

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

eport Detail				
ase Number: 118890 Reported: 08/07/199 spitalisation: Onset Date: Outcome: Not yet re			c	Gender: F Weight: Age: DOB: Causality: Causality possible
action Detai	0010.00			audunty: Gadoanty possible
Preferred Term	Severity	Report Des	cription	Treatment
inary retention				Dose of luvox
edicine Details:		Reason:	Migraine	
5.44	240.0 N			
3atch: PILIM (Suspected)	Started:	L TERM	Stopped:	cified epilepsy
FILIM (Suspecteu)	0.0	(eason.	Otheraurisper	cined epilepsy
3atch:	Started:	L TERM	Stopped:	
UVOX (Suspected)		Reason:	Depression	
Tablet 3atch:	2.0 E	Oose Unspecified Daily S TERM	Stopped:	Oral
boratory Investigat	ions:			
Date Type	Range Date Teste	d Result		Details
		d Result		Details



Date 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 Detai

toaction Botal			_
Preferred Term	Severity	Report Description	Treatment
Mania			Chlorpromazine 200mg daily in divided doses
Affect lability		Elevated mood, religious preoccupation,	
Agitation		Psycomotor agitation, incr energy, reduced	

Medicine Details:

RANITIDINE (Other drug)	Reas		
	300.0 Milligram	Daily	
Заtch:	Started: 01/01/1996	Stopped:	CONTIN
LUVOX (Suspected)	- Real	son: Depression	
	50.0 Milligram	Daily	

3atch: 3tarted: 19/06/1997 3topped: 30/06/1997

Laboratory Investigations:

Date	Туре	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 Detai

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:

MEGICINE DELANS.				
MOGADON (Other drug)		Reason:	Specific disor	ders of sleep
Tablet	5.0 Milligr	am Daily	,	Oral
Зatch:	Started:	L TERM	Stopped:	
LUVOX (Suspected)		Reason:	Depression	
Tablet	50.0 Milligr	am Daily	,	Oral
3atch:	Started: 28/07/199	7	Stopped:	01/08/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

Report Detail

Case Number:121078Seq:1Gender:FReported:25/09/1997Weight:70.00Hospitalisation:Admitted to hospitalAge:56Y

Onset Date: 21/07/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

100000000000000000000000000000000000000		-	
Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures	
Coma			
Coordination abnormal			
Hyponatraemia			Icu, ventilation

Medicine Details:

FLUPHENAZINE DECANOATE (Other drug	1)		Reason:	Depression	
	2.5	Milligram	Daily		
3atch:	Started:		L TERM	Stopped:	22/07/1997
LITHIUM CARBONATE (Other drug)			Reason:	Depression	
	500.0	Milligram	Daily		
3atch:	Started:		L TERM	Stopped:	22/07/1997
GLIBENCLAMIDE (Other drug)			Reason:	Diabetes mell	litus
GLIBENCLAMIDE (Other drug)	2.5	Milligram	Reason: Daily	Diabetes mell	litus
GLIBENCLAMIDE (Other drug) 3atch:	2.5	ŭ		Diabetes mell	22/07/1997
		ŭ	Daily		
Satch:			Daily L TERM	Stopped:	

Laboratory Investigations:

	<u> </u>				
Date	Туре	Range	Date Tested	Result	Details
	Sodium				Na 118 lowest.



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

Seq: 1		Gender: F Weight: 60.00 Age: 70Y DOB: ausality: Causality possible
,	C	Weight: 60.00 Age: 70Y DOB: ausality: Causality possible
,		Age: 70Y DOB: ausality: Causality possible
		Age: 70Y DOB: ausality: Causality possible
Severity		DOB: ausality: Causality possible
Severity		ausality: Causality possible
Severity		
Severity	Report Description	i
Severity	Report Description	
		Treatment
	Reason: Depression	
100.0 M	lilligram Daily	
Started: 15/08	/1997 Stopped :	
ons:		
	d Result	Details
	Started: 15/08	100.0 Milligram Daily Started: 15/08/1997 Stopped:



Date 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 Detai

touction botal			
Preferred Term	Severity	Report Description	Treatment
Asthma			
Hypercapnia			
Hypoventilation			
Нурохіа	Severe		
Respiratory depression			

Medicine Details:

METHADONE HYDROCHLORIDE (Interact	ion)	Reason:
	70.0 Milligram	Daily
Зatch:	3tarted: 01/01/1996	Stopped: 07/08/1997
FLUVOXAMINE MALEATE (Interaction)		Reason: Depression
	100.0 Milligram	Daily
3atch:	3tarted: 01/07/1997	Stopped:
DIAZEPAM (Interaction)		Reason: Anxiety neurosis
	4.0 Milligram	Daily
3atch:	Started: 01/07/1997	Stopped: 07/08/1997
3atch: IPRATROPIUM BROMIDE (Other drug)	Started: 01/07/1997	\$topped: 07/08/1997 Reason:
	Started: 01/07/1997	· ·

Laboratory Investigations:

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

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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Date 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 Detai

Medicine Details:

Medicine Details.					
SPIRONOLACTONE (Other drug)	(Other drug)				
	200.0	Milligram	Daily		
3atch:	Started:			Stopped:	
RANITIDINE (Other drug)			Reason:		
	300.0	Milligram	Daily		
3atch:	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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Date 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 Detai

todotion Botal			
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

3atch: 3tarted: 24/09/1997 3topped: 26/09/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Recovered within days without treatment.



Date 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 Gender: F Seq: 1

Reported: 17/10/1997 Weight: 68.00 Hospitalisation: Age: 43Y

Onset Date: 15/08/1997 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Severe		

Medicine Details:

MURELAX (Other drug) 30.0 Milligram Daily 3tarted: 01/01/1986 3atch: Stopped:

Reason:

Specific disorders of sleep

LUVOX (Suspected) Reason: Depression

Tablet 0.5 Milligram Daily Oral 3atch: 3tarted: 28/07/1997 Stopped: 29/09/1997

Laboratory Investigations:

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

Re	por	t D	etail
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 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 Detai

Neaction Detai			
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
3atch:	Started:	30/09/1997		Stopped:	01/10/1997
LUVOX (Interaction)			Reason:	Depression	
Tablet	2	25.0 Milligram	Daily		Oral
3atch:	Started:	15/09/1997		Stopped:	01/10/1997
VENTOLIN (Other drug)			Reason:	Asthma	
VENTOLIN (Other drug)		0.0	Reason:	Asthma	
VENTOLIN (Other drug) 3atch:		0.0 23/09/1997	Reason:	Asthma Stopped:	
, J	Started:		Reason:		
3atch:	Started: drug)				

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

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 Detai

Preferred Term	Severity	Report Description	Treatment
Anorgasmia			Same reaction to zoloft

Medicine Details:

DAPA-TABS (Other drug)		Reason:	
	0.0		
Зatch:	Started:	Stopped:	
GAVISCON (Other drug)		Reason:	
	0.0		
3atch:	Started:	Stopped:	
ZOCOR (Other drug)		Reason:	
	0.0		
Зatch:	Started:	Stopped:	
3atch: LUVOX (Suspected)	Started:	Stopped: Reason: Depression	
	Started: 100.0 Milligram	•••	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 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 Detai

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

Medicine Details:

LUVOX (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 24/10/1997 3topped: 30/11/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date 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 Detai

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

Medicine Details:

FLUVOXAMINE MALEATE (Suspected) Reason: Depression

Tablet 100.0 Milligram Daily Oral

3atch: 3tarted: 12/12/1997 3topped: 19/12/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Possible earlier similar reaction to sertraline.



Date 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 Detai

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

Medicine Details:

LUVOX (Interaction)		Reason:	Depression
	20.0 Milligram	Daily	
Зatch:	Started: 18/11/1997		Stopped: 05/01/1998
ROCALTROL (Interaction)		Reason:	Other specified symptoms nec
Capsule	1.0 Milligram	Daily	Oral
Зatch:	Started: 01/01/1992		Stopped:
OROXINE (Other drug)		Reason:	Myxedema
Tablet	50.0 Microgram	Daily	Oral
3atch:	Started: 01/01/1967		Stopped:
PROGYNOVA (Other drug)		Reason:	Menopausal symptoms
PROGYNOVA (Other drug) Tablet	1.0 Milligram	Reason: Daily	

Laboratory Investigations:

Date	Туре	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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Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome			
Hallucination			

Medicine Details:

LUVOX (Suspected) Reason: Depression

150.0 Milligram Daily

3atch: **30/09/1997 3topped**:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



DOB:

Date 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

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Onset Date: 06/02/1998

Preferred Term	Severity	Report Description	Treatment
Mydriasis			

Medicine Details:

LUVOX (Suspected)	₹	eason: Depre	ssion	
Tablet	500.0 Milligram	Daily	Oral	
3atch:	Started: 05/02/1998	3to	pped:	
SERZONE (Suspected)	₹	eason: Depre	ssion	

300.0 Milligram Daily

3atch: 3tarted: 03/01/1998 3topped: 04/02/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

Report Detail

Case Number:125073Seq:1Gender:FReported:18/02/1998Weight:64.00Hospitalisation:Admitted to hospitalAge:37Y

Onset Date: 15/01/1998 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Hepatitis		Fluvoxamine-induced hepatitis.	
Dehydration	Severe	Patient significantly dehydrated.	
Diarrhoea	Severe		Patient hospitalised. intravenous rehydration.
Vomiting			Till Voyamino oogeod

Medicine Details:

LUVOX (Suspected)		Reason:	Depression	
Tablet	50.0 Milligram	Daily		Oral
3atch:	Started: 14/01/1998		Stopped:	19/01/1998

Laboratory Investigations:

Date	Туре	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	



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Tremor Severe			Discontinued luvox.

Medicine Details:

Medicine Details.				
PETHIDINE HYDROCHLORIDE (Other of	drug)	Reason: Migraine		
Injection	100.0 Milligram	As necessary	Intravenous	
3atch:	Started:	Stopped:		
LUVOX (Suspected)		Reason: Depression		
Tablet	0.0		Oral	
3atch:	3tarted: 30/01/1998	Stopped:	02/02/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Possible interaction with pethidine. "serotonin syndrome".



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

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

3atch: 3tarted: S TERM **3topped:** 04/03/1998

FLUVOXAMINE MALEATE (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 20/02/1998 3topped: 26/02/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

Re	po	rt	D	et	ai∣
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 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 Detai

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

Medicine Details:

DIAZEPAM (Other drug)	Reason: Lumbalgia
Tablet	5.0 Milligram As necessary Oral
3atch:	Started: 27/02/1998 Stopped:
CODALGIN FORTE (Other drug)	Reason: Lumbalgia
	2.0 Dose Unspecified As necessary
3atch:	Started: 27/02/1998 Stopped:
LUVOX (Suspected)	Reason: Depression
	50.0 Milligram Daily
3atch:	Started : 20/03/1998 Stopped : 24/03/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number: 127250 Reported: 06/05/19	Seq: 98	1	Gender: F Weight:				
lospitalisation:			Age:				
Onset Date:					DOB:		
Outcome: Unknown	า			Cau	sality: Causality possible		
eaction Detai							
Preferred Term	Seve	erity	Report	Description	Treatment		
Oedema							
Medicine Details:							
ZYPREXA (Suspected)			Reaso	on:			
Tablet		0.0			ral		
3atch:	3ta	rted:		Stopped:			
FLUVOXAMINE MALEATE (S	uspected)	0.0	Reaso	on:			
Зatch:	3ta	rted:		Stopped:			
Laboratory Investiga	tions:						
Date Type	Range	Date Tested	Result		Details		
Additional Information	nn:						
Additional information	711.						
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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:
 127465
 Seq: 1
 Gender:
 F

 Reported:
 15/05/1998
 Weight:
 70.00

Hospitalisation: Age: 65Y
Onset Date: 31/05/1998
DOB:

Onset Date: 31/05/1998

Outcome: Recovered

Causality: Causality probable

Reaction Detai

cuotion betai								
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

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Luvox ceased

Medicine Details:

LUVOX (Suspected) Reason: Depression

250.0 Milligram Daily

3atch: 3tarted: 12/03/1998 3topped: 14/05/1998

Laboratory Investigations:

Date	Туре	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:127838Seq:1Gender:FReported:27/05/1998Weight:Hospitalisation:Admitted to hospitalAge:56Y

Onset Date: 13/04/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

10404011 20441			
Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage		Gastrointestinal tract bleed	Admitted to icu - transfusion
Anaemia			
Haematemesis			
Prothrombin level decreased			

Medicine Details:

COUMADIN (Interaction)		Reason:		
	5.0 Milligram	Daily		
Зatch:	3tarted: 01/01/1990		Stopped:	
LUVOX (Interaction)		Reason:	Depression	
	100.0 Milligram	Daily		
3atch:	3tarted: 16/03/1998		Stopped:	13/04/1998
LARGACTIL (Interaction)		₹eason:	Depression	
LAITOAOTIL (IIIteraction)		Reason.	Depression	
LANGACTIE (IIIteraction)	50.0 Milligram	Daily	Depression	
3atch:	50.0 Milligram Started: 16/03/1998		Stopped:	13/04/1998
, ,	· ·		·	13/04/1998
3atch:	· ·	Daily	·	13/04/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin				Haemoglobin 2.6
	International				Inr on admision > 20

Additional Information:

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: 12783 Reported: 27/05/ Hospitalisation: Admitt Onset Date: 13/04/ Outcome: Recov Reaction Detai	1998 ed to hospital 1998		Gender: Weight: Age: DOB: Causality:	56Y
Medicine Details: SPAN-K (Other drug)		Reas o 1.2 Gram	on: Daily	
Заtch:	Started:	L TERM	Stopped:	
LANOXIN (Other drug)	107	Reason 7.0 Microgram		
3atch:	Started:	7.0 Microgram L TERM	Daily Stopped:	
Laboratory Investig	gations:			
Additional Information does not be dosage start date is not be a second or s		that start occurred so	metime 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:
 128095
 Seq: 1
 Gender: M

 Reported:
 05/06/1998
 Weight:

Hospitalisation: Hospitalisation prolonged
Onset Date: 24/05/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

10404011 2044		-	-
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	
3atch:	Started: 22/05/1998		Stopped:		CONTIN
ENDONE (Suspected)		Reason:	Pain		
Tablet	30.0 Milligram	Daily		Oral	
3atch:	Started: 21/05/1998		Stopped:		CONTIN
LUVOX (Suspected)		Reason:	Depression		
Tablet	100.0 Milligram	Daily		Oral	
3atch:	Started: 21/05/1998		Stopped:	25/05/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient had similar reaction to fluoxetine



Date 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 Detai

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
Syncope		Fainting	
Dizziness		Light headed	
Nausea			Luvox ceased
Vomiting			

Medicine Details:

LUVOX (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 17/04/1998 3topped: 20/04/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



DOB:

Date 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

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Onset Date: 31/01/1998

Preferred Term	Severity	Report Description	Treatment
Hyperthyroidism			Propyl thiouracil

Medicine Details:

WARFARIN SODIUM (Other drug)		Reason:		
Tablet	4.0 Milligram	Daily	Oral	
3atch:	3tarted: 01/01/1995		Stopped:	CONTIN
ZESTRIL (Other drug)		Reason:		
Tablet	20.0 Milligram	Daily	Oral	
3atch:	3tarted: 01/01/1995		Stopped:	CONTIN
AMIODARONE HYDROCHLORIDE (Suspected)		Reason: Pro	phylaxis	
Tablet	200.0 Milligram	Daily	Oral	
3atch:	Started: 01/01/1996		Stopped:	CONTIN
FLUVOXAMINE MALEATE (Suspected)		Reason: Ob	sessive compulsive	neurosis
Tablet	150.0 Milligram	Daily	Oral	
3atch:	Started: 01/01/1996		Stopped: 28/02/	1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run 01/08/200 01:35PN Database: pusime ADRS004 Page 28 of 326

⁻ 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.



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

Report D)etail
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 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 Detai

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

Medicine Details:

OGEN (Other drug)		Reason:				
	0.0					
Зatch:	Started:		Stopped:			
PROVERA (Other drug)		Reason:				
	0.0					
Зatch:	Started:		Stopped:			
RANITIDINE (Other drug)		Reason:				
	150.0 Milligram	Daily				
Зatch:	3tarted: 01/01/1995		Stopped:	28/05/1997		
LUVOX (Suspected)		Reason: De	epression			
	1.0 Dose Unsp	pecified Daily				
Зatch:	3tarted: 01/05/1998		Stopped:	28/06/1998	2W	

Laboratory Investigations:

ĺ	Date	Туре	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.



Date 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 Detai

104011011 20141			-
Preferred Term	Severity	Report Description	Treatment
Mania			Commenced rivotril and ceased luvox and sandomigran.

Medicine Details:

Micarchic Details.			
LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
3atch:	Started: 01/06/1997	Stopped:	28/07/1998
SANDOMIGRAN (Suspected)		Reason: Headache	
	1.5 Milligram	Daily	
3atch:	Started: 02/05/1998	Stopped:	23/05/1998

Laboratory Investigations:

Date	Туре	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.

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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:128765Seq:1Gender:FReported:29/06/1998Weight:Hospitalisation:Admitted to hospitalAge:

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

ZYPREXA (Suspected)	₹	eason:		
Tablet	20.0 Milligram	Daily	Oral	
3atch:	Started: 01/05/1998	Stopped:	28/06/1998	1M
LUVOX (Suspected)	₹	eason:		
Tablet	300.0 Milligram	Daily	Oral	
3atch: Started:		Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 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 Detai

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

Medicine Details:

 FLUVOXAMINE MALEATE (Suspected)
 Reason:
 Depression

 Tablet
 100.0
 Milligram
 Daily
 Oral

3atch: 3tarted: 01/03/1998 3topped: 28/04/1998

Laboratory Investigations:

Date	Туре	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.

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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

Rep	00	rt	D	eta	il
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Case Number:129061Seq:1Gender:FReported:09/07/1998Weight:35.00Hospitalisation:Admitted to hospitalAge:73Y

Onset Date: 30/06/1998 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason:	Depression
	0.0		
Зatch:	Started:		Stopped:
PLENDIL ER (Suspected)		Reason:	Essential benign hypertension
	5.0 Milligra	m Daily	1
3atch:	Started:		Stopped:
CLONAZEPAM (Suspected)		Reason:	
	500.0 Microgr	am Daily	1
3atch:	Started:		Stopped:
TEMAZEPAM (Suspected)		Reason:	
	10.0 Milligra	m Daily	1
3atch:	Started:		Stopped:

Laboratory Investigations:

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



Date 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 Detai

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

Medicine Details:

SERZONE (Suspected) Reason: Depression

0.0

3atch: 3tarted: 3topped: 29/06/1998

LUVOX (Suspected) Reason: Depression

50.0 Milligram Total

3atch: **3tarted**: 01/07/1998 **3topped**: 01/07/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date 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 Detai

todotion Botai	dotton Botan				
Preferred Term	Severity	Report Description	Treatment		
Amenorrhoea			Ceased luvox. therapy changed to zoloft.		

Medicine Details:

LUVOX (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 01/10/1997 3topped: 28/04/1998

Laboratory Investigations:

Date	Туре	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.

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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: 129375 Reported: 23/07/1998 ospitalisation:			Ag	nt: 95.00 e: 24Y			
Onset Date: 03/06/1998 Outcome: Recovered			DO Causalit	ន: y: Causality probable			
eaction Detai			,				
Preferred Term	Severity	Report	Description	Treatment			
Erectile dysfunction							
Medicine Details: LUVOX (Suspected)		20250	n:				
LOVON (Guspecteu)	200.0 Mi	Reason: 200.0 Milligram Daily					
3atch:	Started: 02/06/1998 Stopped: 04/06/1998						
_aboratory Investigatio	O NS: Range Date Tested	Result	D	etails			



Date 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 Detai

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

Medicine Details:

 LUVOX (Suspected)
 Reason:
 Depression

 Tablet
 100.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 29/06/1998
 3topped: 16/07/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
		Mild swelling of hands, feet and lower	Luvox ceased.

Medicine Details:

Micarcine Betans.			
LARGACTIL (Other drug)		Reason: Anxiety neurosis	
	100.0 Milligram	1 time	
Зatch:	Started: 18/07/1998	Stopped: 18/07/1998	
ATIVAN (Other drug)		Reason: Anxiety neurosis	
Tablet	1.0 Milligram	Daily Oral	
Зatch:	Started: 18/12/1997	Stopped:	
LUVOX (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily Oral	
3atch:	Started: 17/07/1998	Stopped: 22/07/1998	

Laboratory Investigations:

Date	Туре	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.

Report Run 01/08/200 01:35PN Database: pusime ADRS004 Page 38 of 326



Date 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 Detai

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

Medicine Details:

LITHIUM CARBONATE (Other drug)		₹eason:			
Tablet	1.2 Gram	Daily		Oral	
3atch:	Started: 01/01/1994		Stopped:		CONTIN
ZYPREXA (Suspected)		₹eason:	Schizophrenia	ĺ	
Tablet	10.0 Milligram	Daily		Oral	
3atch:	Started: 31/07/1998		Stopped:	10/08/1998	
LUVOX (Suspected)		₹eason:	Depression		
Tablet	100.0 Milligram	Daily		Oral	
Зatch:	3tarted: 31/07/1998		Stopped:		CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 1989 To 31 Dec 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 Detai

•	caction botal			
	Preferred Term	Severity	Report Description	Treatment
F	Purpura		Widespread limbs and truncal ecchymosis	
1	Nausea	Severe		Luvox ceased
١	Vomiting	Severe		

Medicine Details:

XANAX (Other drug)	₹e.	ason:	
Tablet	500.0 Microgram	Daily	Oral
3atch:	Started: 01/01/1997	Stopped:	CONTIN
LUVOX (Suspected)	₹e.	ason: Depression	
(•	
Tablet	100.0 Milligram	Daily	Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report	: Detail
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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 Detai

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

Medicine Details:

Medicine Details.					
DIAZEPAM (Other drug)	Reason:				
	5.0 Milligram	As necessary			
3atch:	Started:	Stopped:			
LUVOX (Suspected)		Reason: Depression			
Tablet	100.0 Milligram	Daily	Oral		
3atch:	Started: 23/07/1998	3topped:	24/08/1998		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

_	etail						
	ber: 131160	Seq:	1			Gend	
_	ted: 14/09/1998	3				_	ht: 72.00
ospitalisat							ge: 59Y
Onset D						DO	
	me: Recovered				•	Jausaii	ty: Causality probable
action D	eferred Term	Seve	rity	Renor	Description		Treatment
	phageal reflux dis		inty	ТСРОП	Bescription		rredunent
ledicine LUVOX (Sus	Details:			Reas	on: Depression		
			50.0 Mill	iarom			
					Daily		
3atcl	h:	3tar	ted: 04/09/1		Stopped:	08/09/1	1998
	ry Investigatio	ons:					1998 Details



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

Report	: Detail
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 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 Detai

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

Medicine Details:

Medicine Details.			
CLOZAPINE (Interaction)		Reason:	
	0.0		
3atch:	Started:	Stopped:	
LUVOX (Interaction)		Reason:	
	0.0		
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Seq: 1	Gen	der: F
3	Wei	ght: 90.00
	,	Age: 35Y
		OB:
covered	Causa	ality: Causality possible
		•
Severity	Report Description	Treatment
S	pots on face, papules over nose & cheek	
	Reason:	
0.0		
Started:	Stopped:	
	Reason:	
1.0	Gram Daily	
Started:	Stopped:	
	Reason:	
300.0	Milligram Daily	
Started:	L TERM Stopped :	
Started:	Reason:	
30.0	Reason: Milligram Daily	
Started:	Reason:	
Started: 30.0 Started:	Reason: Milligram Daily	
30.0	Reason: Milligram Daily L TERM Stopped:	Details
	Severity 0.0 Started:	Severity Report Description Spots on face, papules over nose & cheeks Reason: 0.0 Started: Stopped: Reason: 1.0 Gram Daily Started: Stopped: Reason:



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

Rei	port	: Det	tail
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 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 Detai

104011011 20141		-	
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

 3atch:
 3tarted:
 26/08/1998
 3topped:
 04/09/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Anxiety		Anxious for 2 - 3 days after one tablet	
Disturbance in attention		Could not concentrate on conversation for	
Amnesia		Could not retain information from	
Visual disturbance		Experienced lightning flashes in both eyes	
Drug ineffective		Generally depressed for 2-3 days after one	
Depersonalisation		1-1-1	

Medicine Details:

LUVOX (Suspected)	Reason:				
Tablet	1.0	Dose Unspecified	1 time	Oral	
3atch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Chills			
Dizziness			

Medicine Details:

Modifile Botalie.			
LUVOX (Suspected)	र	eason: Depression	
Tablet	100.0 Milligram	Daily	Oral
3atch:	Started: 01/10/1997	Stopped:	
LITHICARB (Suspected)		eason:	
Tablet	750.0 Milligram	Daily	Oral
3atch:	Started: 01/12/1997	Stopped:	
NUROFEN (Suspected)		eason: Pain in joint	
Tablet	2.0 Dose Unspecific	ed Daily	Oral
3atch:	Started: 11/10/1998	Stopped:	12/10/1998

Laboratory Investigations:

Date	Туре	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.

