Started: 24/03/2004	Stopped: 25/03/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 196629 **Seq:** 1 **Gender:** F
Reported: 19/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 52
Onset Date: **DOB:** 14/07/1951
Outcome: Recovered 12/01/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		hyponatraenia	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	10/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/04/2004	Sodium		09/01/2004	126	
19/04/2004	Sodium		10/01/2004	128	
19/04/2004	Sodium		12/01/2004	142	

Additional Information:

Patient was also taking Baclofen and Oxybutynin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 196715 **Seq:** 1 **Gender:** M
Reported: 22/04/2004 **Weight:** 80.00
Hospitalisation: **Age:** 36
Onset Date: 06/04/2004 **DOB:** 06/01/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Required Visit to Doctor	Sweats and agitation	
Agitation	Required Visit to Doctor		

Medicine Details:

TRAMAL SR (Interaction)		Reason: Pain
	200.0 Milligram	Daily
Batch:	Started:	Stopped: 06/04/2004 8 months
FLUVOXAMINE MALEATE (Interaction)		Reason: Depression
Tablet	1.0 Dose Unspecified	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Pariet and Ciprofloxacin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 197314 **Seq:** 1 **Gender:** F
Reported: 13/05/2004 **Weight:** 85.50
Hospitalisation: **Age:** 28
Onset Date: **DOB:** 29/05/1975
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyporeflexia		Hyporeflexia, hypoxia, drug exposure during pregnancy.	One twin needed intubation, mechanical ventilation for 48 hours
Drug exposure during pregnancy			
Hypoxia			

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/05/2004	Prolactin				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 197395

Seq: 1

Gender: M

Reported: 17/05/2004

Weight: 0.00

Hospitalisation:

Age: 64Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Feeling abnormal Diarrhoea		Unpleasant feeling and diarrhoea.	Luvox ceased.

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	1.0	Dose Unspecified Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 197425

Seq: 1

Gender: F

Reported: 17/05/2004

Weight: 85.50

Hospitalisation:

Age: 28

Onset Date:

DOB: 29/05/1975

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyporeflexia		Hyporeflexia, drug exposure during	
Drug exposure during pregnancy			

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 197433 **Seq:** 1 **Gender:** F
Reported: 18/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 44
Onset Date: 14/05/2004 **DOB:** 16/12/1959
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting	Required Visit to Doctor	Vomiting, diarrhoea, nausea.	Luvox ceased.
Diarrhoea	Required Visit to Doctor		
Nausea	Required Visit to Doctor		

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 13/05/2004	Stopped:	16/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 197558 **Seq:** 1 **Gender:** M
Reported: 25/05/2004 **Weight:** 45.00
Hospitalisation: **Age:** 10
Onset Date: 25/04/2004 **DOB:** 03/10/1993
Outcome: Recovered 16/05/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression	Required Visit to Doctor	Severe outbursts of aggression with little provocation.	

Medicine Details:

LUVOX (Suspected)		Reason: Anxiety neurosis	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 02/03/2004	Stopped:	14/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 198400 **Seq:** 1 **Gender:** F
Reported: 23/06/2004 **Weight:** 65.00
Hospitalisation: **Age:** 53Y
Onset Date: 20/04/2004 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest discomfort Dyspnoea		Acute onset chest tightness and shortness of breath	Luvox ceased.

Medicine Details:

PROMENSIL (Other drug)		Reason:	
Tablet		Dose Unspecified	Oral
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason: Anxiety neurosis	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 16/04/2004	Stopped: 20/04/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had previous SOB as part of anxiety syndrome.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 198507 **Seq:** 1 **Gender:** F
Reported: 25/06/2004 **Weight:** 60.00
Hospitalisation: **Age:** 99u
Onset Date: 15/06/2004 **DOB:**
Outcome: Recovered 17/06/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention	Required Visit to Doctor	Urinary retention, lockjaw and dyskinesia.	Cogentin
Dyskinesia	Required Visit to Doctor		
Trismus	Required Visit to Doctor		

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Largactil and Efexor.



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 198932 **Seq:** 1 **Gender:** F
Reported: 14/07/2004 **Weight:** 50.00
Hospitalisation: **Age:** 71
Onset Date: 08/07/2004 **DOB:** 02/01/1933
Outcome: Recovered 11/07/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flushing		Flushes and panic attacks.	
Panic attack			

Medicine Details:

LUVOX (Suspected)		Reason: Anxiety neurosis	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 08/07/2004	Stopped: 10/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 199137 Seq: 1

Gender: F

Reported: 19/07/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 26/08/2002

DOB:

Outcome: Death, maybe drug

26/08/2002

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug exposure during pregnancy		Sudden and unexpected death of baby.	
Sudden death			

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason:	Depression
Tablet		Dose Unspecified	Oral
Batch:	Started:	Stopped:	23/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

At autopsy Fluvoxamine was detected in liver and blood in baby but not stomach, indicating trans placental passage. Conclusion of Coroner's report - Fluvoxamine as a contributory factor to death could not be ruled out.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 199263 **Seq:** 1 **Gender:** M
Reported: 21/07/2004 **Weight:** 92.00
Hospitalisation: **Age:** 44
Onset Date: 15/04/2004 **DOB:** 24/01/1960
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal impairment	Required Visit to Doctor	Renal impairment.	Dose of Luvox reduced to 100mg daily and Solian reduced to 100mg daily.

Medicine Details:

LUVOX (Suspected)		Reason: Depression
Tablet	300.0 Milligram	Daily Oral
Batch:	Started: 26/03/2003	Stopped:
SOLIAN (Suspected)		Reason: Unspecified psychosis
Tablet	400.0 Milligram	Daily Oral
Batch:	Started: 23/03/2004	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/07/2004	Creatinine				
21/07/2004	Creatinine				
21/07/2004	Urea				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 200980 **Seq:** 1 **Gender:** F
Reported: 21/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 16
Onset Date: 28/08/2004 **DOB:** 19/09/1987
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypokalaemia		Hypokalaemia, suicidal thoughts.	K+ infusion
Suicidal ideation			

Medicine Details:

MARVELON (Other drug)		Reason: Contraception
Tablet	1.0 Dose Unspecified Daily	
Batch:	Started:	Stopped:
OMEPRAZOLE (Suspected)		Reason: Other diseases of esophagus
Capsule	40.0 Milligram Daily Oral	
Batch:	Started: 25/07/2004	Stopped: 31/08/2004
LUVOX (Suspected)		Reason: Depression
Tablet	100.0 Milligram Daily Oral	
Batch:	Started:	Stopped: 31/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 201074 **Seq:** 1 **Gender:** M
Reported: 22/09/2004 **Weight:** 55.00
Hospitalisation: Admitted to hospital **Age:** 46Y
Onset Date: 09/08/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coagulopathy	Life	Over coagulation disorder.	Required medical attention, FFP, prothrombin and 3mg of Vitamin K
International normalised ratio incl	Life		

Medicine Details:

COUMADIN (Interaction)				Reason:
Tablet	4.0	Milligram	Daily	Oral
Batch:	Started:		Stopped:	08/08/2004
LUVOX (Interaction)				Reason: Depression
Tablet	100.0	Milligram	Daily	Oral
Batch:	Started: 14/07/2004		Stopped:	0
LOSEC (Other drug)				Reason: Peptic ulcer nos w/o ment perf
Tablet	20.0	Milligram	Daily	Oral
Batch:	Started: L TERM		Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/09/2004	International		10/08/2004	1.0	INR - 11.4 on presentation to hospital.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202041 **Seq:** 1 **Gender:** M
Reported: 26/10/2004 **Weight:** 75.00
Hospitalisation: **Age:** 47
Onset Date: 25/08/2004 **DOB:** 13/12/1956
Outcome: Recovered 20/10/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	Patient experienced agitation, nausea, muscle pain in upper arm and lower limbs and excess drowsiness.	Somac ceased
Myalgia	Required Visit to Doctor		
Nausea	Required Visit to Doctor		
Somnolence	Required Visit to Doctor		

Medicine Details:

LUVOX (Interaction)		Reason: Anxiety neurosis	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 24/09/2003	Stopped:	
SOMAC (Interaction)		Reason: Other diseases of esophagus	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started: 25/08/2004	Stopped: 17/10/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202097 **Seq:** 1 **Gender:** M
Reported: 27/10/2004 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 16/07/1973
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
White blood cell count increased		White blood cell count increased, suspected interaction between Clozaril and Luvox and drug level increased.	
Drug interaction			
Drug level increased			

Medicine Details:

LUVOX (Interaction)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason:	
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started: 05/08/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/10/2004	Serum drug level				05/10/04: High plasma Clozapine level of 1090ng/ml (reference range unspecified).

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202656 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 58
Onset Date: **DOB:** 16/10/1946
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia		SSRI-induced akathisia. Committed	Got ECT and Efexor later admission later admission. Reduced Fluvoxamine to 50mg. Remitted out
Completed suicide			

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason:	
Tablet	200.0 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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202722 **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:

LUVOX (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202738 **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
Homicidal ideation		Homicidal ideation - attacked teacher with	Ceased Luvox, commenced Efexor at 75mg daily.

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202749 **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
Mania Aggression Akathisia Suicidal ideation		Patient became manic, had suicidal ideation, was violent, had angry violent outbursts and akathisia	Discharged on Fluvoxamine 200mg and Olanzapine 200mg or 5mg tablets

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202769 **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 Akathisia		Suicidal ideation and akathisia.	

Medicine Details:

LUVOX (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202787 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 22
Onset Date: **DOB:** 02/01/1982
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		5 days after ceasing Luvox the patient became violent.	Discharged on Luvox.
Aggression			

Medicine Details:

LUVOX (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202804 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 37
Onset Date: **DOB:** 09/06/1967
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Aggression Overdose		Patient experienced suicidal ideation, violence and overdose.	

Medicine Details:

LUVOX (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202809 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia		Patient developed akathisia and had a suicide attempt.	
Suicide attempt			

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected)	Reason:
Injection	
Batch:	Started: Stopped:
OLANZAPINE (Suspected)	Reason:
Batch:	Started: Stopped:
LUVOX (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202815

Seq: 1

Gender: M

Reported: 18/11/2004

Weight: 0.00

Age: 99U

Hospitalisation:

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia		Patient experienced suicide attempt, akathisia and completed suicide.	
Completed suicide			

Medicine Details:

EFEXOR (Suspected)	Reason:	Oral
Batch:	Started:	Stopped:
FLUVOXAMINE MALEATE (Suspected)	Reason:	Oral
Tablet		
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202838 **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:

FLUVOXAMINE MALEATE (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
	15.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection	200.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202845 **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		Suicidal ideation.	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 202891 **Seq:** 1 **Gender:** U
Reported: 19/11/2004 **Weight:** 22.60
Hospitalisation: Admitted to hospital **Age:** 7
Onset Date: **DOB:** 30/07/1997
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder	Caused or prolonged inpatient hospitalisation	The patient developed obsessive compulsive disorder.	Luvox ceased.

Medicine Details:

LUVOX (Suspected)	Reason: Behavior disorders of childhood
Tablet	Oral
Batch:	Started: Stopped: 0
DEXAMPHETAMINE SULPHATE (Suspected)	Reason: Behavior disorders of childhood
5.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 203026 **Seq:** 1 **Gender:** M
Reported: 24/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 54
Onset Date: 25/10/2004 **DOB:** 19/10/1950
Outcome: Recovered 25/10/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania		Patient suffered mania was aggressive and	Patient took himself off the medication and improved.
Aggression			
Agitation			

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	25/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Second time patient's had a manic/hypomanic reaction to Luvox in the last 2 weeks.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 203045 **Seq:** 1 **Gender:** M
Reported: 25/11/2004 **Weight:** 75.00
Hospitalisation: **Age:** 32
Onset Date: 03/11/2004 **DOB:** 02/05/1972
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	On Fluvoxamine 300mg/daily. When withdrawn gradually over 4 days, patient experienced severe agitation, sleep-walking, nightmares, dizziness, nausea and a "whooshing sound in his	
Dizziness	Required Visit to Doctor		
Drug withdrawal syndrome	Required Visit to Doctor		
Nausea	Required Visit to Doctor		
Nightmare	Required Visit to Doctor		

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
Tablet	300.0 Milligram	Daily Oral
Batch:	Started: 20/07/2004	Stopped: 03/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is cert/rechallenge. Similar symptoms 2 months earlier when he forget to take medication away on an overnight trip.



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 203045 **Seq:** 1 **Gender:** M
Reported: 25/11/2004 **Weight:** 75.00
Hospitalisation: **Age:** 32
Onset Date: 03/11/2004 **DOB:** 02/05/1972
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sleep walking	Required Visit to Doctor		
Tinnitus	Required Visit to Doctor		

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 20/07/2004	Stopped:	03/11/2004

Laboratory Investigations:

Additional Information:

Suspected drug is cert/rechallenge. Similar symptoms 2 months earlier when he forget to take medication away on an overnight trip.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 203508 **Seq:** 1 **Gender:** F
Reported: 13/12/2004 **Weight:** 55.00
Hospitalisation: **Age:** 46
Onset Date: **DOB:** 25/09/1958
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal distension		The patient experienced flatulence, bloating and belching.	
Eructation			

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 20/09/2004	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 203509 **Seq:** 1 **Gender:** M
Reported: 13/12/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sleep walking		Patient experienced sleep walking and nightmares while withdrawing from Luvox.	
Drug withdrawal syndrome			
Nightmare			

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 203510

Seq: 1

Gender: F

Reported: 13/12/2004

Weight: 55.00

Hospitalisation:

Age: 46

Onset Date:

DOB: 25/09/1958

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hot flush		The patient had hot flushes and electric shock sensations after ceasing Luvox.	
Drug withdrawal syndrome			
Sensory disturbance			

Medicine Details:

LUVOX (Suspected)	Reason: Depression
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 20/09/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 204776 **Seq:** 1 **Gender:** F
Reported: 01/02/2005 **Weight:** 50.00
Hospitalisation: **Age:** 39
Onset Date: 26/12/2004 **DOB:** 17/01/1965
Outcome: Recovered 07/01/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Severe	Excess sweatiness, severe nausea & vomiting and giddiness.	Fluvoxamine ceased.
Dizziness	Severe		
Nausea	Severe		
Vomiting	Severe		

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 09/11/2004	Stopped:	26/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 205229 **Seq:** 1 **Gender:** F
Reported: 14/02/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 49
Onset Date: 15/10/2004 **DOB:** 22/08/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Seizures	Sodium Valproate.

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

A possibly of suffering from reflex occipital epilepsy was diagnosed



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 205891 **Seq:** 1 **Gender:** M
Reported: 09/03/2005 **Weight:** 0.00
Hospitalisation: **Age:** 66Y
Onset Date: 15/01/2005 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia	Required Visit to Doctor	Patient waited 2 days and then started Luvox half a tablet mane for 2 days. Hair started to fall out	

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	50.0 Milligram	Total	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient felt hair loss was due to Luvox.
Report 205889 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 207578 **Seq:** 1 **Gender:** M
Reported: 03/05/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 99u
Onset Date: 14/04/2005 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Euphoric mood Flushing Paraesthesia		Feelings of euphoria, buzzing with "electric shocks" and flushing.	Stongly recommended ceasing Codral.

Medicine Details:

CODRAL FLU AND COLD TABLETS (Suspected)		Reason: Acute nasopharyngitis,com cold
Tablet		Oral
Batch:	Started: 13/04/2005	Stopped: 0
LUVOX (Suspected)		Reason: Depression
Tablet	50.0 Milligram	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 207749 **Seq:** 1 **Gender:** M
Reported: 12/05/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 32
Onset Date: 15/01/2005 **DOB:** 11/08/1972
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Incapacity/disability	Aripiprazole initiated 20mg/day on 15/11/2004, increased to 40mg/day (prescribed overdose)	
Cellulitis	Caused or prolonged inpatient hospitalisation	The patient developed cellulitis in the legs and suspected neuroleptic malignant syndrome while on Aripiprazole. The cellulitis was severe and there was concern that amputation may be required.	
Blood creatine phosphokinase increased	Incapacity/disability		
Drug prescribing error	Incapacity/disability		

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason:	
Batch:	Started: 15/11/2004	Stopped: 17/04/2005	
Abilify (Suspected)		Reason:	
Tablet	Milligram	Daily	Oral
Batch:	Started: 15/11/2004	Stopped: 17/04/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Neurologist suspected MacArdlesdisease with widespread myoneurosis founf on the biopsy examination



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 207749 **Seq:** 1 **Gender:** M
Reported: 12/05/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 32
Onset Date: 15/01/2005 **DOB:** 11/08/1972
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason:	
Batch:	Started: 15/11/2004	Stopped: 17/04/2005	
Abilify (Suspected)		Reason:	
Tablet	Milligram	Daily	Oral
Batch:	Started: 15/11/2004	Stopped: 17/04/2005	0

Laboratory Investigations:

Additional Information:

Neurologist suspected MacArdlesdisease with widespread myoneurosis founf on the biopsy examination



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 207888 **Seq:** 1 **Gender:** M
Reported: 16/05/2005 **Weight:** 37.00
Hospitalisation: **Age:** 11
Onset Date: **DOB:** 22/08/1993
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erythema nodosum		Erythema nodosum type reaction	

Medicine Details:

LUVOX (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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 207959 **Seq:** 1 **Gender:** F
Reported: 18/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 11/04/2005 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Anxiety Back pain Diarrhoea Nausea		Patient experienced agitation, anxiety, back pain, nausea and diarrhoea.	