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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: 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 Detai

104041011 20441			
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:DepressionCapsule100.0MilligramDailyOral

3atch: 3tarted: 01/10/1998 3topped: 05/10/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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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

Caso Numl						
Case Nulli	ber: 133200	Seq:	1		Gene	der: F
Report	ted: 16/11/1998	_			Wei	ght: 55.00
ospitalisati						. ge : 38
-	ate: 28/10/1998	3				OB : 13/02/1960
	me: Not yet red					lity: Causality possible
eaction D		overed			Gausa	iity. Causality possible
	ferred Term	Seve	rity	Report De	escription	Treatment
		0070	inty	report Be	2001ption	rreatment
lyperhidros	is					
nsomnia						
Nausea						
Pruritus						
Rash						
ledicine LUVOX (Susi	Details:			Reason:	Depression	
(,		1.0 Dose	e Unspecified Da		
3atch	·•	Start	ted: 14/09/19		stopped: 12/11	/1998
ahorator	v Investigati	one:				
_aborator	y Investigati _{Type}		Date Tested	Result		Details
			Date Tested	Result		Details



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Blurred peripheral vision	

Medicine Details:

LISINOPRIL (Other drug)		Reason:	Essential benign hypertension	
	10.0 Milligram	Daily		
3atch:	3tarted: 01/01/1994		Stopped:	CONTIN
FLUVOXAMINE MALEATE (Suspected)		Reason:	Depression	
	150.0 Milligram	Daily		

3atch: 3tarted: 24/09/1998 **3topped:** CONTIN

Laboratory Investigations:

Date	Туре	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.

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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:
 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 Detai

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

Medicine Details:

 LUVOX (Suspected)
 Reason:
 Depression

 Tablet
 100.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 15/10/1998
 \$topped:
 26/11/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient stopped breast feeding at age 46.



Date 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 Detai

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

3atch: 3tarted: 23/09/1998 3topped: 04/11/1998

Laboratory Investigations:

 <u>-uporator</u>	y mivoongat				
Date	Туре	Range	Date Tested	Result	Details
	Other data				Assessed by opthalmologist. diagnosis of oscillopathy which is apparently a cerebellar effect.

Additional Information:

Similar response to prozac several years ago



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

		Seq: 8	1		We	nder: F eight: Age: 20 DOB: 12/11/1978
	ome: Recovered	d				ality: Causality possible
action D	Detai					_
Pre	eferred Term	Sev	erity	Report De	scription	Treatment
rothrombin	n level decreased	d				Fluvoxamine discontinued.
	Details: SODIUM (Interactio	on)		Reason:		
			0.0			
3atcl			arted:	L TERM	Stopped:	
FLUVOXAMINE MALEATE (Interaction)				Reason:		
Ratcl	h:	Sta		Unspecified Tota		
3atcl			3.0 Dose	Reason:	itopped:	
	h: FRACEPTIVE NOS (
	RACEPTIVE NOS (Other drug)	arted:			
3atcl aborator	ry Investigati	Other drug) Sta	o.0	Result	Stopped:	Details
3atcl	raceptive nos (h: ry Investigati	Other drug) Sta	0.0 arted:	Result	Stopped:	Details



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

Report I	Jetaii
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 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 Detai

Preferred Term	Severity	Report Description	Treatment
Purpura	Excessive bruising		

Medicine Details:

Medicine Details.			
BREVINOR (Other drug)		Reason:	
	0.0		
Зatch:	Started:	Stopped:	
LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily Oral	
3atch:	Started: 04/11/1998	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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	Gender: M			
Reported: 12/01/1999		Weight: 69.00			

Hospitalisation: Age: 20Y
Onset Date: 01/12/1998
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Nausea			

Medicine Details:

LUVOX (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 01/12/1998 3topped: 04/12/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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
 Gender: M

 Reported:
 15/01/1999
 Weight:

Hospitalisation: Age: 72Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

todotion Botal	_		
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

3atch: Started: Stopped: 2M

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Onset Date: Outcome: Reconction Detai Preferred Termolence inary incontinence edicine Details: OXEPIN HYDROCHLOR Batch: LUVOXAMINE MALEAT	covered rm S BRIDE (Other drug)	0.0 Started:	Report	Description	Weight: Age: DOB: Causality: C	ausality possible Treatment
Outcome: Reconstruction Detail Preferred Termolence Innary incontinence Details: DOXEPIN HYDROCHLOR Satch: LUVOXAMINE MALEAT Satch: ELOZARIL (Suspected)	rm S	0.0		Description	DOB:	
Outcome: Reconction Detail Preferred Termolence mary incontinence edicine Details: OXEPIN HYDROCHLOR 3atch: LUVOXAMINE MALEAT 3atch: LOZARIL (Suspected)	rm S	0.0		Description		
Preferred Termolence inary incontinence inary inary incontinence inary inary incontinence inary i	rm S	0.0		Description	Causality: C	
Preferred Termolence inary incontinence inary inary incontinence inary in	RIDE (Other drug)	0.0				Treatment
edicine Details: OXEPIN HYDROCHLOR 3atch: LUVOXAMINE MALEAT 3atch:	RIDE (Other drug)	0.0				Treatment
edicine Details: OXEPIN HYDROCHLOI 3atch: LUVOXAMINE MALEAT 3atch:	RIDE (Other drug)		Reaso	on:		
edicine Details: DOXEPIN HYDROCHLOR 3atch: LUVOXAMINE MALEAT 3atch: CLOZARIL (Suspected)	RIDE (Other drug)		Reaso	on:		
3atch: LUVOXAMINE MALEAT 3atch: 3atch:	RIDE (Other drug)		Reaso	on:		
OXEPIN HYDROCHLOI 3atch: LUVOXAMINE MALEAT 3atch: LOZARIL (Suspected)	RIDE (Other drug)		Reaso	on:		
OXEPIN HYDROCHLOI 3atch: LUVOXAMINE MALEAT 3atch: LOZARIL (Suspected)	RIDE (Other drug)		Reaso	on:		
OXEPIN HYDROCHLOI 3atch: LUVOXAMINE MALEAT 3atch: LOZARIL (Suspected)	RIDE (Other drug)		Reaso	on:		
OXEPIN HYDROCHLOI 3atch: LUVOXAMINE MALEAT 3atch: LOZARIL (Suspected)	RIDE (Other drug)		Reaso	on:		
OXEPIN HYDROCHLOI 3atch: LUVOXAMINE MALEAT 3atch: LOZARIL (Suspected)	RIDE (Other drug)		Reaso	n:		
OXEPIN HYDROCHLOI 3atch: LUVOXAMINE MALEAT 3atch: LOZARIL (Suspected)	RIDE (Other drug)		Reaso	on:		
3atch: Satch: Satch: Satch: Satch: Satch: Satch: CLOZARIL (Suspected)	RIDE (Other drug)		Reaso	n:		
3atch: LUVOXAMINE MALEAT 3atch: 3atch:	RIDE (Other drug)		Reaso	n:		
3atch: LUVOXAMINE MALEAT 3atch: LOZARIL (Suspected)			Reaso	on:		
LUVOXAMINE MALEAT 3atch: CLOZARIL (Suspected)	TE (Suspected)					
BLUVOXAMINE MALEAT Batch: CLOZARIL (Suspected)	TE (Suspected)	started.		M		
3atch: LOZARIL (Suspected)	I E (Suspectea)	Juitou.	>	Stopped:		
LOZARIL (Suspected)		0.0	Reaso	on:		
LOZARIL (Suspected)		0.0 Started:		Mannada		
		Started:		Stopped:	ahi=anhrania	
		600.0 Milligrar		Reason: Unspecified schizophrenia am Daily Oral		
Batch:		3tarted: 13/11/199		Stopped:	Olai	3M
Saton:		started: 13/11/1	1997	stopped:		SIVI
aboratory Inves		Date Tested	Result		Details	
Date Type	range	Bute resteu	resuit		Detailo	



Date 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:
Onset Date: 31/10/1998
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

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

Medicine Details:

HALDOL DECANOATE (Other drug)		₹e	ason:	Unspecified pa	sychosis	
Injection	50.0	Milligram	Month	nly	Intramuscular	
Зatch:	Started:	L TER	RM	Stopped:		CONTIN
NORMISON (Other drug)		₹e	ason:	Specific disord	ders of sleep	
	2.0	Dose Unspecifie	ed Daily			
Зatch:	Started:	L TER	RM	Stopped:		CONTIN
VALIUM (Other drug)		₹e	ason:	Anxiety neuro	sis	
	2.0	Milligram	Daily			
3atch:	Started:	L TER	RM	Stopped:		CONTIN
LUVOX (Suspected)		₹e	ason:	Depression		
Tablet	150.0	Milligram	Daily		Oral	
3atch:	Started: 01	/06/1998		Stopped:	28/01/1999	

Laboratory Investigations:

Date	Туре	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.

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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: 136302 Gender: F Seq: 1 Reported: 16/02/1999 Weight:

Hospitalisation: **Age: 39Y** Onset Date: 29/01/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

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

Medicine Details:

PERINDOPRIL (Other drug) Reason: Essential benign hypertension 0.0

Started: 28/01/1999 3atch: Stopped:

FLUVOXAMINE MALEATE (Suspected) Reason: Depression

Tablet 200.0 Milligram Daily Oral 3atch: 3tarted: 04/08/1998 Stopped: 28/01/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date 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 Detai

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

Medicine Details:

COGENTIN (Other drug)		Reason: Unspecified schizophrenia
	1.0 Milligram	Daily
3atch:	Started: 01/01/1997	Stopped:
LARGACTIL (Other drug)		Reason: Unspecified schizophrenia
	200.0 Milligram	Daily
3atch:	3tarted: 01/01/1997	Stopped:
DIAZEPAM (Other drug)		Reason: Unspecified schizophrenia
	5.0 Milligram	Daily
3atch:	3tarted: 01/01/1997	Stopped:
LUVOX (Suspected)		Reason: Depression
Tablet	100.0 Milligram	Daily Oral
3atch:	Started: 01/08/1998	Stopped: 08/02/1999

Laboratory Investigations:

Date	Туре	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.

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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: 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 Detai

100000000000000000000000000000000000000		-	-
Preferred Term	Severity	Report Description	Treatment
Hypertonia		Abdominal and jaw muscles spasm	
Depersonalisation		Feel.of watchi.herself & ot people from a	
Nausea		-1:-1	
Tremor			

Medicine Details:

MEGICINE DELANS.				
NORIMIN (Other drug)	- Rea	son: Cor	ntraception	
Tablet	1.0 Dose Unspecified	l Daily	Oral	
Зatch:	Started:	3	Stopped:	CONTIN
LUVOX (Suspected)	- Rea	son: Dep	oression	
Tablet	100.0 Milligram	1 time	Oral	
3atch:	Started: 30/01/1999	3	Stopped: 30/01/1999	9

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Allergic to iodine and septrim.



Date 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 Detai

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
3atch:	Started: 28/01/1999		Stopped:	CONTIN
ALDAZINE (Suspected)		Reason:	Otr spec symp	psychopathol nec
ALDAZINE (Suspected) Tablet	50.0 Milligram	Reason: Daily	Otr spec symp	o psychopathol nec Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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		Gen	der: F		
Reported: 05/03/1			We	ight: 85.00		
Hospitalisation:				Age : 28Y		
Onset Date: 30/11/1				OOB:		
Outcome: Recove	red		Causa	ality: Causality possible		
Reaction Detai Preferred Term	Severity	Report Des	porintion	Treatment		
	·	•	scription	Пеашет		
Myalgia Bronchospasm	Acr	nes & pains.				
Generalised oedema						
Medicine Details: LUVOX (Suspected) Tablet	100.0 Mi	Reason: Illigram Daily	Depression / Oral			
3atch:	Started: 17/11/	1998	3topped: 22/0	1/1999		
Laboratory Investigations:						
Date Type	Range Date Tested	Result		Details		
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:
 137312
 Seq:
 1
 Gender:
 M

 Reported:
 16/03/1999
 Weight:
 70.00

 Hospitalisation:
 Age:
 62Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Prothrombin level decreased			

Medicine Details:

LUVOX (Suspected) Reason:

0.0

3atch: 3tarted: 03/02/1999 3topped:

Laboratory Investigations:

Date	Туре	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, asprin, prazosin, & warfarin.



Date 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 Detai

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

Medicine Details:

LUVOX (Suspected) Reason: Depression

100.0 Milligram 2 times

3atch: 3tarted: 03/04/1999 **3topped:** 04/04/1999

Laboratory Investigations:

Date	Туре	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 medci- iation was stopped. taking no other medications and no illicit drugs, no herbal remedies, was not using alcohol.

Report Run 01/08/200 01:35PN Database: pusime ADRS004 Page 65 of 326



Date 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.

Reported: 07/05/1999 Weight: 55.00 Hospitalisation: Age: 29Y

Onset Date: 01/04/1999 **DOB**:

Outcome: Recovered with sequelae Causality: Causality probable

Reaction Detai

todotion botal		_	
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

3atch: 3tarted: 22/03/1999 3topped: 06/04/1999

Laboratory Investigations:

Date	Туре	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.

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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: 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 Detai

todotion Dotai		E	
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

 3atch:
 3tarted:
 16/12/1998
 \$topped:
 09/04/1999

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

todotion Botal		_	
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		-1	
Obesity			

Medicine Details:

OLANZAPINE (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral	
3atch:	Started: 01/01/1999		Stopped: 07/05/1999	
LARGACTIL (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	150.0 Milligram	Daily	Oral	
3atch:	Started: 01/01/1999		Stopped: 07/05/1999	
LUVOX (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	100.0 Milligram	Daily	Oral	
3atch:	Started: 01/01/1999		3topped: 07/05/1999	

Laboratory Investigations:

	<u> </u>						
Date	Туре	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.

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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
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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 Detai

Preferred Term	Severity	Report Description	Treatment
Gingivitis			

Medicine Details:

LUVOX (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 26/12/1998 3topped: 26/01/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

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

Medicine Details:

LUVOX (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 18/05/1999 3topped: 22/05/1999

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Astigmatism	

Medicine Details:

LUVOX (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 30/04/1999 **3topped:**

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date 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 Detai

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

Medicine Details:

Medicine Details.					
LUVOX (Suspected)		Reason:	Depression		
Tablet	100.0 Milligram	Daily		Oral	
3atch:	Started: 28/04/1999		Stopped:	09/06/1999	
METHADONE HYDROCHLORIDE	Reason:	: Dependence on unspecifid drugs			
Oral application	40.0 Milligram	Daily		Oral	
3atch:	Started: 02/06/1999		3topped:		CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

Report	Detail
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 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 Detai

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Somnolence			

Medicine Details:

 LUVOX (Suspected)
 Reason:
 Depression

 Tablet
 100.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 26/06/1999
 \$topped: 27/06/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

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116	\mathbf{v}		\boldsymbol{L}	CLA	ш

 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 Detai

todotion Dotal		E	
Preferred Term	Severity	Report Description	Treatment
Libido decreased		Also decreased arousal	
Anorgasmia			

Medicine Details:

LUVOX (Suspected)

0.0

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

FLUVOXAMINE MALEATE (Suspected) Reason:

Oral application 100.0 Milligram Daily Oral

3atch: Started: Stopped: 01/07/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report D)etail
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 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 Detai

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

Medicine Details:

LUVOX (Suspected) Reason: Depression

300.0 Milligram Daily

3atch: 3tarted: 03/03/1999 3topped: 23/07/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

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

Medicine Details:

LUVOX (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 12/06/1999 3topped:

Laboratory Investigations:

Date	Туре	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 presciption med other than antibiotics. patient has very mild milk-allergy with resp symptoms.



Date 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 Detai

			=
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	
3atch:	Started: 01/07/1999		Stopped:	12/08/1999	3W
NATRILIX (Suspected)		Reason:	Essential ben	ign hypertension	
Tablet	2.5 Milligram	Daily		Oral	
3atch:	Started:		Stopped:	12/08/1999	
COUMADIN (Suspected)		Reason:	Prophylaxis		
Tablet	6.5 Milligram	Daily		Oral	
3atch:	Started: 01/01/1992		3topped:		CONTIN

Laboratory Investigations:

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

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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: 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 Detai

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

3atch: Started: 01/01/1999 Stopped:

Laboratory Investigations:

Date	Туре	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.

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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

Reported: 05/11/1999	Seq: 1	Gender: U Weight:			
Onset Date:			Age: 42Y DOB:		
Outcome: Unknown				y: Causality possible	
ction Detai			-		
Preferred Term erapeutic response unexpecte	Severity	Report	Description	Treatment	
edicine Details:		Reaso	n:		
ov ox (odopostou)	150.0		Daily		
3atch:	Started:		Stopped:		
aboratory Investigations Date Type Ra	iange Date To	ested Result	De	etails	
		ested Result	De	etails	
Date Type Ra		ested Result	De	etails	



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

 Case Number:
 145571
 Seq: 1
 Gender: M

 Reported:
 09/11/1999
 Weight:
 65.00

 Hospitalisation:
 Age: 33Y

Hospitalisation: Age: 3
Onset Date: 04/10/1999
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			

Medicine Details:

Medicine Details.			
MELLERIL (Suspected)		Reason:	
	50.0 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN
LUVOX (Suspected)		Reason: Depression	
	100.0 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

reaction Detai	ā.		
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 disor	ders of sleep
Oral application	30.0 Milligram	Daily		Oral
3atch:	3tarted: 15/10/1999		Stopped:	CONTIN
FLUVOXAMINE MALEATE (Suspected)		Reason:	Depression	
Tablet	100.0 Milligram	Daily		Oral
3atch:	3tarted: 27/10/1999		Stopped:	18/11/1999
PAROXETINE HYDROCHLORIDE (Suspec	eted)	Reason:	Depression	
Tablet	20.0 Milligram	Daily		Oral
3atch:	Started: 13/10/1999		Stopped:	26/10/1999
SODIUM VALPROATE (Suspected)		Reason:	Otr spec symp	psychopathol nec
Tablet	600.0 Milligram	Daily		Oral
3atch:	Started: 20/10/1999		Stopped:	26/10/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

todotion Botal		_	<u> </u>
Preferred Term	Severity	Report Description	Treatment
Dystonia		Pt developed a lean to one side	Fluvoxamine reduced to
Drug level increased			100

Medicine Details:

CLOZARIL (Suspected)	Reason:					
Tablet	300.0	Milligram	Daily		Oral	
3atch:	Started:	L	TERM	Stopped:	CONTIN	
FLUVOXAMINE MALEATE (Suspected)	Reason:					
	200.0	Milligram	Daily			
3atch:	Started:			Stopped:	CONTIN	
SODIUM VALPROATE (Suspected)			Reason:			
	500.0	Milligram	Daily			
Зatch:	Started:			Stopped:		

Laboratory Investigations:

	<u> </u>						
Date	Туре	Range	Date Tested	Result	Details		
	Serum drug level		30/12/1999	1.92	Clozaril level was 3.8.		



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Drug level increased			

Medicine Details:

Medicine Details.					
LUVOX (Interaction)	Reason:				
	0.0				
Зatch:	Started:		Stopped:		
CLOZARIL (Interaction)		Reason:			
Tablet	600.0 Mil	ligram Daily	Oral		
3atch:	Started:	L TERM	Stopped:	CONTIN	

Laboratory Investigations:

	,						
Date	Туре	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).

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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: 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 Detai

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

Medicine Details:

LUVOX (Suspected) Reason: Depression

150.0 Milligram Daily

3atch: 3tarted: 01/02/1999 3topped: 28/01/2000

Laboratory Investigations:

Date	Туре	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.

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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: 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 Detai

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
3atch:	Started: 01/01/1998	Stopped:	02/03/2000
ISOPTIN (Suspected)		Reason: Migraine	
	160.0 Milligram	Daily	
3atch:	Started: 20/01/1999	Stopped:	02/03/2000

Laboratory Investigations:

Date	Туре	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.

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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:
 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 Detai

Reaction Detai		<u>-</u>	
Preferred Term	Severity	Report Description	Treatment
Vomiting		Patient vomited once.	
Nausea		Sensation of nausea.	
Flushing		Still experienced flushing after 2 days.	
Hyperhidrosis			
Paraesthesia			
Tremor			

	ed					

LUVOX (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 06/03/2000 3topped: 10/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

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

Medicine Details:

Medicine Details.						
ZYPREXA (Suspected)		Reason:	Unspecified s	chizophrenia		
Tablet	10.0 Milligram	Daily		Oral		
Зatch:	Started: 14/12/1999		Stopped:	10/02/2000		
LUVOX (Suspected)		Reason:	Depression			
Tablet	100.0 Milligram	Daily		Oral		
3atch:	Started: 14/12/1999		Stopped:		CONTIN	

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Urticaria			Phenergan 25mg, hydrocortisone 100mg.

Medicine Details:

SLOW-K (Suspected) Reason:

0.0

3atch: 3tarted: 30/01/2000 3topped:

MAGMIN (Suspected) Reason:

0.0

3atch: 3tarted: 01/02/2000 3topped:

FLUVOXAMINE MALEATE (Suspected) Reason: Depression

Oral application 50.0 Milligram Daily Oral **3atch**: **3tarted**: 29/01/2000 **3topped**:

CILOXAN (Suspected) Reason:

Ear Drops 12.0 Dose Unspecified Daily Topical

3atch: 3tarted: 04/02/2000 3topped:

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

Medicine Details:

CEFTRIAXONE (Suspected)		Reason:	
Injection	2.0 Gram	Daily	Intravenous
Зatch:	Started: 01/02/2000	Stopped:	04/02/2000
METRONIDAZOLE (Suspected)		Reason:	
Oral application	1.2 Gram	Daily	Oral
Зatch:	Started: 01/02/2000	Stopped:	03/02/2000
FLAGYL (Suspected)		Reason:	
Injection	1.5 Gram	Daily	Intravenous
3atch:	3tarted: 03/02/2000	Stopped:	
CEFTAZIDIME (Suspected)		Reason:	
Injection	3.0 Gram	Daily	Intravenous
Зatch:	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.

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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

	il						
_	i : 05/04/2000	Seq: 1				Gender: Weight:	F
lospitalisation	n: e: 02/04/2000					Age: DOB:	
	e: U2/04/2000 e: Unknown				_		Causality possible
eaction Det						ausanty.	Oddsdifty possible
	red Term	Severit	tv	Report De	scription		Treatment
Muscle twitchin Diarrhoea Headache Tremor	ng			ering of eyes.	·		
Medicine De				Reason:	Depression		
Tablet	ieu)		100.0 Millig			Oral	
3atch:		Starte	d: 30/03/20		} Stopped:	03/04/2000)
FERRO-GRADU	MET (Suspected)			Reason:			
			1.0 Dose	e Unspecified Dail	y		
3atch:		Starte	d : 30/03/20	00	Stopped:		
_aboratory	Investigation		ate Tested	Result		Detai	ls
			ate Tested	Result		Deta	ls



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

D D	
Report Deta	i

 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 Detai

104011011 20141			-
Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction-jaw spasms	Relieved by im cogentin 1.5ml folowed 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

3atch: 31/03/2000 3topped: 02/04/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

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

Medicine Details:

ZYPREXA (Suspected)		Reason:	Otr spec symp psychopathol nec
Tablet	10.0 Milligram	Daily	y Oral
3atch:	Started:		Stopped: 28/02/2000 12M
AURORIX (Suspected)		Reason:	
	600.0 Milligram	Daily	<i>(</i>
3atch:	Started:		Stopped:
CAPTOPRIL (Suspected)		Reason:	
	100.0 Milligram	Daily	/
3atch:	Started:		Stopped:
LUVOX (Suspected)		Reason:	
	100.0 Milligram	Daily	<i>(</i>
3atch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	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.

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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:
 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 Detai

Medicine Details:

ZYPREXA (Suspected)		Reason:	Otr spec sym	p psychopathol r	nec
Tablet	10.0 Milligram	Daily		Oral	
3atch:	Started:		Stopped:	28/02/2000	12M
AURORIX (Suspected)		Reason:			
	600.0 Milligram	Daily			
3atch:	Started:		Stopped:		
CAPTOPRIL (Suspected)		Reason:			
	100.0 Milligram	Daily			
3atch:	Started:		Stopped:		
LUVOX (Suspected)		Reason:			
	100.0 Milligram	Daily			
3atch:	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.

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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:
 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 Detai

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

Medicine Details:

LUVOX (Suspected)

100.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



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

Report I	Detail
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 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hypersensitivity	Severe	Severe allergic reaction	

Medicine Details:

 LUVOX (Suspected)
 Reason:

 Tablet
 100.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 01/05/2000
 3topped: 03/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

caction betai						
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)		leason:	
Tablet	450.0 Milligram	Daily	Oral
3atch:	Started: 01/08/1997	Stopped:	06/04/2000
LUVOX (Suspected)		leason:	
Tablet	100.0 Milligram	Daily	Oral

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

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

Medicine Details:

 FLUVOXAMINE MALEATE (Suspected)
 Reason:
 Depression

 Tablet
 50.0 Milligram
 Daily
 Oral

3atch: Started: 27/04/2000 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date 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 Gender: F Seq: 1

Weight: 60.00 Reported: 27/06/2000 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 3tarted: 07/04/2000 3atch: Stopped: **AUGMENTIN DUO FORTE (Suspected)** Reason: Ac upr resp inf,mult,unsp stes 2.0 Dose Unspecified Daily Oral 3tarted: 07/04/2000 08/04/2000 3atch: Stopped: LUVOX (Suspected) Reason: Anxiety neurosis Daily Oral

200.0 Milligram 3tarted: 07/04/2000 08/04/2000 3atch: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date 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 Detai

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

Medicine Details:

LUVOX (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 25/12/1999 3topped: 22/03/2000

Laboratory Investigations:

Date	Туре	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.



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

Re	po	rt	D	et	ta	i
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 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 Detai

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

Medicine Details:

LUVOX (Suspected)

Tablet

100.0 Milligram
Daily
Oral

3atch: \$tarted: 30/03/2000
\$topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

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

3atch: 3tarted: 10/05/2000 3topped: 14/07/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Lesion resembled blister secondary superficial partial thickness, burn.



Date 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 Detai

104011011 20141			_
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

3atch: 3tarted: 10/05/2000 3topped: 17/07/2000

Laboratory Investigations:

	<u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
	Histology			Bullous drug reaction confirmed by histological exami	



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

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116	\mathbf{v}		\boldsymbol{L}	CLA	ш

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 Detai

caction betain								
Preferred Term	Severity	Report Description	Treatment					
Abdominal pain								
Diarrhoea								
Hyperhidrosis								
Nausea								

Medicine Details:

Medicine Details.						
HYPERICUM-ST JOHN'S WORT (I	nteraction)		Reason:			
Tablet	1.0	Dose Unspe	ecified 1 ti	me	Oral	
3atch:	Started:			Stopped	:	
LUVOX (Interaction)			Reason:	Depression		
	100.0	Milligram	Da	ily		
3atch:	Started: 07	7/04/2000		3topped	:	

Laboratory Investigations:

Date	Туре	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 befor e incident. patient also taking oroxine, kiogest. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



Date Range: 1 Jan 1989 To 31 Dec 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 Detai

		<u>-</u>	
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

3atch: 3tarted: 16/11/2000 3topped: 18/11/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking bi-quinate, lipitor.



Date 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 Detai

todotion Dotal		<u> </u>	
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 Unspe	cified Daily	Ora	I
Зatch:	Started:		Stopped:	
LUVOX (Suspected)		Reason:	Depression	
	100.0 Milligram	Daily		
3atch:	3tarted: 01/03/1999		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report Do						
itchoit D	etail					
Case Num	nber: 159766	Seq: 1		Gender	F	
Repoi	rted: 07/12/2000)		Weight:		
lospitalisa	tion:			Age:	53	
Onset Date:				DOB : 02/02/1947		
	ome: Recovered			Causality:	Causality probable	
eaction E				<u> </u>		
	eferred Term	Severity	Report Description		Treatment	
Diarrhoea						
Medicine LUVOX (Sus			Reason: Depress	ion		
	,	100.0 M	100.0 Milligram Daily			
3atc	h:	Started: 27/11/2000 Stopped: 27/11/2000				
Laborato	ry Investigatio	ons:				
L aborato Date	ry Investigation	O ns: Range Date Tested	d Result	Deta	iils	
			d Result	Deta	iils	



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

Report Do	etail
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 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 Detai

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

Medicine Details:

FLUVOXAMINE MALEATE (Suspected) Reason:

50.0 Milligram Daily

3atch: 3tarted: 3topped: 11/11/2000

Laboratory Investigations:

	, mires algumente:				
Date	Туре	Range	Date Tested	Result	Details
	Electrolytes				Lowest serum sodium was 114



Date 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 Detai

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

Medicine Details:

ZYBAN SR (Interaction)		Reason:	
	0.0		
3atch:	Started: 08/01/2001	Stopped:	
LUVOX (Interaction)		Reason: Depression	
	200.0 Milligram	Daily	
3atch:	Started: 01/01/1999	Stopped:	

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

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

Medicine Details:

LUVOX (Suspected) Reason: Depression
Tablet 100.0 Milligram Daily Oral

3atch: 3tarted: 13/07/2000 **3topped:**

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date 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 Detai

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

3atch: 3tarted: 09/01/2001 3topped: 15/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report De	tail						
Case Numb	ber: 163234	Seq : 1			Gender: M		
Report	ted: 02/03/200)1			Weight:		
lospitalisati	ion:				Age : 54		
Onset Da	ate: 12/02/200)1			DOB : 14/11/1946		
Outcor	me: Recovere	d			Causality: Causality possible		
eaction De					,		
	ferred Term	Severit	ty	Report Description	Treatment		
Eczema		Severe	Sever	e eczematous reaction.	Systemic steroids required settle reaction.		
Jrticaria		Severe	Sever	e urticarial reaction.			
Medicine I	Details:						
LUVOX (Susp				Reason:			
•			0.0				
3atch	ı: 	}tarte∈	d:	Stoppe	d:		
_aborator	y Investigat	ions:					
		ions:	d:	Result	d: Details		
Laborator	y Investigat	ions:					



Date 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 Detai

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

Medicine Details:

HALOPERIDOL (Other drug)		Reason:	Otr spec symp psychopathol nec
	0.5 Milli	igram As ne	cessary
3atch:	Started:		Stopped:
DIAZEPAM (Other drug)		Reason:	Otr spec symp psychopathol nec
	2.0 Milli	igram As ne	cessary
3atch:	Started:		Stopped:
THYROXINE SODIUM (Other drug)		Reason:	Thyroiditis
	100.0 Micr	rogram Daily	
3atch:	Started:		Stopped:
LIPEX (Other drug)		Reason:	
	20.0 Milli	igram Daily	
3atch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Sequelae: recovered but ataxia started again.



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

Report Deta	λį
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 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 Detai

Medicine Details:

Medicine Details.				
FLUVOXAMINE MALEATE (Suspected)		Reason:	Depression	
	100.0 Milligram	Daily		
Зatch:	Started: 21/02/2001		Stopped: 03/04/2001	
LITHIUM CARBONATE (Suspected)		Reason:	Unspecifid affective psychosis	
	900.0 Milligram	Daily		
3atch:	Started: 24/08/1999		Stopped:	

Laboratory Investigations:

Additional Information:

Sequelae: recovered but ataxia started again.



Date 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 Detai

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

3atch: 3tarted: 01/03/2001 **3topped:** 22/03/2001

LUVOX (Interaction) Reason: Depression

25.0 Milligram Daily

3atch: 3tarted: 22/03/2001 3topped: 08/04/2001

Laboratory Investigations:

Date	Туре	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.

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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: 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 Detai

Preferred Term	Severity	Report Description	Treatment
Asthenia			Required visit to doctor

Medicine Details:

ZYBAN SR (Interaction) Reason: Smoker

300.0 Milligram Daily

3atch: 3tarted: 02/04/2001 3topped:

FLUVOXAMINE MALEATE (Interaction) Reason: Depression

100.0 Milligram Daily

3atch: Started: Stopped:

AMITRIPTYLINE HYDROCHLORIDE (Other drug) Reason: Pain

20.0 Milligram Daily

3atch: Started: Stopped:

SANDOMIGRAN (Other drug) Reason: Migraine

2.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Recovery date 17/4/01.



Date 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 Detai

Medicine Details:

FAMOTIDINE (Other drug)		Reason: Other diseases of esophagus	
	80.0 Milligram	Daily	
3atch:	Started:	Stopped:	
OXYCONTIN (Other drug)		Reason:	
	80.0 Milligram	Daily	
3atch:	Started:	Stopped:	
QUINATE (Other drug)		Reason:	
	300.0 Milligram	Daily	
Зatch:	Started:	Stopped:	
		_	
ASPIRIN (Other drug)		Reason:	
ASPIRIN (Other drug)	150.0 Milligram		

Laboratory Investigations:

Additional Information:

Recovery date 17/4/01.



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

Report D				_	
	nber: 164776	Seq: 1			der: M
	rted: 21/05/200)1			ght: 90.00
ospitalisa Onset D					Age: 29 OB: 06/01/1972
	ome: Recovere	d			lity: Causality possible
eaction E		u		Gausa	inty. Causality possible
	eferred Term	Severity	Report Des	cription	Treatment
Salactorrho	ea				Required a visit to doctor.
ledicine	Details:		Reason:		
		200.0	Milligram Daily		
3atc	h:	Started: 12	/02/2001	Stopped:	CONTIN
	ry Investigat				
_aborato Date	ry Investigat	ions: Range Date Te	sted Result		Details



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

Report	: Detail
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 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 Detai

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

Medicine Details:

FAVERIN (Suspected)Reason:DepressionTablet50.0 MilligramDailyOral

3atch: 3tarted: 05/04/2001 **3topped:**

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

todotion botal		-	-
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	
3atch:	Started: 22/11/2000 Stopped:	
INDERAL (Other drug)	Reason: Peptic ulcer nos w/o men	perf
	20.0 Milligram Daily	
3atch:	Started: 01/08/2000 Stopped:	
LUVOX (Suspected)	Reason: Depression	
	100.0 Milligram Daily	
3atch:	Started: 28/02/2001 Stopped: 27/05/200	1

Laboratory Investigations:

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

Additional Information:

Epilepsy as a child



Date 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 Detai

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

Medicine Details:

FEFOL (Other drug)		Reas	on:	Unspecified anemia	
	1.0	Dose Unspecified	Daily		
3atch:	Started:	L TERM		Stopped:	
LUVOX (Suspected)	Reason:				
	200.0	Milligram	Daily		
3atch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

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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 Detai

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

3atch: 3tarted: 20/08/2001 3topped: 26/08/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Cachon Detai			
Preferred Term	Severity	Report Description	Treatment
Dystonia			Luvox discontinued.
Tetany			

Medicine Details:

GELUSIL (Other drug)		Reason:	
Solution	80.0 Millilitre	As necessary	Oral
3atch:	Started:	Stopped:	
PANAMAX (Other drug)		Reason:	
Tablet	500.0 Milligram	As necessary	Oral
Зatch:	3atch: Started:		
PROCTOSEDYL (Other drug)		Reason:	
PROCTOSEDYL (Other drug) Ointment	0.0	Reason: As necessary	Topical
, , , , ,	0.0 Started:		Topical
Ointment		As necessary	Topical
Ointment 3atch:		As necessary Stopped:	Topical Intravenous

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date 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 Detai

Medicine Details:

TEARS PLUS (Other drug)		Reas	on:		
Eye Drops	2.0	Dose Unspecified	Fortnightly	Ophthalmic	
Зatch:	Started:		Stopp	ed:	
ARISTOCORT (Other drug)		Reas	on:		
Ointment	0.0		Daily	Topical	
Зatch:	Started:		3topp	ed:	
NOVASONE (Other drug)		Reas	on:		
Ointment	0.0		Daily	Topical	
Зatch:	Started:		3topp	ed:	
PREDNISOLONE (Other drug)		Reas	on:		
Tablet	5.0	Milligram	Daily	Oral	
Зatch:	Started:		³topp	ed:	

Laboratory Investigations:

Additional Information:

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

Report Run 01/08/200 01:36PN Database: pusime ADRS004 Page 124 of 326



Date 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 Detai

Medicine Details:

TEMAZE (Other drug)			Reason:		
Tablet	10.0	Milligram	Daily	Oral	
3atch:	Started:			Stopped:	
VIOXX (Other drug)			Reason:		
Tablet	12.5	Milligram	Daily	Oral	
3atch:	Started:			Stopped:	
ZOTON (Other drug)			Reason:		
Capsule	60.0	Milligram	Daily	Oral	
3atch:	Started:			Stopped:	
LUVOX (Suspected)			Reason:		
	0.0				
3atch:	Started:			Stopped:	

Laboratory Investigations:

Additional Information:

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

Report Run 01/08/200 01:36PN Database: pusime ADRS004 Page 125 of 326



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

		eta	

 Case Number:
 170378
 Seq: 1
 Gender:
 F

 Reported:
 27/11/2001
 Weight:

Hospitalisation:
Onset Date: 02/11/2001
Age: 40Y
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion			
Syncope			

Medicine Details:

DEPO-PROVERA (Other drug)		Reason:
	0.0	
3atch:	Started:	Stopped:
ALCOHOL (Suspected)		Reason:
	0.0	
Batch:	Started:	Stopped:
LUVOX (Suspected)		Reason: Depression
	100.0 Milligram	Daily
3atch:	Started: 01/10/2001	Stopped: 12/11/2001
ZYPREXA (Suspected)		Reason:
	10.0 Milligram	Daily
3atch:	3tarted: 01/10/2001	Stopped: 02/11/2001

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

todolloli Boldi	-	_	
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,

Medicine Details:

Medicine Details.			
DIAZEPAM (Other drug)		Reason: Depression	
Oral application	5.0 Milligram	As necessary	Oral
3atch:	Started: 25/05/2001	Stopped:	
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
3atch:	3tarted: 27/05/2001	Stopped:	28/05/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

	tail						
	per: 171508 red: 02/01/2002	Seq:	1	Gender: M Weight: 81.00 Age: 20			
-	ate: 16/10/2001	1					DOB: 30/07/1981
	me: Recovered					Car	sality: Causality possible
action D		I				Out	isanty. Causanty possible
	ferred Term	Seve	erity	Report	Desc	cription	Treatment
lepatitis							Withdrawal of fluroxamine. date of recovery 29/10/2001 required a visit to doctor.
fledicine l				₹eas	on:		
THAMME (O	tilei didg/		100.0 Millig		Daily		
3atch	:	3ta	rted:	g. ₩!!!	July	Stopped:	
DIAZEPAM (C	Other drug)			Reas	on:	• •	
			15.0 Millig	gram	Daily		
3atch	:	3ta	rted:			Stopped:	
FLUVOXAMIN	NE MALEATE (Sus	pected)		Reas	on:	Essential benign	hypertension
			100.0 Milligra				
3atch	:	Star	rted:	Stopped:		Stopped:	
	y Investigati		Date Tested	Result			Details
_aborator	y Investigati Type	ONS: Range	Date Tested	Result			Details



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

Rei	port	: Det	tail
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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 Detai

104011011 20141			-
Preferred Term	Severity	Report Description	Treatment
Dystonia			Treated with benztropine. date of recovery 16.8.01.
Visual disturbance			

Medicine Details:

PERICYAZINE (Suspected) Reason: Unspecified psychosis

2.5 Milligram As necessary

3atch: 3tarted: 04/08/2001 3topped: 11/08/2001

FLUVOXAMINE MALEATE (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 03/08/2001 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

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

Medicine Details:

<u>Medicine Details:</u>					
LASIX (Other drug)		Reason:	: Polyuria		
	40.0	Milligram As	s necessary		
Зatch:	Started:	L TERM	Stopped:		
RHINOCORT AQUEOUS NASAL SF	RAY (Other drug)	Reason:	: Hay fever		
	2.0	Dose Unspecified As	s necessary		
Зatch:	Started:	L TERM	Stopped:		
LUVOX (Suspected)		Reason:	Depression		
	200.0	Milligram D	aily		
3atch:	Started: 01/	/09/1999	Stopped:	28/12/2000	

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

todotion Dotal		_	
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

3atch: 3tarted: 29/11/2001 3topped:

RISPERIDONE (Suspected) Reason: Depression

0.5 Milligram Daily

3atch: 3tarted: 29/11/2001 3topped: 04/12/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

 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 Detai

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

Medicine Details:

FAVERIN (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 21/01/2002 3topped: 06/02/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

todotion botal			<u> </u>
Preferred Term	Severity	Report Description	Treatment
Convulsion			Seizure treatment. therapy changed to mirtazapine.

Medicine Details:

TEMAZEPAM (Other drug)	Reason:				
	10.0	Milligram	As ne	ecessary	
Зatch:	Started:			Stopped:	
ASPIRIN (Other drug)			Reason:	Chron isch heart dis no hyper	
	150.0	Milligram	Daily		
3atch:	Started:			Stopped:	
FLUVOXAMINE MALEATE (Suspected)			Reason:	Depression	
	150.0	Milligram	Daily		
3atch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Sequelae: acute brain syndrome.



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

Report D)etail
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 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 Detai

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

Medicine Details:

Micarcinic Details.			
LUVOX (Suspected)		Reason: Depression	
	100.0 Milligram	Daily	
Зatch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Depression	
	10.0 Milligram	Daily	
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

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

Medicine Details:

FAVERIN (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 06/03/2002 3topped: 08/03/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Arthralgia			
Hypoaesthesia			
Myalgia			

Medicine Details:

STILNOX (Other drug) Reason: Specific disorders of sleep

10.0 Milligram Daily

3atch: 3tarted: 01/04/2001 3topped:

LUVOX (Suspected) Reason: Depression

0.0

3atch: 3tarted: 01/08/2001 3topped: 28/02/2002

Laboratory Investigations:

Date	Туре	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).

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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: 174036 Gender: F Seq: 1 Weight: 62.00 Reported: 28/03/2002

Hospitalisation: Age: 35

DOB: 27/07/1966 Onset Date: 23/03/2002

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Tachycardia			Required a visit to doctor. ceased cipramil and luvox.

Medicine Details:

STILNOX (Other drug) Reason: Specific disorders of sleep

> 10.0 Milligram As necessary

Started: 3atch: Stopped: MERSYNDOL (Other drug)

1.0 Dose Unspecified As necessary

Reason:

Headache

Started: 3atch: Stopped:

UNISOM SLEEPGELS (Other drug) Reason: Specific disorders of sleep

1.0 Dose Unspecified As necessary

3atch: Started: Stopped: Depression

CIPRAMIL (Suspected) Reason:

> 20.0 Milligram Daily

3atch: 3tarted: 01/09/2001 Stopped: 18/03/2002

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

licine I	

LUVOX (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 22/03/2002 3topped: 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.

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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: 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 Detai

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

Medicine Details:

 LUVOX (Suspected)
 Reason:
 Depression

 Tablet
 100.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 19/02/2002
 \$topped:
 20/03/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Similar problem with citalogram and paroxetine.



Date 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 Detai

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	
Зatch:	Started:		L TERM	Stopped:
MURELAX (Other drug)			Reason:	Specific disorders of sleep
	15.0	Milligram	Daily	
3atch:	Started:		L TERM	Stopped:
CELEBREX (Other drug)			Reason:	Osteoarthritis
	200.0	Milligram	Daily	
3atch:	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	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number: 1753		Gende	
Reported: 08/05	/2002	Weigh	nt:
Hospitalisation:		Ag	e : 82
Onset Date:		DO	B : 29/05/1919
Outcome: Reco	vered	Causalit	y: Causality probable
Reaction Detai			
Medicine Details:			
LUVOX (Suspected)		Reason: Depression	
	100.0 Milligram	Daily	
3atch:	Started: 17/04/2002	Stopped: 20/04/2	002
Laboratory Investi	gations:		
Additional Informa	ıtion:		

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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: 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hypokalaemia			Ceased avapro hct.