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 07/04/2005 S TERM	Stopped:	Continuing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 208101 **Seq:** 1 **Gender:** U
Reported: 23/05/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 52Y
Onset Date: 12/04/2005 **DOB:**
Outcome: Recovered 23/04/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disturbance in attention Cognitive disorder Communication disorder Dizziness Dry mouth Hyperhidrosis		Patient experienced concentration impaired, dizziness, excess sweating, dry mouth, cognitive impairment, communication disorder	Luvox ceased.

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 12/04/2005	Stopped:	16/04/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 208162 **Seq:** 1 **Gender:** M
Reported: 25/05/2005 **Weight:** 64.00
Hospitalisation: Required a visit to the doctor **Age:** 36
Onset Date: **DOB:** 16/07/1968
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Skin hyperpigmentation		Patient experienced facial	

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified psychosis
Batch:	1.0 Milligram Daily	Started: Stopped:
COMBIVIR (Suspected)		Reason: Hiv infection
Tablet	2.0 Dose Unspecified Daily	Oral
Batch:	Started:	Stopped: Continuing.
LUVOX (Suspected)		Reason: Depression
Tablet	300.0 Milligram Daily	Oral
Batch:	Started:	Stopped:
NEVIRAPINE (Suspected)		Reason: Hiv infection
Tablet	400.0 Milligram Daily	Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 208162 Seq: 1

Gender: M

Reported: 25/05/2005

Weight: 64.00

Hospitalisation: Required a visit to the doctor

Age: 36

Onset Date:

DOB: 16/07/1968

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

VALACICLOVIR HYDROCHLORIDE (Suspected)

Reason:

1.0 Gram

Daily

Batch:

Started:

Stopped:

0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 208468 **Seq:** 1 **Gender:** U
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		The patient experienced a serious suicidal attempt after three months of akathisia - made serious, nearly lethal attempts, and developed deep vein thrombosis.	Withdrawal over prolonged period. Needed Warfarin.
Akathisia			
Deep vein thrombosis			

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection	200.0 Milligram	Weekly	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
	15.0 Milligram	Daily	
Batch:	Started:	Stopped:	
FLUVOXAMINE MALEATE (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 209154 **Seq:** 1 **Gender:** F
Reported: 27/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: 20/05/2005 **DOB:** 28/03/1975
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed Serotonin syndrome Agitation Insomnia Nausea Restlessness Sedation		20/05/2005 dosage was increased to 30mg The patient developed suspected serotonin syndrome after Remeron was initiated with ccbi	

Medicine Details:

REMERON (Suspected)		Reason:			
Tablet	30.0	Milligram	Daily	Oral	
Batch:	Started:	Stopped:	20/05/2005	0	
FLUVOXAMINE MALEATE (Suspected)		Reason:			
Tablet	200.0	Milligram	Daily	Oral	
Batch:	Started:	Stopped:			

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 209395 **Seq:** 1 **Gender:** F
Reported: 01/07/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 27
Onset Date: 02/10/2004 **DOB:** 01/10/1977
Outcome: Recovered 03/10/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness	Caused or prolonged inpatient hospitalisation	The patient collapsed after two drinks of alcohol and lost consciousness. She regained consciousness when nasogastric tube inserted. Scheduled as staff concerned re drug overdose. Released the	Nasogastric tube inserted.
Circulatory collapse	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 18/09/2004	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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 209397 **Seq:** 1 **Gender:** M
Reported: 01/07/2005 **Weight:** 84.00
Hospitalisation: Required a visit to the doctor **Age:** 52
Onset Date: 26/05/2005 **DOB:** 19/04/1953
Outcome: Recovered 28/05/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		The patient experienced suspected serotonin syndrome.	Tramadol ceased.

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction)		Reason:	
	50.0 Milligram	As necessary	
Batch:	Started:	Stopped:	
FLUVOXAMINE MALEATE (Interaction)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RAMIPRIL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ASPIRIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 209397

Seq: 1

Gender: M

Reported: 01/07/2005

Weight: 84.00

Hospitalisation: Required a visit to the doctor

Age: 52

Onset Date: 26/05/2005

DOB: 19/04/1953

Outcome: Recovered

28/05/2005

Causality: Causality probable

Reaction Detail

Medicine Details:

PRAVASTATIN SODIUM (Other drug)

Reason:

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 209399 **Seq:** 1 **Gender:** F
Reported: 01/07/2005 **Weight:** 65.00
Hospitalisation: **Age:** 17
Onset Date: 14/06/2005 **DOB:** 06/10/1987
Outcome: Recovered 19/06/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		The patient developed a large purpura on the skin of her left knee, approximately 5cm	Luvox dosage reduced.

Medicine Details:

STILNOX (Other drug)		Reason: Specific disorders of sleep
	10.0 Milligram	
Batch:	Started:	Stopped:
LUVOX (Suspected)		Reason: Depression
Tablet	300.0 Milligram	Daily Oral
Batch:	Started: 04/05/2005	Stopped: 15/06/2005 Tapering.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 209508 **Seq:** 1 **Gender:** F
Reported: 06/07/2005 **Weight:** 0.00
Hospitalisation: **Age:** 37
Onset Date: 24/05/2004 **DOB:** 10/05/1967
Outcome: Recovered 29/05/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypersensitivity Malaise Pain Pyrexia Rash		Patient experienced an allergic reaction, symptoms included severe rashes with fever, aches, pain and malaise.	All drugs discontinued. Treated with Prednisolone.

Medicine Details:

CHLORAL HYDRATE (Suspected)	Reason: Specific disorders of sleep
Batch:	Started: Stopped: 24/05/2004 0
PANADEINE FORTE (Suspected)	Reason: Migraine
Tablet	Oral
Batch:	Started: Stopped: 24/05/2004 0
LUVOX (Suspected)	Reason: Depression
Tablet	250.0 Milligram Daily Oral
Batch:	Started: 01/05/2004 Stopped: 24/05/2004
EPILIM (Suspected)	Reason:
Tablet	500.0 Milligram Daily Oral
Batch:	Started: Stopped: 24/05/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Multiple drug allergies: Penicillin, Amoxicillin, Erythromycin, Bactrim, Rulide, Norflux, Plactil, Keflex, Clindamycin, Tagamet and Morphine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 209511 **Seq:** 1 **Gender:** F
Reported: 06/07/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 37
Onset Date: 04/06/2004 **DOB:** 10/05/1967
Outcome: Recovered 16/06/2004 **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypersensitivity	Caused or prolonged inpatient hospitalisation	On 04/06/04, allergic reaction re-appeared and the symptoms were more severe than the time before	Luvox discontinued. Treated with a higher dose of Prednisolone

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 31/05/2004	Stopped:	04/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is cert/rechallenge causing the same reaction to occur. History: Multiple drug allergies: Penicillin, Amoxicillin, Erythromycin, Bactrim, Rulide, Norflux, Plactil, Keflex, Clindamycin, Tagamet and Morphine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 210015 **Seq:** 1 **Gender:** F
Reported: 21/07/2005 **Weight:** 54.00
Hospitalisation: Required a visit to the doctor **Age:** 24
Onset Date: 09/07/2005 **DOB:** 21/05/1981
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema		The patient experienced angioedema and arthralgia of the hands and fingers. It was very severe and painful.	Fluvoxamine ceased.
Arthralgia			
Pain			

Medicine Details:

ALPRAZOLAM (Other drug)		Reason:	
Tablet	5.0 Microgram	As necessary	Oral
Batch:	Started: 09/06/2005	S TERM	Stopped:
FLUVOXAMINE MALEATE (Suspected)		Reason: Anxiety neurosis	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 09/06/2005	Stopped: 09/07/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient previously treated with Avanza.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 211026 **Seq:** 1 **Gender:** M
Reported: 24/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Incapacity/disability	After starting Luvox the patient became more depressed and agitated, was unable to watch television, could not sit still, his hearing became acute and he plugged his ears against noise, blacked out his bedroom against light, did not want to wake up, started pacing, spent most days in bed, could not talk to anyone without crying so avoided social contact. Dose was increased to 70mg and the crying became more intense, he was still unable to socialise and crying fits increased. Noise became less of a problem, but he still spent most of the day in bed where he focussed	

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient medical history: heart attack.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 211026

Seq: 1

Gender: M

Reported: 24/08/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Crying	Incapacity/disability		
Therapy regimen changed	Incapacity/disability		

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Patient medical history: heart attack.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 211639 **Seq:** 1 **Gender:** M
Reported: 13/09/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sleep walking Drug withdrawal syndrome Nightmare		The patient experienced sleep walking and nightmares while withdrawing from Luvor therapy.	

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 211651 **Seq:** 1 **Gender:** F
Reported: 13/09/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 78Y
Onset Date: 28/06/2005 **DOB:**
Outcome: Recovered 30/06/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
International normalised ratio inc	Caused or prolonged inpatient hospitalisation	Patient developed raised INR.	Ceased Warfarin, given Vitamin K 6.5mg.

Medicine Details:

COUMADIN (Interaction)		Reason: Otr&nos disord of heart rhythm
Tablet	22.0 Milligram	Weekly Oral
Batch:	Started: 23/06/2005	Stopped: 28/06/2005
LUVOX (Interaction)		Reason: Depression
Tablet	50.0 Milligram	Daily Oral
Batch:	Started: 23/06/2005	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/09/2005	International		28/06/2005	7.3	
13/09/2005	International		27/06/2005	7.1	
13/09/2005	International		29/06/2005	4.8	
13/09/2005	International		30/06/2005	2.4	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 211971 **Seq:** 1 **Gender:** U
Reported: 26/09/2005 **Weight:** 85.00
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction		Patient experienced impotence.	

Medicine Details:

Movox (Suspected)		Reason:	
Batch:	Started: 15/01/2005	Stopped: 15/09/2005	
FLUVOXAMINE MALEATE (Suspected)		Reason: Anxiety neurosis	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 15/01/2005	Stopped: 15/09/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 212065 **Seq:** 1 **Gender:** M
Reported: 28/09/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 52
Onset Date: 10/05/2005 **DOB:** 07/02/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Caused or prolonged inpatient hospitalisation	Patient dose of Movox 50mg was increased to 150mg daily, within 4-5days patient experienced nausea, agitation, sweating, diarrhoea, headache, dry mouth, suicidal ideation leading to suicide attempt.	Monitoring, supportive, dose reduction.
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

XANAX (Other drug)	Reason: Anxiety neurosis
0.5 Milligram	
Batch:	Started: 17/11/2004 Stopped:
TEMAZE (Other drug)	Reason: Specific disorders of sleep
10.0 Milligram	
Batch:	Started: 11/03/2005 Stopped:
Movox (Suspected)	Reason: Depression
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 05/05/2005 Stopped: 10/05/2005 0
Movox (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 28/02/2004 Stopped: 05/05/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient stabilised on maintenance dose 50mg daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 212065 **Seq:** 1 **Gender:** M
Reported: 28/09/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 52
Onset Date: 10/05/2005 **DOB:** 07/02/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Dry mouth	Caused or prolonged inpatient hospitalisation		
Headache	Caused or prolonged inpatient hospitalisation		

Medicine Details:

XANAX (Other drug)	Reason: Anxiety neurosis
0.5 Milligram	
Batch:	Started: 17/11/2004 Stopped:
TEMAZE (Other drug)	Reason: Specific disorders of sleep
10.0 Milligram	
Batch:	Started: 11/03/2005 Stopped:
Movox (Suspected)	Reason: Depression
Tablet 150.0 Milligram Daily Oral	
Batch:	Started: 05/05/2005 Stopped: 10/05/2005 0
Movox (Suspected)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: 28/02/2004 Stopped: 05/05/2005 0

Laboratory Investigations:

Additional Information:

Patient stabilised on maintenance dose 50mg daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 212065 **Seq:** 1 **Gender:** M
Reported: 28/09/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 52
Onset Date: 10/05/2005 **DOB:** 07/02/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		
Suicidal ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

XANAX (Other drug)	Reason: Anxiety neurosis
0.5 Milligram	
Batch:	Started: 17/11/2004 Stopped:
TEMAZE (Other drug)	Reason: Specific disorders of sleep
10.0 Milligram	
Batch:	Started: 11/03/2005 Stopped:
Movox (Suspected)	Reason: Depression
Tablet	
150.0 Milligram	Daily Oral
Batch:	Started: 05/05/2005 Stopped: 10/05/2005 0
Movox (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 28/02/2004 Stopped: 05/05/2005 0

Laboratory Investigations:

Additional Information:

Patient stabilised on maintenance dose 50mg daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 212065 **Seq:** 1 **Gender:** M
Reported: 28/09/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 52
Onset Date: 10/05/2005 **DOB:** 07/02/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation		

Medicine Details:

XANAX (Other drug)	Reason: Anxiety neurosis
0.5 Milligram	
Batch:	Started: 17/11/2004 Stopped:
TEMAZE (Other drug)	Reason: Specific disorders of sleep
10.0 Milligram	
Batch:	Started: 11/03/2005 Stopped:
Movox (Suspected)	Reason: Depression
Tablet	
150.0 Milligram	Daily Oral
Batch:	Started: 05/05/2005 Stopped: 10/05/2005 0
Movox (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 28/02/2004 Stopped: 05/05/2005 0

Laboratory Investigations:

Additional Information:

Patient stabilised on maintenance dose 50mg daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 212224 **Seq:** 1 **Gender:** F
Reported: 05/10/2005 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 39
Onset Date: 24/11/2004 **DOB:** 19/09/1965
Outcome: Recovered 07/12/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal	Caused or prolonged inpatient hospitalisation	The patient experienced raised liver	Changed to Sertraline.

Medicine Details:

TEMAZEPAM (Other drug)		Reason: Specific disorders of sleep
	10.0 Milligram	Oral
Batch:	Started:	Stopped:
FLUVOXAMINE MALEATE (Suspected)		Reason: Anxiety neurosis
Tablet	100.0 Milligram	Daily Oral
Batch:	Started: 15/11/2004	Stopped: 25/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/10/2005	ALT = SGPT	0-55			151 U/L
05/10/2005	GGT = SGGT =	0-60			155 U/L
05/10/2005	AST = ALP	30-110			155 U/L

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 212353 **Seq:** 1 **Gender:** M
Reported: 10/10/2005 **Weight:** 0.00
Hospitalisation: **Age:** 46
Onset Date: 01/08/2005 **DOB:** 04/01/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression		Patient experienced depression in mid Aug 2005 after commencing Neuroral.	