Medicine Details:

CELECOXIB (Other drug) Reason: Osteoarthritis

0.0

3atch: Started: 25/03/2002 Stopped:

FAMOTIDINE (Other drug) Reason:

Tablet 40.0 Milligram Daily Oral

3atch: Started: 25/03/2002 Stopped:

AVAPRO HCT 300/12.5 (Suspected) Reason: Essential benign hypertension

 Tablet
 1.0 Dose Unspecified Daily
 Oral

 3atch:
 3tarted:
 25/03/2002
 3topped:
 26/03/2002

FLUVOXAMINE MALEATE (Suspected) Reason: Depression

Capsule 50.0 Milligram Daily Oral

3atch: 3tarted: 25/03/2002 3topped: 26/03/2002

Laboratory Investigations:

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



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Myocarditis		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 eoxinophil count.	
C-reactive protein increased Cardiac failure Cough			

Medicine Details:

CLOZARIL (Suspected)		Reason:	Unspecified schizophrenia	
	300.0 Milligram	Daily	oral (
3atch:	Started: 20/03/2002		Stopped: 08/04/2002	
LUVOX (Suspected)		Reason:	Schizophrenia	
	300.0 Milligram	Daily	1	
3atch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	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%). Vlaves were normal.
23/05/2002	Electrocardiograph				08/04/2002: ECG: ST segment straigtening 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 Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

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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: 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 Detai

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:

Medicine Details.				
CLOZARIL (Suspected)		Reason:	Unspecified schizophrenia	
	300.0 Milligram	Daily	Oral	
3atch:	Started: 20/03/2002		Stopped: 08/04/2002	
LUVOX (Suspected)		Reason:	Schizophrenia	
	300.0 Milligram	Daily		
3atch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	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 Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

Report Run 01/08/200 01:36PN Database: pusime ADRS004 Page 144 of 326



Date 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 Detai

15454511 2 5 1441			
Preferred Term	Severity	Report Description	Treatment
Red blood cell sedimentation rate			
Tachycardia			
Troponin increased			

Medicine Details:

Medicine Details.				
CLOZARIL (Suspected)		Reason:	Unspecified schizophrenia	
	300.0 Milligram	Daily	Oral	
3atch:	Started: 20/03/2002		Stopped: 08/04/2002	
LUVOX (Suspected)		Reason:	Schizophrenia	
	300.0 Milligram	Daily		
3atch:	Started:		Stopped:	

Laboratory Investigations:

Additional Information:

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

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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
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 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 Detai

reaction Detai			
Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia			
Palpitations			
Paraesthesia			
Tremor			Required a visit to doctor. ceased luvox. patient now taking avanza. date of
Visual disturbance			TECHNOLO TOURNOSTILIS
Vomiting			

Medicine Details:

STILNOX (Suspected) Reason: Specific disorders of sleep 10.0 Milligram As necessary 3atch: 3tarted: 14/05/2002 Stopped: LUVOX (Suspected) Reason: Depression 50.0 Milligram Daily 3atch: 3tarted: 14/05/2002 Stopped: 14/05/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

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 Detai

teaction Detai	ā.		
Preferred Term	Severity	Report Description	Treatment
Dyspepsia			Patient required a visit to doctor. date of

Medicine Details:

LUVOX (Suspected) Reason:

100.0 Milligram Daily

3atch: 31/04/2002 3topped: 04/05/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

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

Medicine Details:

LUVOX (Suspected) Reason:

50.0 Milligram Daily

3atch: 310667 **3tarted**: 11/05/2002 **3topped**: 13/05/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date 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 Detai

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

3atch: 3tarted: 01/08/2001 3topped: 09/05/2002

DEXAMPHETAMINE SULPHATE (Suspected) Reason:

12.5 Milligram Daily

3atch: 3tarted: 01/01/2000 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

everity	Report	Descr	We Caus	ender: F eight: Age: 72Y DOB: sality: Causality possible Treatment Patient was hospitalised. alprazolam and faverin cease
	·	Descr	ription	Patient was hospitalised.
	·	Descr	ription	Patient was hospitalised.
	Poggo			
	Pogeo			<u> </u> '
	Pogeo			
	\easo	n:		
0.0			Managada	
Started:	L TERM	n:	Stopped:	
100.0 Mi			Anxiety neurosis	
	_	- ,	Stopped: 19/	02/2002
4.0 M			Anxiety neurosis	
	_	Dally	3topped: 28/	11/2001
		n: /		
100.0 Mi	lligram	Daily		
Started:			Stopped:	
Date Tested	Result			Details
	4.0 Mi Started: 100.0 Mi Started:	100.0 Milligram Started: 01/11/2001 Reaso 4.0 Milligram Started: L TERM Reaso 100.0 Milligram Started:	100.0 Milligram Daily Started: 01/11/2001 Reason: 4.0 Milligram Daily Started: L TERM Reason: 100.0 Milligram Daily Started:	Reason: Anxiety neurosis 100.0 Milligram Daily Started: 01/11/2001 Stopped: 19/ Reason: Anxiety neurosis 4.0 Milligram Daily Started: L TERM Stopped: 28/ Reason: Anxiety neurosis 100.0 Milligram Daily Started: Stopped: Stopped:



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Drug level increased			
Somnolence			Dose of phenytoin reduced to 200mg daily, patient recovered

Medicine Details:

Medicine Details.			
DILANTIN (Interaction)		Reason: Other&unspecified epilepsy	
	500.0 Milligram	Daily	
Заtch:	Started:	Stopped:	
LUVOX (Interaction)		Reason: Depression	
Tablet	100.0 Milligram	Daily Oral	
3atch:	Started: 10/04/2002	Stopped:	

Laboratory Investigations:

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



DOB: 04/10/1949

Date 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

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Onset Date: 28/06/2001

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

Medicine Details:

FAVERIN (Suspected) Reason: Depression

0.0

3atch: 3tarted: 01/05/2001 **3topped:** 28/06/2001

SEREPAX (Suspected) Reason:

0.0

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

178733 is a seq of 178734.



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion		Myoclonic jerks.	

Medicine Details:

Medicine Details:		
FLUVOXAMINE MALEATE (Suspected)		Reason:
	0.0	
3atch:	Started:	Stopped:
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia
Tablet	300.0 Milligram	Daily Oral
Batch:	3tarted: 01/08/2002	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report Detail Case Number:							
Panartad:	179698	Seq:	1			Gen	der: F
Keporteu.	15/10/2002	<u>, </u>				Wei	ght:
lospitalisation:						Δ	.ge: 71
Onset Date:	26/09/2002	<u>)</u>					OB : 07/07/1931
Outcome:	Recovered					Causa	lity: Causality possible
eaction Detai	i	_	_			_	•
Preferre	d Term	Seve	erity	Repor	Description		Treatment
Muscular weakn	ess		Legs	s weak			Ceased luvox. recovered
Diarrhoea							
Urinary incontine	ence						
Medicine Det				Reas	on:		
Gel	arug)		0.0	\eas	JII.	Vagin	and a
3atch:		2ta	rted:		Stopped:	_	lai
DYMADON P (Oth	er drug)		iiteu.	Reas			
Tablet	er drug,		500.0 Mill		As necessary	Oral	
Tablet				igrain			
Ratch:		Sta	rtod:		Stonnad:		
3atch:	drug)	Sta -	rted:	2020	Stopped:		
FELDENE (Other	gurt)	3ta		Reas	on:		
FELDENE (Other of Tablet	drug)		20.0 Mill		on: As necessary	Oral	
FELDENE (Other of Tablet 3atch:				igram	on: As necessary Stopped:	Oral	
Tablet 3atch: BETALOC (Other			20.0 Mill	igram Reas	As necessary Stopped:	Oral	
Tablet 3atch: BETALOC (Other of Tablet)		€ta	20.0 Mill arted: 100.0 Mill	igram Reas	on: As necessary Stopped: on: Daily	Oral	
Tablet 3atch: BETALOC (Other		€ta	20.0 Mill	igram Reas	As necessary Stopped:	Oral	
Tablet 3atch: BETALOC (Other of Tablet)	drug)	Sta Sta	20.0 Mill arted: 100.0 Mill	igram Reas	on: As necessary Stopped: on: Daily	Oral	Details



Report Detail

Case Number: 179698

Reported: 15/10/2002

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight:

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

Seq: 1

ospitalisation:						Age:	71
Onset Date: 26/09/2002						DOB:	07/07/1931
Outcome: Recovered					C	ausality:	Causality possible
action Detai							
ledicine Details:							
CALTRATE (Other drug)			Reas	on:			
Tablet		1.0	Dose Unspecified			Oral	
3atch:	Started:		•	,	Stopped:		
DIPROSONE (Other drug)			Reas	on:			
Ointment		2.0	Dose Unspecified	Daily		Topical	
Batch:	Started:				Stopped:		
IQUIFILM TEARS (Other drug)			Reas	on:			
Eye Drops		3.0	Dose Unspecified	Daily		Ophthalmic	:
3atch:	Started:				Stopped:		
NOVASONE (Other drug)			Reas	on:			
Ointment		1.0	Dose Unspecified	Daily		Topical	
3atch:	Started:				Stopped:		
aboratory Investigations:							
dditional Information:							
dditional Information:							
dditional Information:							
dditional Information:							



Report Detail

Case Number: 179698

Reported: 15/10/2002

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight:

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

Seq: 1

ospitalisation:					Age:	/ 1
Onset Date: 26/09/2002					DOB:	07/07/1931
Outcome: Recovered				С	ausality:	Causality possible
action Detai						
Medicine Details: OGEN (Other drug)			Reason:			
Tablet	625.0	Miorogram			Oral	
Batch:	625.0 Started:	Microgram	Daily	}tonnod:	Orai	
	Started:		Jacobs	Stopped:		
OROXINE (Other drug) Tablet	500.0	Miorogram	Reason:		Oral	
	Started:	Microgram	Daily	Mannadi	Oral	
3atch:	Started:		Reason:	Stopped:		
LUVOX (Suspected) Tablet	50.0	Milliarom			Oral	
		Milligram	Daily	Mannadi	Orai	
Batch:	Started:			Stopped:		
aboratory Investigations:						
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aboratory Investigations:						



Date 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 Detai

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

Medicine Details:

SINEQUAN (Other drug)		Reason:		
Oral application	0.0			Oral
3atch:	Started: 01/08/2002		Stopped:	02/08/2002
EPILIM (Other drug)		Reason:	Cervicalgia	
Oral application	200.0 Milligram	Daily		Oral
3atch:	Started:	L TERM	Stopped:	
LUVOX (Suspected)		Reason:	Depression	
Tablet	100.0 Milligram	Daily		Oral
3atch:	Started: 23/07/2002		Stopped:	02/08/2002

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

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 Millig	gram Daily	
Зatch:	Started:		Stopped:
OROXINE (Other drug)		Reason:	
	50.0 Micro	ogram Daily	
Зatch:	Started:	L TERM	Stopped:
LOSEC (Other drug)		Reason:	
LOSEC (Other drug)	20.0 Millig		
LOSEC (Other drug) 3atch:	20.0 Millig 3tarted:		Stopped:
		gram Daily	Stopped:
3atch:		gram Daily L TERM Reason:	3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

180216 is the sequence of 180215.



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

Repo	ort D	etai
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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 Detai

Medicine Details:

CLIMARA (Other drug)	Reason:				
	50.0	Milligram	Daily		
3atch:	Started:	L TERM	Stopped:	:	
LIPEX (Other drug)		Reas	on:		
	20.0	Milligram	Daily		
Batch:	Started:	L TERM	Stopped:	:	
LUVOX (Suspected)		Reas	on: Depression		
Tablet	50.0	Milligram	Daily	Oral	
3atch:	Started: 09	08/2002	Stopped:	:	

Laboratory Investigations:

Additional Information:

180216 is the sequence of 180215.



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

Report D)etail
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 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 Detai

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)

Tablet

100.0 Milligram
Daily
Oral

3atch: \$tarted: 23/06/2002 \$topped: contin

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Veaction Detai			
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, Dysponea 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
3atch:	Started:		:	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report	Detail
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 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 Detai

baotion Botal								
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
3atch:	Started:		3to _l	oped:

Laboratory Investigations:

Additional Information:

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



Date 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 Detai

veaction Detai	-		-
Preferred Term	Severity	Report Description	Treatment
	Required Visit to Doctor	Bruising, minor secondary to minor trauma.	Stopped luvox
	Required Visit to Doctor	Purpura and Platelets Abnormal	Stopped luvox

Medicine Details:

ATTENTA (Other drug)		Reason: Beh	navior disorders of ch	nildhod
Tablet	20.0 Milligram		Oral	
3atch:	Started:	:	Stopped:	contin
LUVOX (Suspected)		Reason: Anx	kiety neurosis	
Tablet	50.0 Milligram	Daily	Oral	
3atch:	Started: 09/09/2002	:	Stopped: 25/11/20	002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

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

Medicine Details:

EPILIM (Suspected)		Reason:	Unspecified schizophrenia	
	2.0 Gram	Daily		
3atch:	Started:		Stopped:	Contin
SEROQUEL (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral	
3atch:	Started:		Stopped:	Contin
SOLIAN (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral	
3atch:	Started:		Stopped:	Contin
LUVOX (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	100.0 Milligram	Daily	Oral	
Заtch:	Started:		Stopped:	Contin

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

104011011 20141		-	_
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

3atch: 31/12/2002 3topped: 02/01/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date 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:
 0.0

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 Detai

todotion Botai			
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

3atch: 31/12/2002 3topped: 02/01/2003

Laboratory Investigations:

Additional Information:

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

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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: 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 Detai

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:

Medicine Details.			
NITRAZEPAM (Other drug)		Reason:	
	5.0 Milligram	Daily	
Зatch:	Started:	Stopped:	
FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Заtch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	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.

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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: 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 Detai

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

Medicine Details:

3atch:

FLUVOXAMINE MALEATE (Suspected)	Reason:	Depression

Stopped:

Started:

Laboratory Investigations:

Date	Туре	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.

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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: 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 Detai

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FLUVOXAMINE MALEATE (Suspected) Reason: Depression

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.

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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: 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 Detai

todottott Dotal		<u> </u>	
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)		Reas	on:		
	100.0	Milligram	Daily		
3atch:	Started:	L TERM		Stopped:	
KARVEZIDE 150/12.5 (Other drug)		Reas	on:		
	1.0	Dose Unspecified	Daily		
3atch:	Started:	L TERM		Stopped:	
CLIBENCI AMIDE (Other drug)		200			
GLIBENCLAMIDE (Other drug)		Keas	on:		
GLIDENGLAMIDE (Other drug)	5.0		Daily		
3atch:	5.0		Daily	Stopped:	
, ,		Milligram L TERM	Daily	Stopped:	
3atch:	Started:	Milligram L TERM	Daily	Depression	Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



DOB: 16/11/1960

Date 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

Outcome: Recovered 26/02/2003 Causality: Causality possible

Reaction Detai

Onset Date: 25/02/2003

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

Medicine Details:

LUVOX (Interaction)	Reason: Depression	
Tablet	1.0 Dose Unspecified Daily Oral	
3atch:	Started: 29/01/2003 Stopped:	
TRAMAL SR (Interaction)	Reason: Pain	
Tablet	300.0 Milligram Daily Oral	
3atch:	Started: 25/02/2003 Stopped: 25/02/2003	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

eport Detail				
Case Number: 183479 Reported: 27/02/2003	Seq: 1		Weig	der: M ght: 0.00
ospitalisation:				age: 42
Onset Date: 25/02/2003		00/00/0000		OB : 16/11/1960
Outcome: Recovered		26/02/2003	Causa	lity: Causality possible
eaction Detai	1 0 11		1	
Preferred Term	Severity	Report Des	cription	Treatment
Nasopharyngitis	Required Visit to Doctor			
Tongue oedema	Required Visit			
	to Doctor			
Medicine Details:		Reason:	Depression	
LUVOX (Interaction) Tablet	1.0		Depression Oral	
Satch:	3 tarted: 29	Dose Unspecified Daily	Stopped:	
TRAMAL SR (Interaction)	Started. 29	Reason:	Pain	
Tablet	300.0	Milligram Daily		
3atch:	Started: 25		3topped: 25/02	/2003
Laboratory Investigations	s:			
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:
 183645
 Seq: 1
 Gender:
 F

 Reported:
 03/02/2003
 Weight:
 0.00

Hospitalisation: Admitted to hospital
Onset Date: 01/03/2003

DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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

3atch: 3tarted: 28/02/2003 3topped: 01/03/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
Homicidal ideation		Within a week of ceasing/withdrawing Luvox, he attemped 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

3atch: 3tarted: 25/06/2001 L TERM 3topped: 23/01/2002

Laboratory Investigations:

Date	Туре	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 aslo 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.



Date 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 Detai

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
3atch:	Started: 18/03/2003		Stopped:	21/03/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Dose related.



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

Case Number: 18 Reported: 08 Iospitalisation: Ad Onset Date: 18 Outcome: Ur eaction Detai	/04/2003 mitted to hospital /03/2003	. '		DOE	
Preferred T	erm Se	verity	Report Desc	ription	Treatment
Hyponatraemia Convulsion	Sever Sever	''	natraemia, fitting.	ICI	J admission. Fluvoxamine
			Reason:		
	ATE (Suspected)	tarted:	₹eason:	Stopped:	
	ATE (Suspected)	tarted:	Reason:	Stopped:	
FLUVOXAMINE MALE	Stigations:	tarted:	Result		tails



Date 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 Detai

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

Medicine Details:

FLUVOXAMINE MALEATE (Suspected) Reason: Depression

 Tablet
 100.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 13/12/2002
 3topped:
 31/03/2003

Laboratory Investigations:

Date	Туре	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.



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

Report I	Detail
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 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 Detai

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

Medicine Details:

Medicine Details.				
TOPAMAX (Suspected)		Reason:	Epilepsy	
Oral application	Dose U	nspecified	Oral	
3atch:	Started:		Stopped:	
ESOMEPRAZOLE MAGNESIUM	RIHYDRATE (Suspected)	Reason:		
3atch:	Started:		Stopped:	
FLUVOXAMINE MALEATE (Susp	ected)	Reason:		
3atch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	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.



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

Report Detail

Case Number:185975Seq: 1Gender:MReported:16/05/2003Weight:0.00Hospitalisation:Hospitalisation prolongedAge: 25

Onset Date: 02/05/2003 DOB: 09/02/1978

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

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		
3atch:	Started:		Stopped:			
CLOZARIL (Interaction)		Reason:	Schizophrenia			
Tablet	300.0 Milligram	Daily	,	Oral		
3atch:	Started: 10/04/2003		Stopped:		Contin	
LITHIUM CARBONATE (Other drug)		Reason:				
Tablet	Dose Unsp	ecified		Oral		
3atch:	Started:		Stopped:			
RANITIDINE (Other drug)		Reason:				
Oral application	Dose Unsp	ecified		Oral		
3atch:	Started:		Stopped:			

Laboratory Investigations:

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

Additional Information:

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



Date 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 Gender: F Seq: 1

Reported: 16/05/2003 Weight: 58.50 Hospitalisation: **Age:** 67

Onset Date: DOB: 14/06/1935

Outcome: Unknown Causality: Causality possible

Reaction Detai

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

Medicine Details:

TEVETEN (Other drug)		Reason: Esse	ential benign hypertension	
Tablet	800.0 Milligram	Daily	Oral	
Зatch:	Started:	31	topped:	
HYDRALAZINE HYDROCHLORIDE	(Other drug)	Reason: Esse	ential benign hypertension	
Tablet	200.0 Milligram	Daily	Oral	
Зatch:	Started:	31	topped:	
LUVOX (Suspected)		Reason: Depr	ression	
Tablet	100.0 Milligram	Daily	Oral	
Batch:	Started: 29/11/2002	31	topped: 27/02/2003	

Laboratory Investigations:

Date	Туре	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, poliomyeletis, hyponatriaemia with thiazide diuretics. Presumably pre-existing abnormal LFTs secondary to enzymes from polio. Symptoms occurred in November 2002.



Date 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 Detai

Medicine Details:

modifile Botalie.			
TEVETEN (Other drug)		Reason: Essential benign hypertension	
Tablet	800.0 Milligram	Daily Oral	
3atch:	Started:	Stopped:	
HYDRALAZINE HYDROCHLORID	E (Other drug)	Reason: Essential benign hypertension	
Tablet	200.0 Milligram	Daily Oral	
3atch:	Started:	Stopped:	
LUVOX (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily Oral	
3atch:	Started: 29/11/2002	Stopped: 27/02/2003	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =		14/03/2003	88	
	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, poliomyeletis, hyponatriaemia with thiazide diuretics. Presumably pre-existing abnormal LFTs secondary to enzymes from polio. Symptoms occurred in November 2002.

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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: 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 Detai

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

Medicine Details:

LUVOX (Suspected)		Reason:			
Tablet	300.0	Milligram	Daily	Oral	
3atch:	Started:		Stopp	oed:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date 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 Detai

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

Medicine Details:

Medicine Details.					
FLUVOXAMINE MALEATE (Interaction)			Reason:		
3atch:	Started:			Stopped:	
OLANZAPINE (Interaction)			Reason:	Depression	
	10.0	Milligram	Daily		
3atch:	Started:	S	TERM	Stopped:	27/02/2003

Laboratory Investigations:

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

Additional Information:

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



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

Report Detail

Case Number:186858Seq: 1Gender: MReported:10/06/2003Weight: 0.00Hospitalisation:Admitted to hospitalAge: 84YOnset Date:15/04/2003DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Dyspnoea		SOB, CHF and cardiomyopathy, chronic renal failure.	Lasix IV, then Lasix 80mg/bd po. Ramipril and Carvedilol
Cardiac failure congestive			7777
Cardiomyopathy			
Renal failure chronic			

Medicine Details:

CELEBREX (Suspected)			Reason:		
Capsule	200.0	Milligram	Daily		Oral
3atch:	Started:			Stopped:	16/04/2003
FLUVOXAMINE MALEATE (Suspected)			Reason:		
FLUVOXAMINE MALEATE (Suspected) Tablet	100.0	Milligram	Reason: Daily		Oral

Laboratory Investigations:

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

Additional Information:

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



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

Report Detail

Case Number:188425Seq: 1Gender:FReported:11/07/2003Weight:0.00Hospitalisation:Age: 32

Onset Date: DOB: 09/01/1971

Outcome: Unknown Causality: Causality possible

Reaction Detai

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

Medicine Details:

Medicine Details.				
CLOZARIL (Interaction)		Reason:	Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral	
3atch:	3tarted: 25/07/2000		Stopped:	
FLUVOXAMINE MALEATE (Interaction)		Reason:		
	200.0 Milligram	Daily		
3atch:	Started:		Stopped:	

Laboratory Investigations:

	,				
Date	Туре	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.

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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: 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 Detai

touction Dotal			
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 s	chizophrenia	
Tablet	300.0 Milligram	Daily	•	Oral	
Зatch:	Started: 20/09/2000	·	Stopped:	27/05/2003	
LUVOX (Interaction)		Reason:			
	150.0 Milligram	Daily			
Зatch:	Started:		Stopped:		
LITHIUM CARBONATE (Other drug)		Reason:			
3atch:	Started:		Stopped:		

Laboratory Investigations:

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

Additional Information:

Concomitant Luvox had elevated the clozapine serum levels.



Causality: Causality possible

Date 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

Reaction Detai

Cachon Detai	_	-	
Preferred Term	Severity	Report Description	Treatment
Diabetes insipidus	Required Specialist Consultation	Diabetes insipidus.	Given Minirin.

Medicine Details:

Medicine Details.				
PROVERA (Other drug)		Reason:	Menopausal s	symptoms
	5.0 Milligra	m Daily	,	
Batch:	Started:	L TERM	Stopped:	Contin
ZANTAC (Other drug)		Reason:	Heartburn	
Tablet	450.0 Milligra	m Daily	,	Oral
3atch:	3tarted: 24/05/2002		Stopped:	
LUVOX (Suspected)		Reason:	Depression	
Tablet	50.0 Milligra	m Daily	,	Oral
Batch:	3tarted: 09/05/2002		3topped:	22/11/2002

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Onset date: 10/2002 - 11/2002.



Date 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 Detai

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

Medicine Details:

CLOZARIL (Interaction)	2	Reason:				
Tablet	900.0 Milligram	Daily	Oral			
3atch:	Started: 13/03/1997	št	opped:	Contin		
LUVOX (Interaction)	2	leason: Obse	essive compulsive n	eurosis		
	100.0 Milligram	Daily				
3atch:	Started: 13/06/2003	št	opped:			

Laboratory Investigations:

Date	Туре	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 biopolar disorder (diagnosed 7 years ago). Patient was also taking Epilim, Lithium, Largactil.



Date 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 Detai

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	
Зatch:	Started: 13/03/1997		Stopped:	Contin
LUVOX (Interaction)		Reason: Of	bsessive compulsive ne	urosis
LUVOX (Interaction)	100.0 Milligram	Reason: Ol Daily	bsessive compulsive ne	urosis

Laboratory Investigations:

Additional Information:

History of intellectual disability, autism (diagnosed 7 years ago) and biopolar disorder (diagnosed 7 years ago). Patient was also taking Epilim, Lithium, Largactil.

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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: 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 Detai

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		
3atch:	Started: 13/03/1997	St	opped:	Contin	
LUVOX (Interaction)		Reason: Obse	essive compulsive n	neurosis	
	100.0 Milligram	Daily			
3atch:	Started: 13/06/2003	St	opped:		

Laboratory Investigations:

Additional Information:

History of intellectual disability, autism (diagnosed 7 years ago) and biopolar disorder (diagnosed 7 years ago). Patient was also taking Epilim, Lithium, Largactil.

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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: 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 Detai

		-	
Preferred Term	Severity Report Description		Treatment
Hallucination, visual	Hallucination, visual		
Confusional state		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	
Зatch:	Started: 21/05/2003		Stopped:	
LUVOX (Suspected)		Reason:	Depression	
LUVOX (Suspected) Tablet	50.0 Milligram	Reason: Daily	•	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

HIV history. Other drugs: Lamivudine, Abacavin and Efavirenz.