Medicine Details:

NEORAL (Interaction)	Reason:	Complicatns of transplant orgn
Batch:	Started:	Stopped:
FLUVOXAMINE MALEATE (Interaction)	Reason:	Depression
Batch:	Started:	Stopped: 0
CELLCEPT (Other drug)	Reason:	
Batch:	Started:	Stopped:
PREDNISOLONE (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 212353

Seq: 1

Gender: M

Reported: 10/10/2005

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date: 01/08/2005

DOB: 04/01/1959

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

SOMAC (Other drug)

Reason:

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 212771 **Seq:** 1 **Gender:** M
Reported: 24/10/2005 **Weight:** 0.00
Hospitalisation: **Age:** 24Y
Onset Date: **DOB:**
Outcome: Recovered 15/09/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vision blurred		The patient became very sedated, his neck was rigid, he had blurred vision and felt "crackles"	Luvox and Diazepam ceased.
Musculoskeletal stiffness			
Sedation			

Medicine Details:

DIAZEPAM (Interaction)		Reason: Anxiety neurosis
	5.0 Milligram	Weekly
Batch:	Started: 15/07/2004	Stopped: 15/09/2004
LUVOX (Interaction)		Reason: Anxiety neurosis
Tablet	100.0 Milligram	Daily Oral
Batch:	Started: 15/07/2004	Stopped: 15/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 213080 **Seq:** 1 **Gender:** M
Reported: 03/11/2005 **Weight:** 0.00
Hospitalisation: **Age:** 60Y
Onset Date: 25/06/2005 **DOB:**
Outcome: Death 15/08/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Death	The day after starting Luvox the patient became paranoid with manic behaviour. He was pacing up and down a lot, wanting to poke his eye out and wanting to go to church. He committed suicide on 15/08/2005.	Luvox dose increased. Given Temazepam 20mg daily, Largactil 25mg daily, Risperidone 2mg daily and Allegron 100mg daily. Luvox was ceased on 4 July 2005.
Completed suicide	Death		
Death	Death		
Mania	Death		
Paranoia	Death		

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 24/06/2005	Stopped: 04/07/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 213386 **Seq:** 1 **Gender:** F
Reported: 14/11/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 56
Onset Date: 15/07/2005 **DOB:** 12/10/1948
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Leukocytoclastic vasculitis		The patient experienced an ulcerating rash and was diagnosed with leukocytoclastic vasculitis while being treated with Luvox.	Treated with dressing. Luvox

Medicine Details:

THYROXINE SODIUM (Other drug)		Reason: Myxedema
Tablet	100.0 Microgram	Oral
Batch:	Started:	Stopped:
LUVOX (Suspected)		Reason: Depression
Tablet	50.0 Milligram	Daily Oral
Batch:	Started: L TERM	Stopped: 15/07/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/11/2005	Other data				Biopsy - leukocytoclastic vasculitis.

Additional Information:

Patient has history of depression, anxiety, panic attacks since several years (therefore Luvox was started).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 213593 **Seq:** 1 **Gender:** F
Reported: 18/11/2005 **Weight:** 85.00
Hospitalisation: Required a visit to the doctor **Age:** 35
Onset Date: 17/10/2005 **DOB:** 12/08/1970
Outcome: Recovered 28/10/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Anxiety Lethargy Sedation		The patient experienced long withdrawal symptoms - lethargy, night sweats, palpitations, anxiety, muscle aches within 10 minutes of being up, nocturia and sedation.	

Medicine Details:

LUVOX (Suspected)	Reason: Anxiety neurosis
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 04/08/2005 Stopped: 27/09/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History - very sensitive to medicines (?slow metabolised).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 213760 **Seq:** 1 **Gender:** M
Reported: 24/11/2005 **Weight:** 93.00
Hospitalisation: Required a visit to the doctor **Age:** 22
Onset Date: 19/11/2005 **DOB:** 10/01/1983
Outcome: Recovered 21/11/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Contusion		The patient experienced bruising over the	Luvox ceased.

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 12/11/2005	Stopped: 17/11/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Has had bruising previously with Aropax.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 213963 **Seq:** 1 **Gender:** M
Reported: 02/12/2005 **Weight:** 0.00
Hospitalisation: **Age:** 32
Onset Date: 26/02/2005 **DOB:** 15/01/1973
Outcome: Death, maybe drug 26/02/2000 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug level increased	Death	Pateint died possibly due to olanzapine and valproic acid, possibly due to a drug interaction	
Drug interaction	Death		

Medicine Details:

OLANZAPINE (Interaction)	Reason:
Batch:	Started: Stopped:
FLUVOXAMINE MALEATE (Interaction)	Reason:
Batch:	Started: Stopped:
SODIUM VALPROATE (Interaction)	Reason:
Batch:	Started: Stopped:
ZUCLOPENTHIXOL ACETATE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/12/2005	Serum drug level				Toxicological analysis revealed bloodlevels of 0.58 mg/l of Olanzapine (580 ng/l), which is inconsistent with therapeutic use of Olanzapine, 59 mg/l of Valproic Acid, 0.04 mg/l of Fluvoxamine and 0.03 mg/l of Morphine. No alcohol was detected

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 214091 **Seq:** 1 **Gender:** F
Reported: 07/12/2005 **Weight:** 0.00
Hospitalisation: **Age:** 43
Onset Date: 21/11/2005 **DOB:** 06/02/1962
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia	Incapacity/disability	Client commenced on Luvox 25mg d one month ago, increased to 50mg after 2 weeks and experienced sore elbow. Increased to 75mg on 2nd Dec for 2 nights but felt unwell so reduced back to 50mg. Presented 7/12/05 to emergency department with ongoing generalised "bone" pain -not muscular. Worse in R shoulder and elbow but also including top of feet, legs, hands, L arm. Getting worse each day. Difficulty mobilising, turning over in bed, finds weight of bedclothes painful on R arm. Blood tests normal. No fever, vomiting etc. Prescribed Panadeine forte and advised to stop Luvox. Advice given by pharmacist re- withdrawal effects. Letter to GP for ...	

Medicine Details:

LUVOX (Suspected)	Reason:
Tablet	1 time Oral
Batch:	Started: 06/11/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 214091 **Seq:** 1 **Gender:** F
Reported: 07/12/2005 **Weight:** 0.00
Hospitalisation: **Age:** 43
Onset Date: 21/11/2005 **DOB:** 06/02/1962
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia	Incapacity/disability	... rv Monday. No other meds taken, no recent changes to meds Worse in R shoulder and elbow but also including top of feet, legs, hands, L arm.	
Bone pain	Incapacity/disability		
Malaise	Incapacity/disability		

Medicine Details:

LUVOX (Suspected)	Reason:
Tablet	1 time Oral
Batch:	Started: 06/11/2005 Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 214445 **Seq:** 1 **Gender:** F
Reported: 20/12/2005 **Weight:** 60.00
Hospitalisation: Required a visit to the doctor **Age:** 99
Onset Date: 16/11/2005 **DOB:** 15/12/1905
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Contusion		Patient developed excessive/easy bruising, quering abnormal platelet function. Symptoms began when dose was increased from 50mg daily (for period of 13 days) to 100mg daily.	
Therapy regimen changed			

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 16/11/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 214703 **Seq:** 1 **Gender:** M
Reported: 09/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 15/03/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sperm count decreased	Incapacity/disability	Patient has a very low sperm count.	

Medicine Details:

EPILIM (Suspected) Tablet Batch:	Reason: Unspecifid affective psychosis Oral Started: 15/08/2000 Stopped:
AVANZA (Suspected) Tablet Batch:	Reason: Depression 900.0 Milligram Daily Oral Started: 15/10/2001 Stopped:
LUVOX (Suspected) Tablet Batch:	Reason: 300.0 Milligram Daily Oral Started: 15/05/2000 Stopped: 15/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 214748 **Seq:** 1 **Gender:** M
Reported: 10/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 24
Onset Date: **DOB:** 21/11/1981
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sedation		The patient became very sedated and experienced hypersalivation.	Clozaril dose reduced to 125mg daily
Salivary hypersecretion			

Medicine Details:

LUVOX (Interaction)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 11/01/2005	Stopped: 0	
NALTREXONE HYDROCHLORIDE (Interaction)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 215197 **Seq:** 1 **Gender:** M
Reported: 23/01/2006 **Weight:** 82.00
Hospitalisation: **Age:** 16
Onset Date: 15/12/2005 **DOB:** 17/11/1989
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction		Patient experienced photosensitivity rash, affecting face, neck, upper chest.	Ceased Luvox.

Medicine Details:

EPILIM (Other drug)		Reason:	
	1.0 Gram		
Batch:	Started: 12/02/2005	Stopped:	
LUVOX (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 02/12/2005	Stopped: 12/01/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 215218 **Seq:** 1 **Gender:** F
Reported: 24/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Life threatening	The patient experienced profound relapse of severe depression while being treated with Luvox.	Ceased Luvox, changed back to Zoloft.

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 215216 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 215242 **Seq:** 1 **Gender:** M
Reported: 24/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 36
Onset Date: 23/01/2006 **DOB:** 12/01/1970
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder Atrial hypertrophy Depression Drug interaction Drug level increased Sinus tachycardia		The patient developed depression and obsessional behaviour since commencing Clozaril and he developed elevated Clozapine and Norclozapine levels. Also developed possible right atrial hypertrophy and sinus tachycardia.	Clozaril dose reduced and Fluvoxamine dose reduced.