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Rash	Severe	Severe skin eruption	

Medicine Details:

Medicine Betails.			
FLUVOXAMINE MALEATE (Suspected)		Reason: Depress	sion
Tablet	50.0 Milligram	Daily	Oral
3atch:	3tarted: 02/07/2003	Stop	ped: 28/07/2003
OLANZAPINE (Suspected)		Reason: Depress	sion
Tablet	5.0 Milligram	Daily	Oral
3atch:	Started: 09/07/2003	Stop	ped: 28/07/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Reflux oesophagitis		Heart burn.	
	Required Visit to Doctor	Inability to stay asleep.	Luvox stopped.

Medicine Details:

LUVOX (Suspected)		Reason:		
Oral application	50.0 Milligram	Daily		
3atch:	Started:	Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Coversyl. Panamax, Norvail, Asprin. Onset date. January 2003



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

Report [Detail
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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 Detai

1	Cacilon Detai	ā.		
	Preferred Term	Severity	Report Description	Treatment
		Required Visit to Doctor	Ecchymosis on shins and arms.	

Medicine Details:

Medicine Details.					
BRUFEN (Other drug)		Reas			
Tablet	1.0	Dose Unspecified	As necessary	Oral	
Зatch:	Started:		Stopped	:	
LUVOX (Suspected)		Reas	on:		
Tablet	100.0	Milligram	Daily	Oral	
3atch:	Started:		Stopped	:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Anorexia		Nausea, anorexia, weight loss, nightmares, insomnia, suicidal, worsening of DED.	
Insomnia	to Doctor	Nausea, anorexia, weight loss, nightmares, insomnia, suicidal, worsening of DED.	
Nightmare	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

3atch: 3tarted: 18/08/2003 3topped: 18/09/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



DOB: 18/03/1931

Date 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

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Onset Date: 18/08/2003

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Weight decreased	to Doctor	Nausea, anorexia, weight loss, nightmares, insomnia, suicidal, worsening of DED.	
Nausea	to Doctor	Nausea, anorexia, weight loss, nightmares, insomnia, suicidal, worsening of OCD.	
Obsessive-compulsive disorder		Nausea, anorexia, weight loss, nightmares, insomnia, suicidal, worsening of OCD.	

				tai	

 Movox (Suspected)
 Reason:
 Depression

 200.0
 Milligram
 Daily

 3atch:
 Started:
 18/08/2003
 Stopped:
 18/09/2003

Laboratory Investigations:



Date 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 Detai

Todotton Botal	i		i
Preferred Term	Severity	Report Description	Treatment
Angioedema	Required Visit to Doctor	Angioedema:- periorbital oedema, facial swelling, tongue swelling.	Ceased Risperidone.
	Required Visit to Doctor	Dry cracking skin on face and hands.	
	Required Visit to Doctor	Red hands	
	Required Visit to Doctor		
	Required Visit to Doctor		
Tongue oedema	Required Visit to Doctor		

Medicine Details:

RISPERIDONE (Suspected)		Reason:	Unspecified sch	nizophrenia
Tablet	2.0 Milligram	Daily		Oral
3atch:	3tarted: 25/09/2003		Stopped:	25/09/2003
FLUVOXAMINE MALEATE (Suspected)		Reason:	Depression	
Tablet	100.0 Milligram	Daily		Oral
Заtch:	3tarted: 23/09/2003		Stopped:	01/10/2003
CLOZAPINE (Suspected)		Reason:	Unspecified sch	nizophrenia
CLOZAPINE (Suspected) Tablet	50.0 Milligram	Reason: Daily	•	nizophrenia Oral
` ' '	50.0 Milligram Started: 24/09/2003			'
Tablet	· ·			Oral
Tablet 3atch:	· ·	Daily	Stopped:	Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

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	Case Number: 1	191277	Seq: ´	1		Gender:	M	
Onset Date: 25/08/2003 DOB: 17/03/1974 Causality: Causality possible Reaction Detai Medicine Details: ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 itopped:	Reported:							
Outcome: Not yet recovered Causality: Causality possible Reaction Detail Medicine Details: ATENOLO. (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:	Hospitalisation:					Age:	29	
Medicine Details: ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped:	Onset Date: 2	25/09/2003						
Medicine Details: ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: \$tarted: 23/09/2003 \$topped: Laboratory Investigations:		Not yet recovered				Causality:	Causality possible	
ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:	Reaction Detai							
ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:								
ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:								
ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:								
ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:								
ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:								
ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:								
ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:								
ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:								
ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:								
ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:								
ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:								
ATENOLOL (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: 23/09/2003 Stopped: Laboratory Investigations:	Medicine Deta	ile·						
Tablet 25.0 Milligram Daily Oral 3atch: 3tarted: 23/09/2003 3topped: Laboratory Investigations:	ATENOLOL (Suspec	cted)			Reason:			
Satch: Started: 23/09/2003 Stopped: Laboratory Investigations:				25.0 Milligram	Daily	Oral		
			Start		•			
	l abaratamı lay	·ootimations.						
Additional Information:	Laboratory inv	estigations:						
Additional Information:								
Additional Information:								
Additional Information:								
Additional Information:								
Additional Information:								
Additional Information:								
Additional Information:								
	Additional Info	ormation:						

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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: 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 Detai

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
3atch:	3tarted: 16/07/2002	Stopped:	05/02/2003
CLOZAPINE (Interaction)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
3atch:	3tarted: 16/07/2002	Stopped:	05/02/2003
AMISULPRIDE (Other drug)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
3atch:	Started: 16/07/2002	Stopped:	05/02/2003

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
22/10/2003	Other data				

Additional Information:

? impact of Fluvoxomine causing increased level.



Date 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 Detai

10404011 2044			
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	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction has settled within one week on cessation.



Report Detail

Case Number: 192464

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

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

Seq: 1

lospitalisation:		Weight: 65.00 Age: 40Y						
Onset Date:		DOB:						
Outcome: Recovered		Caus	sality: Causality possible					
eaction Detai								
Preferred Term	Severity	Report Description	Treatment					
Contusion	Pa spo	tient noticed an increase in ontaneous bruising (no trauma).						
Medicine Details:								
LUVOX (Suspected)		Reason:						
3atch:	Started:	Stopped:						
_aboratory Investigation	1S: Range Date Tested	d Result	Details					



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Caused or prolonged inpatient hospitalisation		Fluvoxamine ceased, fluid restrictions resulting in normalisation of sodium

Medicine Details:

FLUVOXAMINE MALEATE (Suspected) Reason: Depression

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 10/10/2003
 3topped:
 17/10/2003

Laboratory Investigations:

					
Date	Туре	Range	Date Tested	Result	Details
16/12/2003	Sodium		15/10/2003	129	



Date 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

04/02/2004

Causality: Causality possible

Reaction Detai

Outcome: Recovered

Cachon Detai			
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)		Rea	ason:	
Tablet	50.0	Milligram	Daily	

3atch: 3tarted: 20/01/2004 3topped: 02/02/2004

MAXOLON (Suspected) Reason:

10.0 Milligram Daily

3atch: 3tarted: 01/02/2004 3topped: 01/02/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
	Required Visit to Doctor		Ceased Luvox, Stilnox, Zoton. Given Diazepam.
	Required Visit to Doctor		
	Required Visit to Doctor		
	Required Visit to Doctor		
	Required Visit to Doctor		
	Required Visit to Doctor		

Medicine Details:

Modifile Botalie.				
LUVOX (Suspected)		Reason:	Depression	
Tablet	20.0 Milligram	Daily		Oral
3atch:	Started: 24/03/2004		Stopped:	25/03/2004
STILNOX (Suspected)		Reason:	Disturbance of	f sleep
Tablet	10.0 Milligram	Daily		Oral
Batch:	Started: 24/03/2004		Stopped:	25/03/2004
ZOTON (Suspected)		Reason:	Other disease	es of esophagus
Capsule	30.0 Milligram	Daily		Oral
3atch:	Started: 24/03/2004		Stopped:	25/03/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
Somnolence	Required Visit to Doctor		

Medicine Details:

LUVOX (Suspected)		Reason:	Depression	
Tablet	20.0 Milligram	Daily		Oral
3atch:	Started: 24/03/2004		Stopped:	25/03/2004
STILNOX (Suspected)		Reason:	Disturbance of	of sleep
Tablet	10.0 Milligram	Daily		Oral
3atch:	Started: 24/03/2004		Stopped:	25/03/2004
ZOTON (Suspected)		Reason:	Other disease	es of esophagus
Capsule	30.0 Milligram	Daily		Oral
3atch:	Started : 24/03/2004		Stopped:	25/03/2004

Laboratory Investigations:



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		hyponatraenia	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected) Reason: Depression

Tablet 150.0 Milligram Daily Oral

Started: Started: Stopped: 10/10/2004

Laboratory Investigations:

Date	Туре	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.

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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:
 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 Detai

Preferred Term	Severity	Report Description	Treatment
	Required Visit to Doctor	Sweats and agitation	
	Required Visit to Doctor		

Medicine Details:

<u>Medicine Details:</u>						
TRAMAL SR (Interaction)		र	leason:	Pain		
	200.0	Milligram	Daily			
3atch:	Started:			Stopped:	06/04/2004	8 months
FLUVOXAMINE MALEATE (Interaction)		र	leason:	Depression		
Tablet	1.0	Dose Unspecif	ied Daily		Oral	
3atch:	Started:			Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Pariet and Ciprofloxacin.



Report Detail

Case Number: 197314

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

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

Seq: 1

Repo	rted: 13/05/200	14				Weig	jht: 85.50			
Hospitalisa	tion:		Age: 28							
Onset D	Date:			DOB: 29/05/1975 Causality: Causality possible						
Outco	ome: Not yet re	covered								
eaction E	Detai									
Pre	eferred Term	Sever	rity	Report [Description		Treatment			
Hyporeflexi	а		Hypo	reflexia, hypoxi g pregnancy.	ia, drug exposure	e (One twin needed intubation, mechanial ventilation for 48			
Drug expos Hypoxia	sure during pregi	nancy		g prognancy.			hours			
	Dataile									
Medicine LUVOX (Sus				Reason	,•					
Tabl			300.0 Millig		oaily	Oral				
3atc		3tart		gram L	Stopped:	Olui				
	ry Investigat		5 · - · · · ·	- · · · ·			D + 11			
Date	Туре	Range	Date Tested	Result			Details			
13/05/2004	Prolactin									
A al al!4! a · · ·	-l l <i>ufa</i> -4' -									
Additiona	al Informatio	n:								



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

Report De	etail				
Repor Hospitalisat		Seq : 1 4		Weig A	ler: M ht: 0.00 ge: 64Y
Onset D	ate: me: Recovered	4			DB: ity: Causality probable
Culco Reaction D		ı		Causai	ity: Causality probable
	ferred Term	Severity	Report	Description	Treatment
Feeling abno	ormal		Unpleasant feeling		_uvox ceased.
Medicine			2000		
LUVOX (Sus		1	Reaso O Dose Unspecified		
3atch		Started:	.o Dose Orispecified	Stopped:	
	'y Investigati		acted Result		Optails
Laborator Date	'y Investigati Type	O ns: Range Date 1	ested Result	[Details



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

Report Detai	<u> </u>						
Case Number: Reported: Hospitalisation: Onset Date:	197425 17/05/200 Not yet red		1				85.50
	ed Term	Seve	erity	Repor	Description		Treatment
Hyporeflexia Drug exposure o	during pregr				exposure during		
Medicine Det LUVOX (Suspecte Tablet 3atch:		Star	300.0 Milli	Reas gram	on: Daily Stopped	Oral :	
Laboratory II	nvestigat Type	ions:	Date Tested	Result		Deta	ils
	,						
Additional In	formatio	n:					



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

Re	po	rt	D	et	ai∣
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Case Number: 197433 Seq: 1 Gender: F
Reported: 18/05/2004 Weight: 0.00
Iospitalisation: Age: 44

 Hospitalisation:
 Age: 44

 Onset Date: 14/05/2004
 DOB: 16/12/1959

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Botai			
Preferred Term	Severity	Report Description	Treatment
	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
3atch:	Started: 13/05/2004	Stopped:	16/05/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
		Severe outbursts of aggression with little provocation.	

Medicine Details:

 LUVOX (Suspected)
 Reason:
 Anxiety neurosis

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 02/03/2004
 3topped:
 14/05/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

100000000000000000000000000000000000000		<u>-</u>	
Preferred Term	Severity	Report Description	Treatment
Chest discomfort		Acute onset chest tightness and shortness	Luvox ceased.
Dyspnoea			

Medicine Details:

Medicine Details.			
PROMENSIL (Other drug)		Reason:	
Tablet	Dose Unsp	ecified	Oral
Зatch:	Started:	Stopped:	
LUVOX (Suspected)		Reason: Anxiety neuro	sis
Tablet	50.0 Milligram	Daily	Oral
3atch:	Started: 16/04/2004	Stopped:	20/04/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has had previous SOB as part of anxiety syndrome.



Date 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 Detai

todotion Botai			
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	
3atch:	Started:	ST	ERM	Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Largactil and Efexor.



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

Re	port	Det	tai
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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 Detai

Cachon Detai		-	
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

 3atch:
 3tarted:
 08/07/2004
 \$topped:
 10/07/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

todotion botal			
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

3atch: 3tarted: 3topped: 23/08/2002

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

todotion Dotal		E	
Preferred Term	Severity	Report Description	Treatment
	Required Visit to Doctor		Dose of Luvox reduced to 100mg daily and Solian reduced to 100mg daily.

Medicine Details:

Micalcinic Details.				
LUVOX (Suspected)		Reason:	Depression	
Tablet	300.0 Milligram	Daily	Oral	
3atch:	Started: 26/03/2003		Stopped:	
SOLIAN (Suspected)		Reason:	Unspecified psychosis	
Tablet	400.0 Milligram	Daily	Oral	
3atch:	3tarted: 23/03/2004		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
21/07/2004	Creatinine				
21/07/2004	Creatinine				
21/07/2004	Urea				



Date 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 Detai

		ā.	a
Preferred Term	Severity	Report Description	Treatment
Hypokalaemia		Hypokalaemia, suicidal thoughts.	K+ infusion
Suicidal ideation			

Medicine Details:

MARVELON (Other drug)		Reason:	Contraception	1
Tablet	1.0 Dose Unspe	ecified Daily		
3atch:	Started:		Stopped:	
OMEPRAZOLE (Suspected)		Reason:	Other disease	es of esophagus
Capsule	40.0 Milligram	Daily		Oral
3atch:	Started: 25/07/2004		Stopped:	31/08/2004
LUVOX (Suspected)		Reason:	Depression	
Tablet	100.0 Milligram	Daily		Oral
3atch:	Started:		Stopped:	31/08/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Coagulopathy	Life		Required medical attention, FFP, prothrombin and 3mg of
International normalised ratio incl	Life		Vitamin V

Medicine Details:

COUMADIN (Interaction)		Reason:			
Tablet	4.0 Milli	gram Daily		Oral	
Зatch:	Started:		Stopped:	08/08/2004	
LUVOX (Interaction)		Reason:	Depression		
Tablet	100.0 Milli	gram Daily		Oral	
Batch:	3tarted: 14/07/20	004	Stopped:		0
LOSEC (Other drug)		Reason:	Peptic ulcer ne	os w/o ment perf	
Tablet	20.0 Milli	gram Daily		Oral	
3atch:	Started:	L TERM	Stopped:		0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
22/09/2004	International		10/08/2004	1.0	INR - 11.4 on presentation to hospital.



Date 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

 pitalisation:
 Age: 47

 Onset Date: 25/08/2004
 DOB: 13/12/1956

Outcome: Recovered 20/10/2004 Causality: Causality possible

Reaction Detai

todotion Botal	ā		
Preferred Term	Severity	Report Description	Treatment
Agitation	to Doctor	Patient experienced agitation, nausea, muscle pain in upper arm and lower limbs and excess drowsiness.	Somac ceased
, ,	Required Visit to Doctor		
	Required Visit to Doctor		
	Required Visit to Doctor		

Medicine Details:

LUVOX (Interaction)		Reason:	Anxiety neurosis	
Tablet	100.0 Milligram	Daily	Oral	
3atch:	Started: 24/09/2003		Stopped:	
001110 (1 4 (1)		•	0	
SOMAC (Interaction)		Reason:	Other diseases of esoph	agus
Tablet	40.0 Milligram	Reason: Daily	Other diseases of esopr	agus

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Do	etail							
Repor Iospitalisat Onset D			1			C		0.00
eaction D								
	eferred Term	Seve	rity	Repo	rt Descri	ption		Treatment
White blood Drug interac	I cell count incre	eased	susp	te blood cell bected intera Luvox and d	ction betw	een Cloza	ril	
Drug Interac Drug level in								
<u>ledicine</u>	Details:			Rea	son:			
Tabl							Oral	
3atc	h:	Start	ed:			Stopped:		
CLOZARIL (Interaction)			₹ea	son:			
Tabl	et		12.0 Mill	ligram	Daily		Oral	
3atc	h:	3tart	ed: 05/08/2	2004		Stopped:		
L aborato Date	ry Investigat		Date Tested	Result	T		Deta	ills
27/10/2004	Serum drug level	J			05/10/04:	: High plasr	na Clozapine	e level of 1090ng/ml (reference
					range un	specified).		



er: 202656 ed: 18/11/2004 en: te: te: Death, maybe tai erred Term icide	Sev dted)	rerity	RI-induced aka	t Description thisia. Committed	Ago DOE Causality	er: U at: 0.00 e: 58 B: 16/10/1946 y: Causality possible Treatment ot ECT and Efexor later admission later admission. educed Fluvoxamine to lama. Remitted out
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e: Death, maybe tai rred Term icide	Sev dted)	200.0 Mil	RI-induced aka	t Description thisia. Committed on: Daily	Gausality Gad Re So	Treatment of ECT and Efexor later dmission later admission. educed Fluvoxamine to the Remitted out
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icide	ted)	200.0 Mil	RI-induced aka	thisia. Committed on: Daily	ad Re sn	ot ECT and Efexor later Imission later admission. educed Fluvoxamine to Ima Remitted out
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etails:		200.0 Mil	Reas	on: Daily	ad Re sn	Imission later admission. educed Fluvoxamine to Ima Remitted out
etails:				Daily	50	Oma Remitted out
etails:				Daily	Oral	0
				Daily	Oral	0
	Sta		ligram		Oral	0
	Sta					0
Investigation	s:					
		Date Tested	Result		De	etails
Information:						
	Туре		Type Range Date Tested	Type Range Date Tested Result	Type Range Date Tested Result	Type Range Date Tested Result De



Report Detail					
Case Number: 202722 Reported: 18/11/2004 Hospitalisation: Onset Date: Outcome: Unknown eaction Detai	Seq: 1		c	DOB	: 0.00 : 99U
Preferred Term	Severity	Report D	escription		Treatment
Suicidal ideation	Sui	icidal ideation.			
Medicine Details:					
LUVOX (Suspected)		Reason:			
Tablet 3atch:	150.0 M Started:	illigram Da	aily Stopped:	Oral	
OLANZAPINE (Suspected)	starteu.	Reason:			
OLYME II III (Guopostou)	10.0 M		aily		
3atch:	Started:		Stopped:		
_aboratory Investigatio	O ns: Range Date Tested	d Result		Deta	ails
Additional Information					



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Reported: 18/11/2004 pspitalisation: Onset Date: Outcome: Unknown paction Detai Preferred Term Somicidal ideation Details: Deta	Severity Started:	Homicida	•	: Description - attacked tea	Caus acher with	Ceased L		
Onset Date: Outcome: Unknown action Detai Preferred Term S omicidal ideation edicine Details: UVOX (Suspected) Tablet		Homicida	al ideation	- attacked tea	Caus acher with	DOB: ality: Cau	sality poss Treatment	
Outcome: Unknown action Detai Preferred Term S omicidal ideation edicine Details: UVOX (Suspected) Tablet		Homicida	al ideation	- attacked tea	acher with	ality: Cau	Treatment	
Preferred Term S omicidal ideation edicine Details: UVOX (Suspected) Tablet		Homicida	al ideation	- attacked tea	acher with	Ceased L	Treatment	
Preferred Term S pmicidal ideation edicine Details: UVOX (Suspected) Tablet		Homicida	al ideation	- attacked tea	acher with	Ceased L	uvox. comm	
edicine Details: UVOX (Suspected) Tablet		Homicida	al ideation	- attacked tea	acher with	Ceased L	uvox. comm	
edicine Details: _UVOX (Suspected) _Tablet		Homicida				Ceased Li Efexor at	uvox, comm 75mg daily.	enced
LUVOX (Suspected) Tablet	Started:		Reaso	on:				
.UVOX (Suspected) Tablet	Started:		deas c	on:				
.UVOX (Suspected) Tablet	Started:		Reasc	on:				
UVOX (Suspected) Tablet	Started:		?eas c	on:				
UVOX (Suspected) Tablet	Started:		Reaso	on:				
Tablet	Started:		Reaso	on:				
	Started:							
3atch:	started:				Ora	I		
				7.00	ped:			
aboratory Investigations:	Ja	1						
Date Type Range	Date Te	ested I	Result			Details		



Hospitalisation:

Case Number: 202749

Reported: 18/11/2004

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Weight: 0.00

Age: 99u

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

					DOB:		
Outcome: Unknown	1		Causality: Causality possible				
action Detai					+		
Preferred Term	Seve	rity	Report D	escription	Treatment		
ania		Patie	nt became mani	c, had suicidal	Discharged on Fluvoxamoine		
		outhu	on, was violent,	had angry violent	200mg and Olanzapine 200mg		
ggression kathisia							
uicidal ideation							
ledicine Details:							
OLANZAPINE (Suspected)			Reason:				
3atch:	3tar	ted:		Stopped:			
LUVOX (Suspected)			Reason:				
Tablet 3atch:		ted:		Ora Stopped:			
aboratory Investiga	tions:						
Date Type	Range	Date Tested	Result		Details		
	<u> </u>				_		
dditional Informatio	on:						



Case Number: 202769

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

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

Reported: 18/11/2004 ospitalisation:			W	/eight: 0.00 Age: 99U
Onset Date:				Age: 990 DOB:
Outcome: Unknown			Cau	sality: Causality possible
action Detai			Jaa	Canty: Cadodity possible
Preferred Term	Severity	Report De	escription	Treatment
uicidal ideation	Sı	icidal ideation and a		
kathisia				
ledicine Details: LUVOX (Suspected)		Reason:		
Tablet Batch:	Started:		Oi Stopped:	ral
oborotory Investigation				
aboratory Investigation Date Type	Range Date Teste	d Result		Details
Туре Туре	Trange Date reste	a Result		Details
Additional Information:				
ort Run 01/08/200 01:37PN	Database: pusime	ADRS	5004	Page 226 of 326



Case Number: 202787

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

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

Reported	d: 18/11/2004	1			W	eight: 0.00
Iospitalisatior						Age: 22
Onset Date	e:					DOB : 02/01/1982
Outcome	e: Unknown				Caus	sality: Causality possible
eaction Det		- i	<u> </u>			•
Prefer	red Term	Sev	erity	Report Des	scription	Treatment
Orug withdrawa	al syndrome		5 da beca	ys after ceasing Lu ime violent.	vox the patient	Discharged on Luvox.
ggression						
ledicine De	etails:					
LUVOX (Suspec	ted)			Reason:		
Tablet					Ora	al
3atch:		3ta	arted:		Stopped:	
aboratory	Investigati	ons:				
Date	Туре	Range	Date Tested	Result		Details
\						
Additional I	ntormation	1:				
ort Run 01/08/2	200 01:37PN	Database: pu	usime	ADRSO	004	Page 227 of 326
		1				1 490 227 01 020



Case Number: 202804

Reported: 18/11/2004

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Weight: 0.00

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

Hospitalisat						Age: 37		
Onset D					_	DOB : 09		
	me: Unknown				Са	usality: Ca	usality poss	ible
Reaction D		Cov	a mids .	Donor	t Decembries		Tractmant	
Suicidal idea	eferred Term	Seve			t Description		Treatment	
Suicidal idea	alion		viole	ence and over	ed suicidal ideation, dose.			
Aggression								
Overdose								
Medicine	Details:							
LUVOX (Sus				Reas	on:			
Table						Oral		
3atcl	h:	3ta	rted:		Stopped:			
Laboratoi Date	ry Investigat Type	Range	Date Tested	Result	<u> </u>	Details		
Date	туре	Naliye	Date Tested	Result		Details		
Additiona	ıl Informatio	1:						
eport Run 01/	08/200 01:37PN	Database: pu	sime	A	DRS004		Page 228	of 326



Case Number: 202809

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: U

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

Ospitalisation: Onset Date: Outcome: Unknown Causality: Causal	Age: 99U DOB: Causality: Causality possible Severity Report Description Treatment Patient developed akathisia and had a suicide attempt. d) Reason: Started: Stopped: Reason: Oral	spitalisation: Onset Date: Outcome: Unknown Preferred Term Preferred Term Severity Patient developed akathisia and had a suicide attempt. Sedicine Details: UCLOPENTHIXOL ACETATE (Suspected) Injection Satch: Started: Started: Stopped: ULANZAPINE (Suspected) Tablet Noral Regort Description Treatment Treatment Report Description Treatment Reason: Started: Stopped: Stopped: Stopped: Stopped: Stopped: UVOX (Suspected) Tablet Oral					ight: 0.00
Outcome: Unknown Preferred Term Severity Report Description Irrelated attempt Patient developed akathisia and had a suicide attempt.	Causality: Causality possible Severity Report Description Treatment Patient developed akathisia and had a suicide attempt. d) Reason: Started: Stopped: Reason: Started: Stopped: Reason: Oral	Outcome: Unknown Preferred Term Severity Report Description Treatment athisia Patient developed akathisia and had a suicide attempt Bedicine Details: UCLOPENTHIXOL ACETATE (Suspected) Reason: Injection 3 atch: Started: Stopped: ULANZAPINE (Suspected) Reason: ULANZAPINE (Suspected) Reason: Tablet Started: Stopped: UVOX (Suspected) Reason: Tablet Started: Stopped: UNOX (Suspected) Reason: Tablet Started: Stopped: UVOX (Suspected) Reason: Tablet Started: Stopped:	Onset Date:				_
Action Detail Preferred Term Severity Report Description Tree kathisia Patient developed akathisia and had a suicide attempt. Patient developed akathisia and had a suicide attempt. Pati	Severity Report Description Treatment Patient developed akathisia and had a suicide attempt. d) Reason: Started: Stopped: Reason: Started: Stopped: Oral	Preferred Term Severity Report Description Treatment athisia Patient developed akathisia and had a suicide attempt. Bedicine Details: UCLOPENTHIXOL ACETATE (Suspected) Reason: Injection 3 atch: Started: Stopped: ULANZAPINE (Suspected) Reason: ULANZAPINE (Suspected) Reason: ULANZAPINE (Suspected) Reason: 3 atch: Started: Stopped: UVOX (Suspected) Reason: Tablet Started: Stopped: UVOX (Suspected) Reason: Tablet Oral 3 atch: Started: Stopped:				D	OB:
Preferred Term Severity Report Description Tree kathisia Patient developed akathisia and had a suicide attempt. Patient developed akathisia and had a suicide attempt. Patient developed akathisia and had a suicide attempt. Patient developed akathisia and had a suicide attempt. Patient developed akathisia and had a suicide attempt. Patient developed aka	Patient developed akathisia and had a suicide attempt. d) Reason: Started: Stopped: Reason: Started: Stopped: Reason: Oral	Preferred Term Severity Report Description Treatment athisia Patient developed akathisia and had a suicide attempt.				Causa	ality: Causality possible
Redicine Details: Patient developed akathisia and had a suicide attempt.	Patient developed akathisia and had a suicide attempt. d) Reason: Started: Stopped: Reason: Started: Stopped: Reason: Oral	Patient developed akathisia and had a suicide attempt. Patient developed akathisia an		0	Danad	Describette	To also set
Suicide attempt Suicide at	d) Reason: Started: Stopped: Reason: Started: Stopped: Oral	suicide attempt.				·	Treatment
edicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Injection 3atch: Started: Stopped: DLANZAPINE (Suspected) 3atch: Started: Stopped: LUVOX (Suspected) Tablet Oral	Started: Stopped: Reason: Started: Stopped: Oral	edicine Details: UCLOPENTHIXOL ACETATE (Suspected) Injection 3atch: Started: Stopped: ULANZAPINE (Suspected) 3atch: Started: Stopped: UVOX (Suspected) Tablet 3atch: Started: Stopped: UVOX (Suspected) Tablet 3atch: Started: Stopped:	kathisia	ļ ļ	Patient developed suicide attempt.	akathisia and had a	
CUCLOPENTHIXOL ACETATE (Suspected) Injection 3atch: Started: Stopped: CLANZAPINE (Suspected) Started: Stopped: CLANZAPINE (Suspected) Tablet Coral	Started: Stopped: Reason: Started: Stopped: Ceason: Oral	Injection Started: Stopped:	uicide attempt				
CUCLOPENTHIXOL ACETATE (Suspected) Injection 3atch: Started: Stopped: CLANZAPINE (Suspected) Started: Stopped: CUCLOPENTHIXOL ACETATE (Suspected) Stopped: Clanzapine (Suspected) Stopped: Cuvox (Suspected) Tablet Oral	Started: Stopped: Reason: Started: Stopped: Ceason: Oral	UCLOPENTHIXOL ACETATE (Suspected) Injection 3atch: Started: Stopped: DLANZAPINE (Suspected) 3atch: Started: Stopped: UVOX (Suspected) Tablet 3atch: Started: Stopped: Oral 3atch: Started: Stopped:					
CUCLOPENTHIXOL ACETATE (Suspected) Reason:	Started: Stopped: Reason: Started: Stopped: Ceason: Oral	UCLOPENTHIXOL ACETATE (Suspected) Injection 3atch: Started: Stopped: DLANZAPINE (Suspected) 3atch: Started: Stopped: UVOX (Suspected) Tablet 3atch: Started: Stopped: Oral 3atch: Started: Stopped:					
UCLOPENTHIXOL ACETATE (Suspected) Injection 3atch: Started: Stopped: CLANZAPINE (Suspected) 3atch: Started: Stopped: UVOX (Suspected) Tablet Ceason: Oral	Started: Stopped: Reason: Started: Stopped: Oral	Injection Started: Stopped:					
CUCLOPENTHIXOL ACETATE (Suspected) Reason:	Started: Stopped: Reason: Started: Stopped: Ceason: Oral	Injection Started: Stopped:					
CUCLOPENTHIXOL ACETATE (Suspected) Reason:	Started: Stopped: Reason: Started: Stopped: Ceason: Oral	UCLOPENTHIXOL ACETATE (Suspected) Injection 3atch: Started: Stopped: DLANZAPINE (Suspected) 3atch: Started: Stopped: UVOX (Suspected) Tablet 3atch: Started: Stopped: Oral 3atch: Started: Stopped:					
CUCLOPENTHIXOL ACETATE (Suspected) Reason:	Started: Stopped: Reason: Started: Stopped: Oral	Injection Started: Stopped:					
CUCLOPENTHIXOL ACETATE (Suspected) Reason:	Started: Stopped: Reason: Started: Stopped: Oral	Injection Started: Stopped:					
UCLOPENTHIXOL ACETATE (Suspected) Injection 3atch: Started: Stopped: CLANZAPINE (Suspected) 3atch: Started: Stopped: UVOX (Suspected) Tablet Ceason: Oral	Started: Stopped: Reason: Started: Stopped: Oral	Injection Started: Stopped:	adiaina Dataila.				
Injection 3atch: Started: Stopped: PLANZAPINE (Suspected) Reason: Stopped: Stopped: UVOX (Suspected) Reason: Tablet Oral	Started: Stopped: Reason: Started: Stopped: Oral	Injection 3atch: Started: Stopped: ILANZAPINE (Suspected) Reason: Started: Stopped: UVOX (Suspected) Reason: Tablet Oral Started: Stopped:		Suspected)	Reaso	on:	
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UVOX (Suspected) Reason: Tablet Oral	Reason: Oral	UVOX (Suspected) Tablet Oral 3atch: Started: Stopped:	LANZAPINE (Suspected)		Reaso		
UVOX (Suspected) Reason: Tablet Oral	Reason: Oral	UVOX (Suspected) Tablet Oral 3atch: Started: Stopped:					
Tablet Oral	Oral	Tablet Oral 3atch: Started: Stopped: boratory Investigations:	3atch:	Started:		3topped:	
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			Tablet	Started:		Stopped:	
			Tablet	Started:		Stopped:	
			Tablet	Started:		Stopped:	
boratory Investigations:			Tablet	Started:		3topped:	
Date Type Range Date Tested Result Details	Date Tested Result Details		Tablet 3atch :			3topped:	
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			Tablet 3atch: aboratory Investigation	ons:	sted Result	€ Stopped:	Details
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Additional Information:		iditional Information:	Tablet 3atch: aboratory Investigation Date Type	Ons: Range Date Tes	sted Result	Stopped:	Details



Case Number: 202815

Reported: 18/11/2004

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

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

ospitalisati						Age: 99U		
Onset Da				DOB:				
	ne: Death, ma	lybe drug			Caus	sality: Causality possible		
action De	etai erred Term	Sev	verity	Renor	t Description	Treatment		
kathisia	Circa reiiii	- 00				rreament		
			akat	thisia and com	ed suicide attempt, pleted suicide.			
ompleted s	uicide							
edicine [Details:							
FEXOR (Sus	spected)			Reas				
3atch:		24	arted:		Ora Stopped:	al		
	IE MALEATE (Sus		laiteu.	Reas				
Tablet		. ,			Ora	al		
3atch:	:	31	arted:		Stopped:			
	y Investigat	ions:						
Date	Туре	Range	Date Tested	Result		Details		
dditional	Information	ո։						
ort Run 01/0	8/200 01:37PN	Database: p	ousime	A	DRS004	Page 230 of 326		



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Report	er: 202838	Seq: 1			Gender: U
_	ed: 19/11/2004	,			Weight: 0.00
spitalisatio Onset Da					Age: 99U DOB:
	ne: Unknown			Ca	nusality: Causality possible
action De				O.	desailty. Causality possible
	erred Term	Severity	R	eport Description	Treatment
uicide atten	npt		Suicidal idea	tion and suicide attempt.	
edicine [Details: E MALEATE (Susp	pected)		Reason:	
Tablet	:				Oral
3atch:	:	Started:		Stopped:	
ZYPREXA (Su	spected)			Reason:	
		15	5.0 Milligram	Daily	
		Started:		Stopped:	
3atch:					
ZUCLOPENTH	IIXOL ACETATE (S	Suspected)		Reason:	
UCLOPENTI Injection	HIXOL ACETATE (S	Suspected)	0.0 Milligram	Daily	
ZUCLOPENTH	HIXOL ACETATE (S	Suspected)	0.0 Milligram		
ZUCLOPENTH Injecti 3atch:	HIXOL ACETATE (S	Suspected) 200 Started:	0.0 Milligram	Daily	
ZUCLOPENTH Injecti 3atch:	HIXOL ACETATE (S	Suspected) 200 Started:	0.0 Milligram Tested Resu	Daily Stopped:	Details



Case Number: 202845

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

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

Reported: 19/11/20/ Hospitalisation:	04		Weight: 0.00 Age: 99U
Onset Date:			DOB:
Outcome: Unknown	1	Ca	ausality: Causality possible
eaction Detai	- 		
Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Suic	idal ideation.	
Medicine Details:	uspected)	Reason:	
Tablet			Oral
3atch:	Started:	Stopped:	0
ZYPREXA (Suspected)		Reason:	
3atch:	Started:	Stopped:	
Laboratory Investiga Date Type	tions: Range Date Tested	Result	Details
Additional Informatio		ADDS004	Down 200 £ 200
eport Run 01/08/200 01:37PI	M Database: pusime	ADRS004	Page 232 of 326



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Hospitalisation: Onset Date:	19/11/2004 Admitted to hos	Seq: 1		Wei	der: U ght: 22.60 Age: 7 OB: 30/07/1997 Ality: Causality possible
	ed Term	Severity	Repo	t Description	Treatment
Obsessive-comp	oulsive disorder	Caused or prolonged inpatient hospitalisation	The patient devel compulsive disord	oped obsessive	Luvox ceased.
Medicine De			Reas	s on: Behavior disorders o	of childhod
Tablet	su,		\\	Oral	or Grindriod
3atch:		Started:		Stopped:	0
DEXAMPHETAMI 3atch:	NE SULPHATE (Sus		Reas Milligram	son: Behavior disorders of Daily Stopped:	of childhod
Laboratory I	nvestigations	:			
Date		ange Date Te	sted Result		Details
Additional In	formation:	l			



Date 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 Detai

reaction Detai	=		
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			
3atch:	Started:	Stopped:	25/06/2004			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Second time patient's had a manic/hypomanic reaction to Luvox in the last 2 weeks.



Date 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 Detai

Todotion Dotai	1		
Preferred Term	Severity	Report Description	Treatment
Agitation	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

3atch: 3tarted: 20/07/2004 3topped: 03/11/2004

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

Veaction Detai	saction betai								
Preferred Term	Severity	Report Description	Treatment						
Sleep walking	Required Visit to Doctor								
Tinnitus	Required Visit to Doctor								

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)Reason:DepressionTablet300.0 MilligramDailyOral3atch:3tarted:20/07/20043topped: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.

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Additional Information:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Hospitalisat Onset D	ate: me: Recovered	Seq: 1				Age DOE	r: F t: 55.00 e: 46 3: 25/09/1958 r: Causality probable
	eferred Term	Severi	ty	Report D	Description		Treatment
Abdominal o	distension		The bloa	patient experien ting and belching	ced flatulence, g.		
Eructation							
Medicine	Details:						
LUVOX (Sus	pected)			Reason	: Depression		
Table	et		50.0 Mill	ligram D	aily	Oral	
3atch	h:	Starte	ed: 20/09/2	2004	Stopped:		0
	ry Investigatio			T			
Laborator Date	ry Investigatio		Pate Tested	Result		De	tails



Case Number: 203509

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

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

Reported: 13/12/2004	1				Weigh	t: 0.00		
ospitalisation:		Age: 99u						
Onset Date:			DOB:					
Outcome: Unknown			Causality: Causality possible					
eaction Detai								
Preferred Term	Seve	erity	Report D	Description		Treatment		
Sleep walking		Patie night	ent experienced tmares while wit	sleep walking a hdrawing from l	nd _uvox.			
Orug withdrawal syndrome Nightmare								
Medicine Details: LUVOX (Suspected)			20000	<u> </u>				
Tablet		200 0 Milli	Reason		Oral			
Batch:	240.	300.0 Milli	.gram L	aily Stopped:	Oral			
_aboratory Investigati	ons:							
Date Type	Range	Date Tested	Result		De	etails		
Additional Information	1:							
oort Run 01/08/200 01:37PN	Database: pus	sime	ADF	RS004		Page 238	of 326	



Case Number:					
Reported: Hospitalisation: Onset Date:	203510 13/12/2004 Recovered	Seq:	1	Weiç A Do	der: F ght: 55.00 .ge: 46 OB: 25/09/1958 lity: Causality probable
R <u>eaction Detai</u>					
Preferre	d Term	Seve	erity	Report Description	Treatment
Hot flush Drug withdrawal Sensory disturba	-		The sho	e patient had hot flushes and electric ck sensations after ceasing Luvox.	
Medicine Deta				Reason: Depression	
Tablet	-,		50.0 Mi		
3atch:		3ta	rted: 20/09/		
Laboratory In	vestigation	s:			
Laboratory In		S: Range	Date Tested	Result	Details



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

Re	por	t D	etail
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 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 Detai

todolion Botai		-	
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

 3atch:
 3tarted:
 09/11/2004
 3topped:
 26/12/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Seizures	Sodium Valproate.

Medicine Details:

LUVOX (S	uspected)			Reason:	Depression	
Т	ablet	300.0	Milligram	Daily		Oral
38	tch: Sta	rted:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

A possibly of suffering from reflex occipital epilepsy was diagnosed



Date 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 Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Alopecia		Patient waited 2 days and then started Luvox half a tablet mane for 2 days. Hair	

Medicine Details:

LUVOX (Suspected)	Reason:				
Tablet	50.0 Milligram	Total	Oral		
3atch:	Started:	Sto	opped:	0	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient felt hair loss was due to Luvox. Report 205889 is the second sequence to this report.



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

Rep	00	rt	D	eta	il
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Case Number:207578Seq:1Gender:MReported:03/05/2005Weight:0.00Hospitalisation:Required a visit to the doctorAge:99u

Onset Date: 14/04/2005 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

		<u>-</u>	
Preferred Term Severity		Report Description	Treatment
Euphoric mood		Feelings of euphoria, buzzing with "electric shocks" and flushing.	Stongly recommended ceasing Codral.
Flushing			
Paraesthesia			

Medicine Details:

CODRAL FLU AND COLD TABLET	S (Suspected)	Reason:	Acute nasopharyn	gitis,com cold	
Tablet			Ora	al	
3atch:	Started: 13/04/2005		Stopped:	0	
LUVOX (Suspected)		Reason:	Depression		
Tablet	50.0 Milligram	Daily	ora Ora	al	
3atch:	Started:		Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

Report Detail

Case Number:207749Seq:1Gender:MReported:12/05/2005Weight:0.00Hospitalisation:Admitted to hospitalAge:32

Onset Date: 15/01/2005 **DOB**: 11/08/1972

Outcome: Unknown Causality: Causality possible

Reaction Detai

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Incapacity/dis ability	Aripriprazole initiated 20mg/day on 15/11/2004, increased to 40mg/day (
	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 amoutation may be required.	
Blood creatine phosphokinase in	Incapacity/dis ability		
Drug prescribing error	Incapacity/dis ability		

Medicine Details:

CHLORPROMAZINE HYDROCH)	Reason:				
3atch:	Started:			Stopped:		
LUVOX (Suspected)			Reason:			
3atch:	Started:	15/11/2004		Stopped:	17/04/2005	
Abilify (Suspected)			Reason:			
Tablet		Milligram	Daily		Oral	
3atch:	Started:	15/11/2004		Stopped:	17/04/2005	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Neurologist suspected MacArdlesdisease with widespread myoneurosis founf on the biopsy examination



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

Report Detai	Re	po	rt	De	etai
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Case Number:207749Seq:1Gender:MReported:12/05/2005Weight:0.00Hospitalisation:Admitted to hospitalAge:32

Onset Date: 15/01/2005 DOB: 11/08/1972

Outcome: Unknown Causality: Causality possible

Reaction Detai

todotion Dotai			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug)			Reason:			
3atch:	Started:			Stopped:		
LUVOX (Suspected)			Reason:			
3atch:	Started:	15/11/2004		Stopped:	17/04/2005	
Abilify (Suspected)			Reason:			
Tablet		Milligram	Daily		Oral	
3atch:	Started:	15/11/2004		Stopped:	17/04/2005	0

Laboratory Investigations:

Additional Information:

Neurologist suspected MacArdlesdisease with widespread myoneurosis founf on the biopsy examination



Report Detai								
Case Number: 2 Reported: 1 ospitalisation: Onset Date:		Seq:	1			Weig A	ler: M jht: 37.00 ge: 11	
Onset Date: Outcome: F	Recovered				DB : 22/08/1993 ity : Causality probable			
eaction Detai	CCOVCICU					Odusai	ity. Gausanty probable	
Preferred	Term	Seve	erity	Repo	ort Description		Treatment	
Erythema nodosur				-	um type reactio			
Medicine Deta				₹ea	son:			
Tablet		25.0 Milligram			Daily	Oral		
3atch:		3ta	Started:			Stopped:		
Laboratory Inv		S: Range	Date Tested	Result			Details	



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Case Number	r: 207959	Seq:	1		Ger	ider: F			
Reported	I: 18/05/200)5		Weight: 0.00					
Hospitalisation				Age : 99u					
-	: 11/04/200)5		DOB:					
	: Not yet re			Causality: Causality possible					
Reaction Det	=								
	red Term	Sever	rity	Repor	Description	Treatment			
Agitation					ed agitation, anxiety,				
			back	pain, nausea	and diarrhoea.				
Anxiety									
Back pain									
Diarrhoea									
Nausea									
Medicine De				Reas	on: Depression				
Tablet			50.0 Milli	igram	Daily Oral				
3atch:		3tart	ed: 07/04/2	005 STERM	Stopped:	Continuing.			
Laboratory	Investigat	ions:							
Date	Туре		Date Tested	Result		Details			
Date Type Range Date Tested Result Details Additional Information:									



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

 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 Detai

todolion Botai		<u>-</u>	
Preferred Term	Severity	Report Description	Treatment
Disturbance in attention		Patient experienced concentation impaired, dizziness, excess sweating, dry mouth, cognitive impairment, communication	Luvox ceased.
Cognitive disorder			
Communication disorder			
Dizziness			
Dry mouth			
Hyperhidrosis			

Medicine Details:

LUVOX (Suspected)		Reason: De	epression
Tablet	50.0 Milligram	Daily	Oral
3atch:	Started: 12/04/2005		Stopped: 16/04/200

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Skin hyperpigmentation		Patient experienced facial	

Medicine Details:

RISPERDAL (Suspected)		₹ea	son:	Unspecified p	sychosis	
	1.0	Milligram	Daily			
3atch:	Started:			Stopped:		
COMBIVIR (Suspected)		Rea	son:	Hiv infection		
Tablet	2.0	Dose Unspecified	Daily		Oral	
3atch:	Started:			Stopped:		Continuing.
LUVOX (Suspected)		Rea	son:	Depression		
Tablet	300.0	Milligram	Daily		Oral	
3atch:	Started:			Stopped:		
NEVIRAPINE (Suspected)		Rea	son:	Hiv infection		
Tablet	400.0	Milligram	Daily		Oral	
3atch:	Started:			Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Case Number:	208162	Seq: 1			Gender:	M	
Reported:	25/05/2005				Weight:	64.00	
Hospitalisation:	Required a visit t	the docto	or		Age:	36	
Onset Date:					DOB:	16/07/1968	
Outcome:	Not yet recovered	i			Causality:	Causality possible	
Reaction Detai							
Medicine Deta	ails:						
VALACICLOVIR H	YDROCHLORIDE (Su	spected)		Reason:			
			1.0 Gram	Daily			
3atch:		Started:			Stopped:	0	
Laboratory In	vestigations:						
•	J						
Additional Inf	formation:						