Medicine Details:

CLOZARIL (Interaction)		Reason:	
Tablet	475.0 Milligram	Daily	Oral
Batch:	Started: 08/08/1994	L TERM	Stopped:
FLUVOXAMINE MALEATE (Interaction)		Reason: Depression	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2006	Electrocardiograph				5 january 2006: Electrocardiogram: sinus tachycardia, possible right atrial hypertrophy, compatible with a bundle branch block.
24/01/2006	Other data		11/01/2006	844	Norclozapine level.
24/01/2006	Other data		19/01/2005	-	Norclozapine level.
24/01/2006	Other data		11/01/2006	-	Norclozapine level.
24/01/2006	Other data		26/04/2005	-	Norclozapine level.
24/01/2006	Serum drug level		23/07/2001	320	Clozapine level.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 215242

Seq: 1

Gender: M

Reported: 24/01/2006

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date: 23/01/2006

DOB: 12/01/1970

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

CLOZARIL (Interaction)		Reason:	
Tablet	475.0 Milligram	Daily	Oral
Batch:	Started: 08/08/1994	L TERM	Stopped:
FLUVOXAMINE MALEATE (Interaction)		Reason: Depression	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2006	Serum drug level		19/01/2005	1102	Clozapine level.
24/01/2006	Serum drug level		26/04/2005	1950	Clozapine level.
24/01/2006	Serum drug level		11/01/2006	3486	Clozapine level.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 215247 **Seq:** 1 **Gender:** F
Reported: 24/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Agitation Atrial fibrillation Blood creatine phosphokinase in Chills Clonus Confusional state		Patient developed severe serotonergic features, including confusion, nausea, fever, clonus, hyperreflexia, hypertonia, shivering and tachycardia, serotonin syndrome, restless, agitated, febrile, atrial fibrillation, incoordination, mydriasis and elevated CK level	Ceased Fluvoxamine, Oxycodone, Doxepin.

Medicine Details:

OXYCODONE HYDROCHLORIDE (Interaction)		Reason:	
Tablet	80.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
FLUVOXAMINE MALEATE (Interaction)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
DOXEPIN HYDROCHLORIDE (Interaction)		Reason:	
Capsule	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
DICLOFENAC SODIUM (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2006	Creatine				Creatine kinase (SK) level was 485 units/L.

Additional Information:

Literature Reference: Karunatilake H, Buckley NA. Serotonin syndrome induced by Fluvoxamine and Oxycodone. The annals of Pharmacotherapy 2005; 40 (1); 155-157. Following admission, the patient's thyroid indices were normal. Also published: Serotonin syndrome due to fluvoxamine-oxycodone interaction. Psychopharmacology Reviews, Primary Psychiatry 2006; May: 25-26.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 215247

Seq: 1

Gender: F

Reported: 24/01/2006

Weight: 0.00

Hospitalisation:

Age: 70Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Hyperreflexia Hypertonia Mydriasis Nausea Pyrexia Restlessness Tachycardia			

Medicine Details:

Rationale Details:		
RALOXIFENE (Other drug)		Reason:
Batch:	Started:	Stopped:
CALCIUM CARBONATE (Other drug)		Reason:
Batch:	Started:	Stopped:
Dilzem CD (Other drug)		Reason:
Batch:	Started:	Stopped:
SIMVASTATIN (Other drug)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Literature Reference: Karunatilake H, Buckley NA. Serotonin syndrome induced by Fluvoxamine and Oxycodone. The annals of Pharmacotherapy 2005; 40 (1); 155-157. Following admission, the patient's thyroid indices were normal. Also published: Serotonin syndrome due to fluvoxamine-oxycodone interaction. Psychopharmacology Reviews, Primary Psychiatry 2006; May: 25-26.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 215418 **Seq:** 1 **Gender:** F
Reported: 31/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 37
Onset Date: 15/12/2005 **DOB:** 05/05/1968
Outcome: Recovered 21/12/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Hyperhidrosis Pruritus		Patient experienced rash, red, erythematous, hot and itchy, arms, legs, groin, palms, associated with sweating.	Ceased Fluoxetine, treated with Sigmacort cream.

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 29/11/2005	Stopped: 16/12/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 216344 **Seq:** 1 **Gender:** F
Reported: 09/03/2006 **Weight:** 0.00
Hospitalisation: **Age:** 89
Onset Date: 03/12/2005 **DOB:** 20/02/1916
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Agitation Confusional state Delirium Hyponatraemia		Patient experienced serotonin syndrome, confusion, delerium, agitation and hyponatraemia	Ceased Tramadol and Fluvoxamine. Fluid restriction.

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction)		Reason: Otr&unsp vertebrogen pain synd	
Capsule	150.0 Milligram	Daily	Oral
Batch:	Started: 12/11/2005	Stopped: 03/12/2005	
FLUVOXAMINE MALEATE (Interaction)		Reason:	
Capsule	50.0 Milligram	Daily	Oral
Batch:	Started: 30/11/2005	Stopped: 03/12/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 217318 **Seq:** 1 **Gender:** M
Reported: 11/04/2006 **Weight:** 120.00
Hospitalisation: Required a visit to the doctor **Age:** 46
Onset Date: 29/03/2006 **DOB:** 25/11/1959
Outcome: Recovered 31/03/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed		Patient was very depressed.	
Drug ineffective			

Medicine Details:

FAVERIN (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 26/03/2006	Stopped:	29/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 217475 **Seq:** 1 **Gender:** F
Reported: 19/04/2006 **Weight:** 58.00
Hospitalisation: Required a visit to the doctor **Age:** 54
Onset Date: 15/01/2006 **DOB:** 13/06/1951
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombocythaemia		Patient developed thrombocytopenia.	Ceased Fluvoxamine and

Medicine Details:

PREMARIN (Other drug)		Reason: Menopausal symptoms	
Batch:	Started:	Stopped:	
PROVERA (Other drug)		Reason: Menopausal symptoms	
Batch:	Started:	Stopped:	
Blackmores Fish Oil (Other drug)		Reason: Oral	
Batch:	Started:	Stopped:	
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 08/01/2006	Stopped: 27/02/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/04/2006	Platelets	(150-450)	14/02/2006	72 x 10 ⁹ /C	
19/04/2006	Platelets	(150-450)	27/02/2006	3/1 x 10 ⁹ /C	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 217475

Seq: 1

Gender: F

Reported: 19/04/2006

Weight: 58.00

Hospitalisation: Required a visit to the doctor

Age: 54

Onset Date: 15/01/2006

DOB: 13/06/1951

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

QUETIAPINE (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 15/04/2005	Stopped: 18/02/2006	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 217483 **Seq:** 1 **Gender:** F
Reported: 19/04/2006 **Weight:** 165.40
Hospitalisation: **Age:** 36
Onset Date: **DOB:** 14/08/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased	Incapacity/disability	Patient experienced weight gain of 75.4kg, poor control of diabetes	
Blood glucose increased		blood sugar level 7.9	
Diabetes mellitus inadequate control			

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
PANADEINE FORTE (Other drug)	Reason:
Batch:	Started: Stopped:
OGEN (Suspected)	Reason:
Batch:	Started: Stopped: 0
LUVOX (Suspected)	Reason:
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 217483

Seq: 1

Gender: F

Reported: 19/04/2006

Weight: 165.40

Hospitalisation:

Age: 36

Onset Date:

DOB: 14/08/1969

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

GABAPENTIN (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 22/01/2002	Stopped:	27/03/2006 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 217534

Seq: 1

Gender: F

Reported: 20/04/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination, visual		Visual hallucinations when Luvox was increased from 100mg to 200mg daily.	
Therapy regimen changed			

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 217918 **Seq:** 1 **Gender:** F
Reported: 02/05/2006 **Weight:** 101.00
Hospitalisation: Required a visit to the doctor **Age:** 31
Onset Date: 11/04/2006 **DOB:** 29/08/1974
Outcome: Recovered 16/04/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash pruritic		Patient developed itchy rash on face, trunk (front and back)-> limbs.	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 19/03/2006	Stopped: 11/04/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 218666 **Seq:** 1 **Gender:** M
Reported: 24/05/2006 **Weight:** 80.00
Hospitalisation: **Age:** 48
Onset Date: 14/04/2006 **DOB:** 01/07/1957
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Diarrhoea on Fluvoxamine. Did not subside, increased when dose was increased from 40mg to 100mg nocte.	Fluvoxamine ceased.

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 13/04/2006	Stopped:	05/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 219306 **Seq:** 1 **Gender:** F
Reported: 20/06/2006 **Weight:** 60.00
Hospitalisation: **Age:** 42
Onset Date: 30/05/2006 **DOB:** 05/12/1963
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting Dizziness		Patient experienced vomiting and	

Medicine Details:

NAPROXEN (Other drug)		Reason: Other diseases of bone
Tablet	1.0 Gram	Oral
Batch:	Started: 07/07/2005	Stopped:
SOMAC (Other drug)		Reason:
	40.0 Milligram	
Batch:	Started: 29/12/2005	Stopped:
LUVOX (Suspected)		Reason: Depression
Tablet	50.0 Milligram	Daily Oral
Batch:	Started: 30/05/2006	Stopped: 03/06/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 219420 **Seq:** 1 **Gender:** F
Reported: 19/06/2006 **Weight:** 52.00
Hospitalisation: Required a visit to the doctor **Age:** 35Y
Onset Date: 01/01/2006 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash neonatal		Breastfed infant developed florid maculopapular rash on chin, trunk, arms and then legs	Luvox stopped.
Drug exposure via breast milk			

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Breast milk transfer
Batch:	Started:	Stopped: 15/03/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 219547 **Seq:** 1 **Gender:** F
Reported: 28/06/2006 **Weight:** 0.00
Hospitalisation: **Age:** 21
Onset Date: 01/05/2006 **DOB:** 29/04/1985
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disturbance in attention Asthenia Dizziness Drug withdrawal syndrome Lethargy Therapy regimen changed		Patient experienced loss of concentration, withdrawal reaction, lethargy, dizziness and weakness. The adverse event started immediately after dose reduction from 300mg to 250mg.	Patient returned to 300mg/daily on 03/05/06.

Medicine Details:

SEROQUEL (Other drug)		Reason: Depression
Tablet		Oral
Batch:	Started:	Stopped:
LUVOX (Suspected)		Reason: Depression
Tablet	250.0 Milligram	Daily Oral
Batch:	Started: 01/05/2006	Stopped: 03/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: depression since 1999 and obsessive compulsive disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 219909 **Seq:** 1 **Gender:** F
Reported: 11/07/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 21
Onset Date: 29/06/2006 **DOB:** 25/08/1984
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria	Caused or prolonged inpatient hospitalisation	Confluent urticarial rash.	

Medicine Details:

Movox (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	1 time	Oral
Batch:	Started: 29/06/2006	Stopped:	29/06/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 221397 **Seq:** 1 **Gender:** F
Reported: 05/09/2006 **Weight:** 75.00
Hospitalisation: Required a visit to the doctor **Age:** 76Y
Onset Date: 07/08/2006 **DOB:**
Outcome: Recovered 10/08/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache Vomiting		Severe headache, severe vomiting	Stopped taking.

Medicine Details:

MODURETIC (Other drug)	Reason: Essential benign hypertension
1.0 Dose Unspecified Daily	
Batch:	Started: Stopped:
CARTIA (Other drug)	Reason:
1.0 Dose Unspecified Daily	
Batch:	Started: Stopped:
PREMARIN (Other drug)	Reason: Menopausal symptoms
0.6 Milligram Daily	
Batch:	Started: Stopped:
LIPITOR (Other drug)	Reason: Othr&unspec metabolic diseases
1.0 Dose Unspecified Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 221397	Seq: 1	Gender: F
Reported: 05/09/2006		Weight: 75.00
Hospitalisation: Required a visit to the doctor		Age: 76Y
Onset Date: 07/08/2006		DOB:
Outcome: Recovered	10/08/2006	Causality: Causality probable

Reaction Detail

Medicine Details:

LUVOX (Suspected)		Reason: Depression
	1.0 Dose Unspecified Daily	
Batch:	Started: 06/08/2006	Stopped: 09/08/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 222780 **Seq:** 1 **Gender:** M
Reported: 31/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 21
Onset Date: **DOB:** 09/04/1985
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Disorientation Disturbance in attention Dizziness Thinking abnormal		Nausea, dizziness, disorientation	

Medicine Details:

EPILIM (Suspected)	Reason: Depression
1.5 Milligram Daily Oral	
Batch: Started: 01/02/2004 Stopped: 13/10/2006 0	
LUVOX (Suspected)	Reason: Depression
212.0 Milligram Daily Oral	
Batch: Started: 01/02/2004 Stopped: 13/10/2006 0	
SEROQUEL (Suspected)	Reason: Depression
400.0 Milligram Daily Oral	
Batch: Started: 01/02/2004 Stopped: 13/10/2006 0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 222988 **Seq:** 1 **Gender:** F
Reported: 09/11/2006 **Weight:** 65.00
Hospitalisation: Required a visit to the doctor **Age:** 16
Onset Date: 25/09/2006 **DOB:** 21/01/1990
Outcome: Recovered 05/10/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mydriasis Therapy regimen changed		Dilated pupils only occurred when dose	

Medicine Details:

LUVOX (Suspected)		Reason: Depression
Tablet	50.0 Milligram	Daily Oral
Batch:	Started: 11/09/2006	Stopped: 05/10/2006
DEXAMPHETAMINE SULPHATE (Suspected)		Reason: Behavior disorders of childhood
	22.5 Milligram	Daily
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Similar reaction with Zoloft and dexamphetamine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 223720 **Seq:** 1 **Gender:** M
Reported: 04/12/2006 **Weight:** 0.00
Hospitalisation: **Age:** 75
Onset Date: **DOB:** 18/12/1930
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bradycardia		bradycardia hypotension	
Drug interaction			
Hypotension			

Medicine Details:

FAVERIN (Interaction)		Reason:	
Batch:	Started:	Stopped:	
REMINYL (Interaction)		Reason: Presenile dementia	
16.0 Milligram Daily			
Batch:	Started: 15/11/2004	Stopped: 0	
NOTEN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ASPIRIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reporter questioned whether fluvoxamine inhibits metabolism of galatamine: Yes, potent CYP2C9 inhibitors such as fluvoxamine have been shown to increase galantamine bioavailability



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 223720

Seq: 1

Gender: M

Reported: 04/12/2006

Weight: 0.00

Hospitalisation:

Age: 75

Onset Date:

DOB: 18/12/1930

Outcome: Recovered with sequelae

Causality: Causality possible

Reaction Detail

Medicine Details:

AZITHROMYCIN (Other drug)		Reason:
Batch:	Started:	Stopped:
ZOCOR (Other drug)		Reason:
Batch:	Started:	Stopped:
CORDARONE X (Other drug)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Reporter questioned whether fluvoxamine inhibits metabolism of galatamine: Yes, potent CYP2C9 inhibitors such as fluvoxamine have been shown to increase galantamine bioavailability



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 223728 **Seq:** 1 **Gender:** M
Reported: 04/12/2006 **Weight:** 0.00
Hospitalisation: **Age:** 60Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastric haemorrhage Gastrointestinal haemorrhage		Later shown to be a bleeding gastric polyp Patient experienced gastrointestinal bleeding while being treated with Luvox.	

Medicine Details:

LUVOX (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
ASPIRIN (Suspected)	Reason:
	Oral
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Not yet recovered but abating



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 224718 **Seq:** 1 **Gender:** M
Reported: 16/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 86Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension Cough Dysphagia Oedema peripheral Tachycardia		Hypertension, tachycardia, coughing, difficult swallowing, ankle oedema.	Covereyl was started after Luvox for the treatment of hypertension and was continued throughout

Medicine Details:

COVERSYL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: 15/10/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history: Stroke 2004.
Patient restarted Luvox and experienced same symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 224915 **Seq:** 1 **Gender:** F
Reported: 22/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 06/02/1977
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Remarkable rise in the serum level of	Clozaril dose reduced.