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Reported: 03/06/2005 Weight: 0.00 Age: 70Y Onset Date: DOB: Outcome: Unknown Causality: Causality possible eaction Detai Preferred Term Severity Report Description Treatment Suicide attempt The patient experienced a serious suicidal attempt after three months of akathisia made serious, nearly lethial attempts, and developed deep vein thrombosis. Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Injection 200.0 Milligram Weekly 3atch: Started: Started: Stopped: OLANZAPINE (Suspected) Reason: 15.0 Milligram Daily 3atch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily Oral 3atch: Started: Stopped:
Onset Date: Outcome: Unknown Preferred Term Preferred Term Sourcide attempt Authorized Search Started: Preferred Term Sourcide attempt Authorized Search Started: Authorized Search Started: Preferred Term Sourcide attempt Authorized Search Started: Preferred Term Sourcide attempt Authorized Search Sear
Outcome: Unknown Preferred Term Severity Report Description Treatment Unicide attempt Unicide attempt Description Treatment The patient experienced a serious suicidal attempt after three months of akathisia - made serious, nearly lethal attempts, and developed deep vein thrombosis Description Serious Needed Warfarii Redicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Injection 200.0 Milligram Weekly 3atch: Started: Started: Stopped: OLANZAPINE (Suspected) Reason: 15.0 Milligram Daily 3atch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet 200.0 Milligram Daily Oral
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. Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Injection 200.0 Milligram Weekly 3atch: 3tarted: 3topped: OLANZAPINE (Suspected) Reason: 15.0 Milligram Daily 3atch: 3tarted: 3topped: FLUVOXAMINE MALEATE (Suspected) Tablet 200.0 Milligram Daily Oral
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. Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Injection 3atch: 3tarted: 3tarted: 3tarted: 3tarted: 3tarted: 3tarted: 3tarted: 3tarted: 3tarted: 3topped: FLUVOXAMINE MALEATE (Suspected) Tablet 200.0 Milligram Daily Oral
The patient experienced a serious suicidal attempt after three months of akathisia made serious, nearly lethal attempts, and developed deep vein thrombosis. Injection
attempt after three months of akathisia - made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed Warfarii made serious, nearly lethal attempts, and developed deep vein thrombosis. period. Needed
Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Injection 3atch: 3tarted: 3tarted: 3topped: OLANZAPINE (Suspected) 15.0 Milligram Daily 3atch: 3tarted: 3tarted: 3topped: FLUVOXAMINE MALEATE (Suspected) Tablet 200.0 Milligram Daily Oral
Medicine Details: ZUCLOPENTHIXOL ACETATE (Suspected) Injection 200.0 Milligram Weekly 3atch: Started: Stopped: OLANZAPINE (Suspected) Reason: 15.0 Milligram Daily 3atch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily Oral
Injection 200.0 Milligram Weekly Stopped: Started: Stopped:
3atch: Started: Stopped: Classon: 15.0 Milligram Daily 3topped: FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily Oral
OLANZAPINE (Suspected) 15.0 Milligram Daily 3atch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Tablet 200.0 Milligram Daily Oral
15.0 Milligram Daily 3atch: Started: Stopped: FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily Oral
3atch: 3tarted: 3topped: FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily Oral
FLUVOXAMINE MALEATE (Suspected) Reason: Tablet 200.0 Milligram Daily Oral
Tablet 200.0 Milligram Daily Oral
Laboratory Investigations: Date Type Range Date Tested Result Details



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Case Number:	209154	Seq:	1			Gender	: F
	27/06/200	-				Weight	: 0.00
Hospitalisation:						Age	: 30
Onset Date:	20/05/200	5				DOB	: 28/03/1975
Outcome:	Recovered	d				Causality	: Causality possible
Reaction Deta	<u>i</u>						
Preferre	ed Term	Sev	erity	Repor	t Description		Treatment
Therapy regimer	n changed				e was increased t		
Serotonin syndro	ome		The	e patient develonder drome after Re	oped suspected se emeron was initiate	erotonin ed with	
Agitation				DI.			
Insomnia							
Nausea							
Restlessness							
Sedation							
Medicine Det			30.0 M	Reas	on: Daily	Oral	
3atch:		21:	arted:	illigraili	Stopped:		05 0
FLUVOXAMINE M	ALEATE (Sus		arteu.	Reas		20/03/200	0
Tablet	(0.00	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	200.0 M		Daily	Oral	
3atch:		Sta	arted:		Stopped:		
Laboratory Ir	nvestigat	ions:					
Date	Type	Range	Date Tested	I Result		Deta	ails
		-					
Additional In	formatio	n:					



Date 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 Detai

odotron Botal								
Preferred Term	Severity	Report Description	Treatment					
Loss of consciousness	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						
Circulatory collapse	Caused or prolonged inpatient hospitalisation							

Medicine Details:

LUVOX (Suspected)	Reason:					
Tablet	100.0 Milligram	Daily	Oral			
3atch:	Started: 18/09/2004	Stopped:	02/10/2004			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

Re	po	rt	D	et	ta	i
----	----	----	---	----	----	---

 Case Number:
 209397
 Seq:
 1
 Gender:
 M

 Reported:
 01/07/2005
 Weight:
 84.00

Hospitalisation: Required a visit to the doctor

Onset Date: 26/05/2005

Age: 52

DOB: 19/04/1953

Outcome: Recovered 28/05/2005 Causality: Causality probable

Reaction Detai

todotion Botai		E	
Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		The patient experienced suspected serotonin syndrome.	Tramadol ceased.

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction	on)	Reason:			
	50.0	Milligram	As neces	ssary	
3atch:	Started:			Stopped:	
FLUVOXAMINE MALEATE (Interaction)			Reason:		
Tablet	100.0	Milligram	Daily	Oral	
3atch:	Started:			Stopped:	
RAMIPRIL (Other drug)			Reason:		
3atch:	Started:			Stopped:	
ASPIRIN (Other drug)			Reason:		
3atch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number: 209397 Reported: 01/07/2005 Hospitalisation: Required a visit Onset Date: 26/05/2005 Outcome: Recovered Reaction Detai Medicine Details:	Seq: 1	28/05/2005		84.00
PRAVASTATIN SODIUM (Other drug)	Reason:		
Заtch:	Started:		Stopped:	
Laboratory Investigations	3:			
Additional Information:				

Report Run 01/08/200 01:38PN Database: pusime ADRS004 Page 255 of 326



Date 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 Detai

Caction Detai	-		
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		
3atch:	Started:		Stopped:
LUVOX (Suspected)		Reason:	Depression

Tablet 300.0 Milligram Daily Oral

3atch: 3tarted: 04/05/2005 **3topped:** 15/06/2005 Tapering.

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



DOB: 10/05/1967

Date 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

Outcome: Recovered 29/05/2004 Causality: Causality possible

Reaction Detai

Onset Date: 24/05/2004

Preferred Term	Severity	Report Description	Treatment
Hypersensitivity			All drugs discontinued. Treated with Prednisolone.
Malaise			
Pain			
Pyrexia			
Rash			

Medicine Details:

CHLORAL HYDRATE (Suspected)		Reason:	Specific disor	ders of sleep	
				Oral	
Зatch:	Started:		Stopped:	24/05/2004	0
PANADEINE FORTE (Suspected)		Reason:	Migraine		
Tablet				Oral	
Зatch:	Started:		Stopped:	24/05/2004	0
LUVOX (Suspected)		Reason:	Depression		
Tablet	250.0 Milligram	Daily		Oral	
3atch:	3tarted: 01/05/2004		Stopped:	24/05/2004	
EPILIM (Suspected)		Reason:			
Tablet	500.0 Milligram	Daily		Oral	
Зatch:	Started:		Stopped:	24/05/2004	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History: Multiple drug allergies: Penicillin, Amoxicillin, Erythromycin, Bactrim, Rulide, Norflux, Plactil, Keflex, Clindamycin, Tagamet and Morphine.

Report Run 01/08/200 01:38PN Database: pusime ADRS004 Page 257 of 326



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	prolonged		

Medicine Details:

 LUVOX (Suspected)
 Reason:
 Depression

 Tablet
 250.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 31/05/2004
 \$topped:
 04/06/2004

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is cert/rechallenge causing the same reaction to occure. History: Multiple drug allergies: Penicillin, Amoxicillin, Erythromycin, Bactrim, Rulide, Norflux, Plactil, Keflex, Clindamycin, Tagamet and Morphine.



Date 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 Detai

i todotioni Botai		_	
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

3atch: 3tarted: 09/06/2005 S TERM 3topped:

FLUVOXAMINE MALEATE (Suspected) Reason: Anxiety neurosis

Tablet 50.0 Milligram Daily Oral

3atch: 3tarted: 09/06/2005 3topped: 09/07/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient previously treated with Avanza.



DOB:

Date 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

Outcome: Unknown Causality: Causality possible

Reaction Detai

Onset Date:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Incapacity/dis ability	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:

Ī	LUVOX (Suspected)			Reason:	
	Tablet	50.0	Milligram	Daily	Oral
	3atch:	Started:		3to	opped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient medical history: heart attack.



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

Danant Datail			
Report Detail			
Case Number: 211026	Seq: 1		der: M
Reported: 24/08/2005			ght: 0.00
Hospitalisation:			ge : 99u
Onset Date:			OB:
Outcome: Unknown		Causai	ity: Causality possible
Reaction Detai Preferred Term	Severity	Report Description	Treatment
Crying	Incapacity/dis ability	repert 2 coorpaon	Troduno.it
Therapy regimen changed	Incapacity/dis ability		
Medicine Details:		Name	
LUVOX (Suspected) Tablet	50.0 Milligran	Reason: n Daily Oral	
Batch:	Started:	Stopped:	
Laboratory Investigations	S :		



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

	er: 211639 d: 13/09/2005 n:	Seq: 1			Wei	der: M ght: 0.00 .ge: 99u
Onset Dat						OB:
Outcom	e: Unknown				Causal	lity: Causality possible
action De	tai					
Prefe	rred Term	Severity		Report Desc	ription	Treatment
Sleep walking			The par	tient experienced	sleep walking and wing from Luvox	
Orug withdraw Nightmare	al syndrome		thoron	ares while withdra ,	wing from Luvox	
Medicine D				Reason:		
	,				01	
Tablet		30	00.0 Milligra	am Daily	Oral	
ablet 3atch:		3(Started:	00.0 Milligra	am Daily	Stopped:	
3atch:	Investigation	Started:		Result Daily	Stopped:	Details
-aboratory		Started:			Stopped:	Details
_aboratory	Туре	DNS: Range Date			Stopped:	Details
_aboratory		DNS: Range Date			Stopped:	Details
-aboratory Date	Туре	DNS: Range Date			Stopped:	Details



Date 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
Onset Date: 28/06/2005

Weight: 0.00
Age: 78Y

Outcome: Recovered 30/06/2005 Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation	·	Ceased Warfarin, given Vitamin K 6.5mg.

Medicine Details:

Micarcine Details.			
COUMADIN (Interaction)		Reason: Otr&nos dise	ord of heart rhythm
Tablet	22.0 Milligram	Weekly	Oral
3atch:	3tarted: 23/06/2005	Stopped:	28/06/2005
LUVOX (Interaction)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
3atch:	Started: 23/06/2005	Stopped:	

Laboratory Investigations:

Date	Туре	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	



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

		•	etai	
-	\sim		 ^+^	

 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 Detai

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction		Patient experienced impotence.	

Medicine Details:

Movox (Suspected) Reason:

3atch: 3tarted: 15/01/2005 **3topped:** 15/09/2005

FLUVOXAMINE MALEATE (Suspected) Reason: Anxiety neurosis

Tablet 100.0 Milligram Daily Oral

3atch: 3tarted: 15/01/2005 3topped: 15/09/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
	prolonged inpatient hospitalisation		
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

XANAX (Other drug) Reason: Anxiety neurosis

0.5 Milligram

3atch: 3tarted: 17/11/2004 3topped:

TEMAZE (Other drug) Reason: Specific disorders of sleep

10.0 Milligram

 3atch:
 3tarted:
 11/03/2005
 3topped:

Movox (Suspected) Reason: Depression

Tablet 150.0 Milligram Daily Oral

3atch: **3tarted**: 05/05/2005 **3topped**: 10/05/2005 0

Movox (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 28/02/2004 **3topped:** 05/05/2005 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient stabilised on maintenance dose 50mg daily.



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

Report Detail

Case Number:212065Seq:1Gender:MReported:28/09/2005Weight:0.00Hospitalisation:Admitted to hospitalAge:52

Onset Date: 10/05/2005 DOB: 07/02/1953

Outcome: Recovered Causality: Causality possible

Reaction Detai

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 neuro	sis	
	0.5 Milligram				
3atch:	Started: 17/11/2004		Stopped:		
TEMAZE (Other drug)		Reason:	Specific disor	ders of sleep	
	10.0 Milligram				
3atch:	Started: 11/03/2005		Stopped:		
Movox (Suspected)		Reason:	Depression		
Tablet	150.0 Milligram	Daily		Oral	
3atch:	Started: 05/05/2005		Stopped:	10/05/2005	0
Movox (Suspected)		Reason:	Depression		
	50.0 Milligram	Daily			

Laboratory Investigations:

Additional Information:

Patient stabilised on maintenance dose 50mg daily.

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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:212065Seq:1Gender:MReported:28/09/2005Weight:0.00Hospitalisation:Admitted to hospitalAge:52

Onset Date: 10/05/2005 DOB: 07/02/1953

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		
	Caused or prolonged inpatient hospitalisation		
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

XANAX (Other drug)		Reason:	Anxiety neuro	sis	
	0.5 Milligram				
3atch:	Started: 17/11/2004		Stopped:		
TEMAZE (Other drug)		Reason:	Specific disor	ders of sleep	
	10.0 Milligram				
3atch:	Started: 11/03/2005		Stopped:		
Movox (Suspected)		Reason:	Depression		
Tablet	150.0 Milligram	Daily		Oral	
3atch:	Started: 05/05/2005		Stopped:	10/05/2005	0
Movox (Suspected)		Reason:	Depression		
	50.0 Milligram	Daily			
3atch:	Started: 28/02/2004		Stopped:	05/05/2005	0

Laboratory Investigations:

Additional Information:

Patient stabilised on maintenance dose 50mg daily.

Report Run 01/08/200 01:38PN Database: pusime ADRS004 Page 267 of 326



Date 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 Detai

<u></u>			
Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation		

Medicine Details:

XANAX (Other drug)		Reason:	Anxiety neuro	sis	
	0.5 Milligram				
3atch:	Started: 17/11/2004		Stopped:		
TEMAZE (Other drug)		Reason:	Specific disor	ders of sleep	
	10.0 Milligram				
3atch:	Started: 11/03/2005		Stopped:		
Movox (Suspected)		Reason:	Depression		
	450 O MUR.	Daily		Oral	
Tablet	150.0 Milligram	Dally		Olai	
Tablet 3atch:	150.0 Milligram Started: 05/05/2005	Dally	Stopped:	10/05/2005	0
	· ·	Reason:	Stopped:		0
3atch:	· ·	,	• • •		0

Laboratory Investigations:

Additional Information:

Patient stabilised on maintenance dose 50mg daily.

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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: 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 Detai

Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation	r	Changed to Sertraline.

Medicine Details:

Medicine Details.				
TEMAZEPAM (Other drug)		Reason:	Specific disorders of sleep	
	10.0 Milligram		Oral	
3atch:	Started:		Stopped:	
FLUVOXAMINE MALEATE (Suspected)		Reason:	Anxiety neurosis	
Tablet (Suspected)	100.0 Milligram	Reason: Daily	,	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
05/10/2005	ALT = SGPT	0-55			151 U/L
	GGT = SGGT =	0-60			155 U/L
	SAP = ALP	30-110			155 U/L



Report Detail

Case Number: 212353

Reported: 10/10/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

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

Seq: 1

Onset Date: 01 Outcome: Ur eaction Detai Preferred T Depression Medicine Details NEORAL (Interaction)	erm	Severity Pati Aug	ent experienced o 2005 after comm	Caus escription depression in mid	DOB: 04/01/1959 sality: Causality possible Treatment
Preferred To Prefe	erm S	Pati	ent experienced o 2005 after comm	escription	1
Preferred T epression ledicine Details NEORAL (Interaction)		Pati	ent experienced o 2005 after comm	depression in mid	Treatment
ledicine Details NEORAL (Interaction) 3atch:		Pati	ent experienced o 2005 after comm	depression in mid	Treatment
ledicine Details NEORAL (Interaction) 3atch:	S :	Pati Aug	2005 after comm	depression in mid lencing Neoral.	
NEORAL (Interaction) 3atch:	5:				
EORAL (Interaction) 3atch:	s:				
NEORAL (Interaction) 3atch:	5:				
IEORAL (Interaction) 3atch:	s:				
IEORAL (Interaction) 3atch:	5:				
NEORAL (Interaction) 3atch:	5:				
			Reason:	Complicatns of tran	nsplant orgn
		Started:		Stopped:	
FLUVOXAMINE MALE	ATE (Interaction)		₹eason:	Depression	
3atch: Started:				Stopped:	0
CELLCEPT (Other dru	g)		Reason:		
3atch:		Started:		Stopped:	
PREDNISOLONE (Oth	er drug)		Reason:		
3atch:		Started:		Stopped:	
aboratory Inve	stigations:				
Date Typ	e Range	Date Tested	Result		Details



Date 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 Reported: 10/10/2005 Hospitalisation: Onset Date: 01/08/2005 Outcome: Unknown Reaction Detai	Seq: 1	W	ender: M eight: 0.00 Age: 46 DOB: 04/01/1959 sality: Causality possible
Medicine Details:			
SOMAC (Other drug)		Reason:	
3atch:	Started:	Stopped:	
Laboratory Investigations:			
Additional Information:			

Report Run 01/08/200 01:38PN Database: pusime ADRS004 Page 271 of 326



Date 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 Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Vision blurred		The patient became very sedated, his neck was rigid, he had blurred vision and felt	Luvox and Diazepam ceased.
Musculoskeletal stiffness			
Sedation			

Medicine Details:

 DIAZEPAM (Interaction)
 Reason:
 Anxiety neurosis

 5.0 Milligram
 Weekly

 3atch:
 3tarted:
 15/07/2004
 3topped:
 15/09/2004

 LUVOX (Interaction)
 Reason:
 Anxiety neurosis

Tablet 100.0 Milligram Daily Oral

3atch: \$tarted: 15/07/2004 \$topped: 15/09/2004

Laboratory Investigations:								
Date	Туре	Range	Date Tested	Result	Details			



Date 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:
Onset Date: 25/06/2005
Age: 60Y
DOB:

Outcome: Death 15/08/2005 Causality: Causality possible

Reaction Detai

teaction betai			5
Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Death	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	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
3atch:	Started: 24/06/2005		Stopped:	04/07/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

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
3atch:	Started:			Stopped:	
LUVOX (Suspected)			Reason:	Depression	
LUVOX (Suspected) Tablet	50.0	Milligram	Reason: Daily	Depression	Oral

Laboratory Investigations:

Date	Туре	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).

Report Run 01/08/200 01:38PN Database: pusime ADRS004 Page 274 of 326



Date 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:
 85.0

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 Detai

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		The patient experienced long withdrawal symptoms - lethargy, night sweats, palpitations, anxiety, muscle aches within 10 minutes of being up, nocturia and sedation.	
Anxiety			
Lethargy			
Sedation			

Medicine Details:

LUVOX (Suspected)		Reason:	Anxiety neuro	sis
Tablet	50.0 Milligram	Daily		Oral
3atch:	Started: 04/08/2005		Stopped:	27/09/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History - very sensitive to medicines (?slow metabolised).



Date 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 Detai

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

3atch: 3tarted: 12/11/2005 **3topped:** 17/11/2005 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Has had bruising previously with Aropax.



Report Detail

Case Number: 213963

Reported: 02/12/2005

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight: 0.00

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

Seq: 1

lospitalisat	tion:					Age: 32	
Onset D	Date: 26/02/2005			DOB : 15/01/1973			
Outco	ome: Death, may	be drug	:	26/02/2000 Causali		sality: Causality possible	
action D	<u>Detai</u>					_	
Pre	eferred Term	Sev	verity	Repo	rt Description	Treatment	
rug level in	ncreased	Death	Patei valpr	int died poss oic acid, pos	sibly due to olanzapine a ssibly due to a drug	nd	
rug interac	ction	Death					
	Details:			Rea	son:		
3atc			arted:		Stopped:		
FLUVOXAM	INE MALEATE (Inter	action)		₹ea	son:		
7-4-	L .	34			Managadi		
3atc	n: LPROATE (Interaction		arted:	202	Stopped:		
SODIOW VA	LFROATE (Interaction	,,,,		\ea	50II.		
3atc	h:	31	arted:		Stopped:		
ZUCLOPEN	THIXOL ACETATE (C	ther drug)		₹ea	son:		
3atc	h:	31	arted:		Stopped:		
aborato	ry Investigatio	nns:					
Date	Туре	Range	Date Tested	Result		Details	
02/12/2005	Serum drug level				Toxicological analysis revo Olanzapine (580 ng/l), whi of Olanzapine, 59 mg/l of Fluvoxamine and 0.03 mg detected	ealed bloodlevels of 0.58 mg/l of ich is inconsistent with terapeutic use Valproic Acid, 0.04 mg/l of /l of Morphine. No alcohol was	
Additiona	al Information	:			Idetected		
	/08/200 01:38PN	Database: p			ADRS004	Page 277 of 326	



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

Case Number: 214091	Seq: 1		Gender:	F
Reported: 07/12/20	•		Weight:	0.00
lospitalisation:			Age:	
Onset Date: 21/11/20	005		_	06/02/1962
Outcome: Unknow	'n		Causality:	Causality possible
eaction Detai			•	, ,
Preferred Term	Severity	Report Description		Treatment
Arthralgia	Incapacity/dis ability	Client commenced on Luvox 25r month ago, increased to 50mg a weeks and experienced sore elb Increased to 75mg on 2nd Dec f but felt unwell so reduced back t Presented 7/12/05 to emergency department with ongoing genera "bone"pain -not muscular. Worse shoulder and elbow but also incl of feet, legs, hands, L arm. Getti each day. Difficulty mobilising, tu in bed, finds weight of bedclother	fter 2 ow. or 2 nights o 50mg. / lised e in R uding top ng worse urning over s painful	
		on R arm. Blood tests normal. N vomiting etc. Prescribed Panade and advised to stop Luvox. Advis	o fever, ine forte ce given	
		by pharmacist re- withdrawal effor	ects.	
Medicine Details:				
LUVOX (Suspected)		Reason:		
Tablet		1 time 3tops	Oral	
		acted Result	Deta	sils
Laboratory Investiga Date Type	ations: Range Date T	ested Result	Deta	ails



Date 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	Gend	er: F
Reported: 07/12/200			ht: 0.00
Hospitalisation:		_	ge: 43
Onset Date: 21/11/200)5		DB : 06/02/1962
Outcome: Unknown		Causali	ty: Causality possible
Reaction Detai			
Preferred Term	Severity	Report Description	Treatment
		rv Monday. No other meds taken, no recent changes to	
Arthralgia	Incapacity/dis ability	Worse in R shoulder and elbow but also including top of feet, legs, hands, L arm.	
Bone pain	Incapacity/dis ability		
Malaise	Incapacity/dis ability		
Medicine Details:			
LUVOX (Suspected)		Reason:	
Tablet		1 time Oral	
3atch:	Started: 06	6/11/2005 Stopped:	
Laboratory Investigat	ions:		
Additional Informatio	n:		

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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

Re	po	rt	D	et	ta	i
----	----	----	---	----	----	---

 Case Number:
 214445
 Seq:
 1
 Gender:
 F

 Reported:
 20/12/2005
 Weight:
 60.0

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 Detai

Caction Detai		_	
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:

 Reason: Depression

 Tablet
 100.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 16/11/2005
 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
Sperm count decreased	Incapacity/dis ability	Patient has a very low sperm count.	

Medicine Details:

Modifile Betaile:				
EPILIM (Suspected)		Reason:	Jnspecifid affe	ective psychosis
Tablet				Oral
3atch:	Started: 15/08/2000		Stopped:	
AVANZA (Suspected)		Reason:	Depression	
Tablet	900.0 Milligram	Daily		Oral
3atch:	Started: 15/10/2001		Stopped:	
LUVOX (Suspected)		Reason:		
Tablet	300.0 Milligram	Daily		Oral
3atch:	Started: 15/05/2000		Stopped:	15/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

	tail								
Case Numl	oer: 214748	Seq:	1			Gen	der: M		
-	ted: 10/01/200	6		Weight: 0.00					
ospitalisati				Age : 24					
Onset Da							OB : 21/11/1981		
	me: Recovered	t			(Causa	lity: Causality possible		
eaction D			Ī						
	ferred Term	Seve			t Description		Treatment		
Sedation			The p	patient becan rienced hype	ne very sedated an	ıd	Clozaril dose reduced to		
Salivary hyp	ersecretion		lexhe	пенсеч пуре	sanvation.				
, anvary myp	5.55575tiOH		1						
Medicine	Details:								
LUVOX (Inter				Reas	on:				
Table						Oral			
3atch		3ta	rted:		Stopped:				
CLOZARIL (II	nteraction)			Reason: Unspecified schizophrenia					
Table			450.0 Milli	gram	Daily	Oral			
3atch	:	3ta	rted: 11/01/20	005	Stopped:		0		
NALTREXON	E HYDROCHLORI	DE (Interaction)		Reas	on:				
Table	t		50.0 Milli	gram	Daily Oral				
3atch	:	3ta	rted:		Stopped:				
_aborator	y Investigati	ions:	Date Tested	Result			Details		
			Date Tested	Result			Details		



Date 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 Detai

Cachon Detai				
Preferred Term	Severity	Report Description	Treatment	ı
Photosensitivity reaction		Patient experienced photosensitivity rash, effecting face, neck, upper chest.	Ceased Luvox.	Ì

Medicine Details:

EPILIM (Other drug) Reason:

1.0 Gram

3atch: **3tarted**: 12/02/2005 **3topped**:

LUVOX (Suspected) Reason: Depression

Tablet 200.0 Milligram Daily Oral

3atch: 3tarted: 02/12/2005 3topped: 12/01/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Drug ineffective		The patient experienced profound relapse of severe depression while being treated	Ceased Luvox, changed back to Zoloft.

Medicine Details:

LUVOX (Suspected)		Reason:	Depression	
Tablet	200.0 Milligram	Daily	C	Oral
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report 215216 is the first sequence to this report.



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

Report Detail

Case Number:215242Seq:1Gender:MReported:24/01/2006Weight:0.00Hospitalisation:Age:36

Onset Date: 23/01/2006 DOB: 12/01/1970

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder			Clozaril dose reduced and Fluvoxamine dose reduced.
Atrial hypertrophy			
Depression			
Drug interaction			
Drug level increased			
Sinus tachycardia			

Medicine Details:

CLOZARIL (Interaction)		Reason:		
Tablet	475.0 Milligrar	n Daily		Oral
Зatch:	Started: 08/08/1994	L TERM	Stopped:	
FLUVOXAMINE MALEATE (Interaction)		Reason:	Depression	
Tablet	150.0 Milligrar	n Daily		Oral
Зatch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

Medicine Details:

Medicine Details.			
CLOZARIL (Interaction)		Reason:	
Tablet	475.0 Milligram	Daily	Oral
Зatch:	3tarted: 08/08/1994 L	L TERM Stopped:	
FLUVOXAMINE MALEATE (Interaction)		Reason: Depression	
Tablet	150.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

Desferred Terre	0	Descrit Description	T t
Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Ceased Fluvoxamine, Oxycodone, Doxepin.
Agitation			
Atrial fibrillation			
Blood creatine phosphokinase in			
Chills			
Clonus			
Confusional state			

Medicine Details:

OXYCODONE HYDROCHLORIDE (Interacti						
Tablet	80.0	Milligram	Daily		Oral	
3atch:	Started:			Stopped:		0
FLUVOXAMINE MALEATE (Interaction)			Reason:			
Tablet	200.0	Milligram	Daily		Oral	
3atch:	Started:			Stopped:		
DOXEPIN HYDROCHLORIDE (Interaction)			3			
DOVELIN HIDROCHFORIDE (Interaction)			Reason:			
Capsule (Interaction)	50.0	Milligram	Reason: Daily		Oral	
,	50.0 Started:	Milligram		Stopped:	Oral	
Capsule		Milligram		Stopped:	Oral	
Capsule 3atch:		Milligram	Daily	Stopped:	Oral	

Laboratory Investigations:

Date	Туре	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.



Report Detail

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

Case Number: 215247 Reported: 24/01/2006 Hospitalisation: Onset Date: Outcome: Unknown Reaction Detai	Seq: 1	Weig A De	der: F ght: 0.00 age: 70Y OB: lity: Causality possible
Preferred Term	Severity	Report Description	Treatment
Coordination abnormal	Ceventy	Report Bescription	rreatment
Hyperreflexia			
Hypertonia			
Mydriasis			
Nausea			
Pyrexia			
Restlessness			
Tachycardia			
Medicine Details: RALOXIFENE (Other drug)		Reason:	
Зatch:	Started:	Stopped:	
CALCIUM CARBONATE (Other drug)		Reason:	
3atch:	Started:	Stopped:	
Dilzem CD (Other drug)		Reason:	
3atch:	Started:	Stopped:	
SIMVASTATIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
		лорроц.	
Laboratory Investigations:			

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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.



Date 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 Detai

reaction Detai	ā.	-	-
Preferred Term	Severity	Report Description	Treatment
Rash			Ceased Fluoxamine, treated with Sigmacort cream.
Hyperhidrosis Pruritus			

Medicine Details:

FLUVOXAMINE MALEATE (Suspected) Reason: Depression

 Tablet
 150.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 29/11/2005
 3topped:
 16/12/2005

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

i todotion botal			
Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		Patient experienced serotonin syndrome, confusion, delerium, agitation and	Ceased Tramadol and Fluvoxamine. Fluid restriction.
Agitation			
Confusional state			
Delirium			
Hyponatraemia			

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction	on)	Reason:	Otr&unsp vert	ebrogen pain synd	
Capsule	150.0 Milligram	Daily		Oral	
3atch:	3tarted: 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	Туре	Range	Date Tested	Result	Details



Date 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 Detai

104041011 20441		-	
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

 3atch:
 3tarted:
 26/03/2006
 3topped:
 29/03/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

			-
Preferred Term	Severity	Report Description	Treatment
Thrombocythaemia		Patient developed thrombocytopaenia.	Ceased Fluvoxamine and

Medicine Details:

PREMARIN (Other drug)		Reason:	Menopausal s	ymptoms	
3atch:	Started:		Stopped:		
PROVERA (Other drug)		Reason:	Menopausal s	ymptoms	
3atch:	Started:		Stopped:		
		_			
Blackmores Fish Oil (Other drug)		Reason:			
Blackmores Fish Oil (Other drug)		Reason:		Oral	
Blackmores Fish Oil (Other drug) 3atch:	Started:	Reason:	Stopped:	Oral	
, , , , , , , , , , , , , , , , , , ,	Started:	Reason:	Stopped:	Oral	
Batch:	Started: 200.0 Milligram		Depression	Oral	

Laboratory Investigations:

Date	Туре	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	



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number:	217475	Seq: 1			Gender:	F	
Reported:	19/04/2006				Weight:	58.00	
Hospitalisation:		o the doctor			Age:		
Onset Date:						13/06/1951	
Outcome:	Not yet recovere	d		(Causality:	Causality possibl	е
Reaction Detai							
Medicine Deta	ails:						
QUETIAPINE (Sus			Reason:	Depression			
Tablet		50.0 Milligram	Daily		Oral		
3atch:		Started: 15/04/2005		Stopped:	18/02/2006	0	
l abaratanı la	vootigationa						
Laboratory In	ivestigations:						
Additional Inf	formation:						
							
04/00/000	04:0001 5 1 1		4 D D C C C			D 00-	

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Hospitalisation:

Case Number: 217483

Reported: 19/04/2006

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Weight: 165.40

Age: 36

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

Seq: 1

	ite:				DC	DB : 14/08/1969
Outcon	ne: Unknown				Causali	ity: Causality possible
action De	etai					
Pref	erred Term	Seve	rity	Report De	escription	Treatment
/eight increa	ased		Patie poor	nt experienced v control of diabet	veight gain of 75.4kg, es	
lood glucos	e increased	Incapacity/dis blood sugar level 7.9 ability				
iabetes mel	litus inadequat	e cor				
edicine [
SODIUM VALI	PROATE (Other di	rug)		Reason:		
3atch:	:	Star	ted:		Stopped:	
PANADEINE F	ORTE (Other dru	g)		Reason:	•	
					Stopped:	
3atch:		3tar	ted:			
OGEN (Suspe	cted)			Reason:		
3atch:	:	Star	ted:		Stopped:	0
UVOX (Susp	ected)			Reason:	•	
3atch:	-	3tar	ted:		Stopped:	0
aboratory	y Investigati	ons:				
Date	Туре	Range	Date Tested	Result	Ι	Details



Case Number: 217483

Reported: 19/04/2006

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 165.40

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

Seq: 1

ospitalisation:				Age:		
Onset Date:					14/08/1969	
Outcome: Unknown			C	ausality:	Causality possible	е
eaction Detai						
ledicine Details:						
GABAPENTIN (Suspected)		Reason:				
Batch:	Started:		Stopped:		0	
CLOZARIL (Suspected)	40.5 1478		Unspecified s			
Tablet	12.5 Milligram	Daily	M	Oral	0	
3atch:	Started: 22/01/2002		Stopped:	27/03/2006	0	
aboratory Investigations:						
dditional Information:						
dditional 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

Case Number: 217	534 Seq :	1			Gender:	F	
Reported: 20/0	4/2006				Weight:	0.00	
lospitalisation:					Age:	99u	
Onset Date:					DOB:		
Outcome: Not	yet recovered				Causality:	Causality possi	ible
eaction Detai		1					
Preferred Te	m Seve	erity	Repor	t Description		Treatment	
Hallucination, visual		Visu incre	Visual hallucinations when Luvox was increased from 100mg to 200mg daily.				
Therapy regimen char	nged						
Medicine Details: LUVOX (Suspected)			2000				
Tablet		100.0 Mil	Reas	on: Daily	Oral		
3atch:	Sta.	rted:	ligram	Stopped:			
Laboratory Inves	tigations:						
Date Type	Range	Date Tested	Result		Deta	ils	
Additional Inform	ation:						
eport Run 01/08/200 0	1:38PN Database: pu	sime	A	DRS004		Page 296	of 326



Date 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

Onset Date: 11/04/2006

Age: 31

DOB: 29/08/1974

Outcome: Recovered 16/04/2006 Causality: Causality probable

Reaction Detai

'	teaction Detai			
	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

3atch: **3tarted**: 19/03/2006 **3topped**: 11/04/2006 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

Report D)etail
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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 Detai

veaction Detai	-	_	
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

 3atch:
 3tarted: 13/04/2006
 3topped: 05/05/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Vomiting		Patient experienced vomiting and	
Dizziness			

Medicine Details:

NAPROXEN (Other drug) Reason: Other diseases of bone

Tablet 1.0 Gram Oral

3atch: 3tarted: 07/07/2005 3topped:

SOMAC (Other drug) Reason:

40.0 Milligram

3atch: Started: 29/12/2005 Stopped:

LUVOX (Suspected) Reason: Depression

Tablet 50.0 Milligram Daily Oral

3atch: 30/05/2006 Stopped: 03/06/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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
Onset Date: 01/01/2006 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Addion Dotal							
Preferred Term	Severity	Report Description	Treatment				
Rash neonatal		Breastfed infant developed florid maculopapular rash on chin, trunk, arms	Luvox stopped.				
Drug exposure via breast milk							

Medicine Details:

 LUVOX (Suspected)
 Reason:
 Depression

 Tablet
 100.0 Milligram
 Daily
 Breast milk transfer

Tablet 100.0 Milligram Daily Breast milk transfer

3atch: Started: Stopped: 15/03/2006 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Caction Betai		<u> </u>	
Preferred Term	Severity	Report Description	Treatment
Disturbance in attention		Patient experienced loss of concentration, withdrawal reaction, lethargy, dizziness and weakness. The adverse event started immediately after dose reduction from 300mg to 250mg.	
Asthenia			
Dizziness			
Drug withdrawal syndrome			
Lethargy			
Therapy regimen changed			

Medicine Details:

SEROQUEL (Other drug)		Reason:	Depression	
Tablet				Oral
3atch:	Started:		Stopped:	
LUVOX (Suspected)		Reason:	Depression	
Tablet	250.0 Milligram	Daily	,	Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History: depression since 1999 and obsessive complusive disorder.



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

Report I	Detail
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 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 Detai

icaction Detai			a
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

 3atch:
 3tarted:
 29/06/2006
 3topped:
 29/06/2006

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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
Onset Date: 07/08/2006 DOB:

Outcome: Recovered 10/08/2006 Causality: Causality probable

Reaction Detai

Veaction Detai			
Preferred Term	Severity	Report Description	Treatment
Headache		Severe headache, severe vomiting	Stopped taking.
Vomiting			

Medicine Details:

MODURETIC (Other drug)		Reason:		Essential benign hypertension
	1.0	Dose Unspecified	Daily	
3atch:	Started:			Stopped:
CARTIA (Other drug)		Reaso	n:	
	1.0	Dose Unspecified	Daily	
3atch:	Started:			Stopped:
PREMARIN (Other drug)		Reaso	n:	Menopausal symptoms
	0.6	Milligram	Daily	
3atch:	Started:			Stopped:
LIPITOR (Other drug)		Reaso	n:	Othr&unspec metabolic diseases
	1.0	Dose Unspecified	Daily	
3atch:	Started:			Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number:	221397	Seq: 1		Gender	: F
Reported:	05/09/2006			Weight	: 75.00
Hospitalisation:	Required a visit t	o the docto	r		: 76Y
Onset Date:	07/08/2006			DOB	:
Outcome:	Recovered		10/08/2006	Causality	: Causality probable
Reaction Detai					
Medicine Deta					1
LUVOX (Suspected	d)		Reason:	Depression	
Jatah.			1.0 Dose Unspecified Daily		00
3atch:		Started:	06/08/2006	Stopped: 09/08/20	06
Laboratory In	vestigations:				
Additional Inf	ormation:				
	04.000		45500	20.4	

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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: 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 Detai

todotion Dotal	-		
Preferred Term	Severity	Report Description	Treatment
Nausea		Nausea, dizziness, disorientation	
Disorientation			
Disturbance in attention			
Dizziness			
Thinking abnormal			

Medicine Details:

EPILIM (Suspected)		Reason:	Depression		
	1.5 Milligram	Daily		Oral	
3atch:	Started: 01/02/2004		Stopped:	13/10/2006	0
LUVOX (Suspected)		₹eason:	Depression		
	212.0 Milligram	Daily		Oral	
3atch:	Started: 01/02/2004		Stopped:	13/10/2006	0
SEROQUEL (Suspected)		Reason:	Depression		
	400.0 Milligram	Daily		Oral	
3atch:	Started: 01/02/2004		Stopped:	13/10/2006	0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Caction Detai		-	
Preferred Term	Severity	Report Description	Treatment
Mydriasis		Dilated pupils only occurred when dose	
Therapy regimen changed			

Medicine Details:

LUVOX (Suspected) Reason: Depression

Tablet 50.0 Milligram Daily Oral

3atch: 3tarted: 11/09/2006 **3topped:** 05/10/2006

DEXAMPHETAMINE SULPHATE (Suspected) Reason: Behavior disorders of childhod

22.5 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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

	ber: 223720	Seq: 1				nder: [
Report Spitalisati	ted: 04/12/2006)		Weight: 0.00 Age: 75				
Onset Da						_	18/12/1930	
	me : Recovered	l with sequelae		Causality: Causality possible				
action D		With Sequelae			Ouut	unity.	oddodiity possible	
	ferred Term	Severity	у	Report D	escription		Treatment	
adycardia			brady hypot	cardia ension				
rug interact potension								
				Zoason:				
				₹eason:				
	teraction)	≷tarted	d:	Reason:	Stopped:			
AVERIN (Int 3atch	teraction) 1:	Started	d:	Reason:	Stopped:	a		
AVERIN (Int 3atch	teraction) 1:	3tarted	d: 16.0 Millig	Reason:	Stopped:	a		
AVERIN (Int 3atch	teraction) n: teraction)			Reason: gram Da	Stopped: Presenile dementia	a	0	
AVERIN (Int 3atch EMINYL (Int 3atch	teraction) n: teraction) n:		16.0 Millig	Reason: gram Da	Stopped: Presenile dementionally Stopped:	a	0	
AVERIN (Int 3atch REMINYL (Int 3atch	teraction) teraction) teraction) teraction)		16.0 Millig d: 15/11/20	Reason: gram Da 04	Stopped: Presenile dementionally Stopped:	a	0	
FAVERIN (Int 3atch REMINYL (Int 3atch NOTEN (Other 3atch	teraction) iteraction) iteraction) iteraction	Started	16.0 Millig d: 15/11/20	Reason: gram Da 04	Stopped: Presenile demention aily Stopped: Stopped:	a	0	
REMINYL (Int	teraction) i: teraction) i: er drug) i: ner drug)	Started	16.0 Millig d: 15/11/20	Reason: gram Da 04 Reason:	Stopped: Presenile demention aily Stopped: Stopped:	a	0	
3atch REMINYL (Int 3atch IOTEN (Othe ASPIRIN (Oth	teraction) i: teraction) i: er drug) i: ner drug)	Started Started	16.0 Millig d: 15/11/20	Reason: gram Da 04 Reason:	Stopped: Presentle demention Stopped: Stopped:	a	0	

Additional Information:

Reporter questioned whether fluvoxamine inhibits metabolism of galatamine: Yes, potent CYP2C9 inhibitors such as fluvoxamine have been shown to increase galantamine bioavailability



Date 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:	
Reported: 04/12/2006			Weight:	
ospitalisation:			Age:	
Onset Date:	201			18/12/1930
Outcome: Recovered v	with sequelae		Causality:	Causality possible
action Detai				
edicine Details:				
edicine Details.				
		Reason:		
AZITHROMYCIN (Other drug)	Started:	Reason:	Stopped:	
AZITHROMYCIN (Other drug) 3atch:	3tarted:	Reason:	3topped:	
AZITHROMYCIN (Other drug) 3atch:	Started:		}topped:	
AZITHROMYCIN (Other drug) Batch:	Started:		Stopped:	
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch:				
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch:		Reason:	3topped:	
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch:		Reason:		
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch: CORDARONE X (Other drug)	Started:	Reason:	3topped:	
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch: CORDARONE X (Other drug)	Started:	Reason:	3topped:	
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch: CORDARONE X (Other drug)	Started:	Reason:	3topped:	
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch: CORDARONE X (Other drug) 3atch:	Started: Started:	Reason:	3topped:	
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch: CORDARONE X (Other drug) 3atch:	Started: Started:	Reason:	3topped:	
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch: CORDARONE X (Other drug) 3atch:	Started: Started:	Reason:	3topped:	
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch: CORDARONE X (Other drug) 3atch:	Started: Started:	Reason:	3topped:	
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch: CORDARONE X (Other drug) 3atch:	Started: Started:	Reason:	3topped:	
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch: CORDARONE X (Other drug) 3atch:	Started: Started:	Reason:	3topped:	
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch: CORDARONE X (Other drug)	Started: Started:	Reason:	3topped:	
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch: CORDARONE X (Other drug) 3atch:	Started: Started:	Reason:	3topped:	
AZITHROMYCIN (Other drug) 3atch: ZOCOR (Other drug) 3atch: CORDARONE X (Other drug) 3atch:	Started: Started:	Reason:	3topped:	

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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

Reported: 04/12/2006 lospitalisation: Onset Date: Outcome: Not yet recovered	Seq: 1		
Reported: 04/12/2006 ospitalisation: Onset Date: Outcome: Not yet recovered	Seq: 1		
ospitalisation: Onset Date: Outcome: Not yet recovered			Gender: M
Onset Date: Outcome: Not yet recovered			Weight: 0.00
Outcome: Not yet recovered			Age: 60Y
· · · · · · · · · · · · · · · · · · ·			DOB:
		C	ausality: Causality possible
action Detai			•
Preferred Term	Severity	Report Description	Treatment
astric haemorrhage	Later	shown to be a bleeding gastric p	polyp
astrointestinal haemorrhage	Patie	nt experienced gastrointestinal ling while being treated with Luvo	
edicine Details:		Reason:	
Tablet			Oral
3atch:	Started:	Stopped:	
ASPIRIN (Suspected)		Reason:	
3atch:	Started:	Stopped:	Oral 0
abaratary Investigations			
aboratory Investigations: Date Type Rang	ge Date Tested	Result	Details



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hypertension Cough		difficult swallowing, ankle oedema.	Covereyl was started after Luvox for the treatment of hypertension and was continued throughout
Dysphagia Oedema peripheral			
Tachycardia			

Medicine Details:

Medicine Details.							
COVERSYL (Other drug)			Reason:				
Зatch:	Started:			Stopped:			
LUVOX (Suspected)			Reason:				
Tablet	100.0	Milligram	Daily		Oral		
3atch:	Started:	L TE	ERM	Stopped:	15/10/2006	0	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Medical history: Stroke 2004.

Patient restarted Luvox and experienced same symptoms.



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Remarkable rise in the serum level of	Clozaril dose reduced.

Medicine Details:

Medicine Details.			
FLUVOXAMINE MALEATE (Interaction	n)	Reason:	
Tablet			Oral
3atch:	Started:	Stopped	: 15/11/2006
CLOZARIL (Interaction)		Reason: Unspecified	schizophrenia
Tablet	400.0 Milligram	Daily	Oral
3atch:	Started: 23/04/1999	3topped:	:

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

Caction Detai	-		
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				
3atch:	Started: 15/11/2006	Stopped:	0				
Abilify (Suspected)	;	Reason: Unspecified so	hizophrenia				
Tablet	10.0 Milligram	Daily	Oral				
	Started: 01/11/2006	Stopped:					

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

		eta	

Case Number:225072Seq:1Gender:FReported:24/01/2007Weight:0.00Hospitalisation:Age:33

Onset Date: 15/12/2006 **DOB**: 03/07/1973

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

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	ral					
Зatch:	Started: 15/11/2006	Stopped:	0					
Abilify (Suspected)		Reason: Unspecified schiz	cophrenia					
Tablet	10.0 Milligram	Daily	ral					
3atch:	Started: 01/11/2006	Stopped:						

Laboratory Investigations:



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

Report Detai				
Case Number: 225072	Seq: 1		Gend	er: F
Reported: 24/01/2007	•		Weig	ht: 0.00
lospitalisation:			_	je : 33
Onset Date: 15/12/2006			_	B : 03/07/1973
Outcome: Not yet recove	ered			ty: Causality possible
eaction Detai			3 3.3.33	.) . • • • • • • • • • • • • • • • • • • •
Preferred Term	Severity	Report Desc	cription	Treatment
Asthenia	Caused or			
	prolonged inpatient			
	hospitalisation			
Medicine Details:				
LUVOX (Suspected)		Reason:		
` ' '				
, ,	100.0 Milligra	am Daily	Oral	
Satch:	100.0 Milligra Started: 15/11/2006		Oral Stopped:	0
3atch:		Reason:	Stopped:	
3atch: Abilify (Suspected)	Started: 15/11/2006	Reason: am Daily	Stopped: Unspecified schizophre	
3atch: Abilify (Suspected) Tablet	Started: 15/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet	Started: 15/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet	Started: 15/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet	Started: 15/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet	Started: 15/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet	Started: 15/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet	Started: 15/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet 3atch:	3tarted: 15/11/2006 10.0 Milligra 3tarted: 01/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet 3atch:	3tarted: 15/11/2006 10.0 Milligra 3tarted: 01/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
Batch: Abilify (Suspected) Tablet Batch:	3tarted: 15/11/2006 10.0 Milligra 3tarted: 01/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet 3atch:	3tarted: 15/11/2006 10.0 Milligra 3tarted: 01/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
Batch: Abilify (Suspected) Tablet Batch:