Medicine Details:

FLUVOXAMINE MALEATE (Interaction)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	15/11/2006
CLOZARIL (Interaction)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 23/04/1999	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/01/2007	Serum drug level				Clozapine levels: 1000, 2900, 2970, 1910 (a wk later), 1480 (6 d later), 1300 (6 d later)

Additional Information:

Patient suffered from treatment-resistant schizophrenia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 225072 **Seq:** 1 **Gender:** F
Reported: 24/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: 15/12/2006 **DOB:** 03/07/1973
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mental status changes	Caused or prolonged inpatient hospitalisation	Acutely mentally disturbed	
Vision blurred	Caused or prolonged inpatient hospitalisation	Blurred vision in left eye	
Expressive language disorder	Caused or prolonged inpatient hospitalisation	Difficulty finding the right word	

Medicine Details:

LUVOX (Suspected)		Reason:	
	100.0 Milligram	Daily	Oral
Batch:	Started: 15/11/2006	Stopped:	0
Abilify (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/11/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 225072 **Seq:** 1 **Gender:** F
Reported: 24/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: 15/12/2006 **DOB:** 03/07/1973
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gait disturbance	Caused or prolonged inpatient hospitalisation	Stumbling when walking	
Paraesthesia	Caused or prolonged inpatient hospitalisation	Tingling right hand	
Urinary incontinence	Caused or prolonged inpatient hospitalisation	Urinary incontinence	

Medicine Details:

LUVOX (Suspected)		Reason:	
	100.0 Milligram	Daily	Oral
Batch:	Started: 15/11/2006	Stopped:	0
Abilify (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/11/2006	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 225072

Seq: 1

Gender: F

Reported: 24/01/2007

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date: 15/12/2006

DOB: 03/07/1973

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LUVOX (Suspected)		Reason:	
	100.0 Milligram	Daily	Oral
Batch:	Started: 15/11/2006	Stopped:	0
Abilify (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/11/2006	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 225231 **Seq:** 1 **Gender:** M
Reported: 31/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 65Y
Onset Date: 19/01/2007 **DOB:**
Outcome: Recovered 12/02/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia		He would revisit places that he had been to days earlier and felt as though he had not been there for months, forgetting the names of friends	
Confusional state		Patient could not think clearly	
Mental impairment		reduced capacity for making decisions	

Medicine Details:

Movox (Suspected)	Reason: Depression
Tablet	50.0 Milligram 1 time Oral
Batch:	Started: 02/01/2007 Stopped: 22/01/2007 discontinued

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 225853

Seq: 1

Gender: M

Reported: 14/02/2007

Weight: 0.00

Hospitalisation:

Age: 49

Onset Date: 22/01/2007

DOB: 02/04/1957

Outcome: Recovered

06/02/2007

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Patient developed neutropenia.	filgrastim, gentamicin/Timentin

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression
Tablet	100.0 Milligram	Daily
Batch:	Started: L TERM	Stopped: 31/01/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/02/2007	Neutrophils		22/01/2007	0.0	
14/02/2007	Neutrophils		29/01/2007	0.1	
14/02/2007	Neutrophils		31/01/2007	0.6	
14/02/2007	Neutrophils		03/02/2007	6.4	
14/02/2007	Neutrophils		02/02/2007	2.0	
14/02/2007	Neutrophils		01/02/2007	0.5	
14/02/2007	White blood cells		22/01/2007	2.6	

Additional Information:

Patient used a mixture of Faverin, Luvox and Movox brands.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 225853

Seq: 1

Gender: M

Reported: 14/02/2007

Weight: 0.00

Hospitalisation:

Age: 49

Onset Date: 22/01/2007

DOB: 02/04/1957

Outcome: Recovered

06/02/2007

Causality: Causality possible

Reaction Detail

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)			Reason:	Depression		
Tablet	100.0	Milligram	Daily	Oral		
Batch:	Started:	L TERM	Stopped:	31/01/2007	0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/02/2007	White blood cells		29/01/2007	3.0	
14/02/2007	White blood cells		31/01/2007	2.9	
14/02/2007	White blood cells		01/02/2007	4.3	
14/02/2007	White blood cells		02/02/2007	6.0	
14/02/2007	White blood cells		03/02/2007	9.9	

Additional Information:

Patient used a mixture of Faverin, Luvox and Movox brands.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 226013

Seq: 1

Gender: M

Reported: 22/02/2007

Weight: 0.00

Hospitalisation:

Age: 49

Onset Date:

DOB: 02/04/1957

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Patient became severely neutropenic.	2 blood transfusions, ongoing doses of filgrastim.
Anaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FAVERIN (Suspected)	Reason: Depression
Batch:	Started: Stopped: 15/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/02/2007	Haemoglobin		31/01/2007	85	
22/02/2007	Neutrophils		11/01/2007	0.2	
22/02/2007	Neutrophils		01/02/2007	1.81	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 226646 **Seq:** 1 **Gender:** M
Reported: 14/03/2007 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 65Y
Onset Date: 19/01/2007 **DOB:**
Outcome: Recovered 29/01/2007 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Amnesia Somnolence		Patient started having trouble remembering things, forgot where the plates were kept in his kitchen, people's names, went shopping and forgot why and bought the wrong things. Couldn't drive as he would forget where he was going, forget to signal properly. More drowsy than usual, slept 1-2 hours every afternoon.	Movox ceased.

Medicine Details:

ASCORBIC ACID (Other drug)		Reason: Unspec vitamin deficien states	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	L TERM	Stopped: Continuing.
Movox (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 05/01/2007	Stopped:	21/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Etoh - nil, coffee 1 x 1/daily and tea 4 x 5/daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 227438 **Seq:** 1 **Gender:** M
Reported: 10/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: 15/02/2007 **DOB:** 29/05/1973
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paradoxical drug reaction Energy increased Euphoric mood		When patient took medication on first occasion it energised him for about 6-8 hours, could not sleep, patient started planning things, making invitations for friends to come and see him, cleaning, he seemed normal again, next day when did not take medication, fatigued, withdrawn	Ceased Stilnox.

Medicine Details:

STILNOX (Interaction)		Reason: Specific disorders of sleep	
Tablet	10.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped: 15/02/2007	
LUVOX (Interaction)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 15/01/2007	Stopped:	
ATIVAN (Other drug)		Reason:	
Batch:	Started: 15/02/2007	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 227467

Seq: 1

Gender: M

Reported: 11/04/2007

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia		Numbness in left side of face and leg,	
Lethargy		lethargy, malaise	
Malaise			

Medicine Details:

LUVOX (Suspected)		Reason: Depression	
Tablet	200.0 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 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 227710 **Seq:** 1 **Gender:** M
Reported: 18/04/2007 **Weight:** 75.00
Hospitalisation: Required a visit to the doctor **Age:** 21
Onset Date: 04/02/2007 **DOB:** 01/02/1986
Outcome: Recovered 06/02/2007 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Throat tightness Confusional state Dizziness Dysarthria Nausea Somnolence		Patient experienced a choking sensation, slept 19 hour a day for 3 days. Extreme dizziness, spilt things, nausea, confused as to what was real or a nightmare, grogginess and slurred speech.	Ceased Movox

Medicine Details:

Movox (Suspected)	Reason: Anxiety neurosis
Tablet 25.0 Milligram Daily Oral	
Batch:	Started: 02/02/2007 Stopped: 05/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 228521 **Seq:** 1 **Gender:** M
Reported: 15/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis		Hepatitis while being treated with Luvox.	

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox

Report Detail

Case Number: 229830 **Seq:** 1 **Gender:** F
Reported: 18/06/2007 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 77Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fall Abnormal sleep-related event Amnesia Hallucination Sleep walking		Over the 4 years the patient took Stilnox, she was plagued by hallucinations, falls and other bizarre behaviour.	Hospitalised several times for injuries. Ceased Stilnox.

Medicine Details:

EVISTA (Other drug)	Reason:
60.0 Milligram	
Batch:	Started: Stopped:
NOTEN (Other drug)	Reason:
50.0 Milligram	
Batch:	Started: Stopped:
PERIACTIN (Other drug)	Reason:
2.0 Dose Unspecified As necessary	
Batch:	Started: L TERM Stopped:
LIPITOR (Other drug)	Reason:
40.0 Milligram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 229830 Seq: 1

Gender: F

Reported: 18/06/2007

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 77Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug)		Reason:	
	500.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
OSTELIN 1000 (Other drug)		Reason:	
	2.0 Dose Unspecified	Daily	
Batch:	Started:	L TERM	Stopped:
DYAZIDE (Other drug)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started:	L TERM	Stopped:
STILNOX (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	15/01/2007

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
FAVERIN,FLUVOXAMINE MALEATE,LUVOX,Movox

Report Detail

Case Number: 229830	Seq: 1	Gender: F
Reported: 18/06/2007		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 77Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Medicine Details:

FAVERIN (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
			Contin

Laboratory Investigations:

Additional Information: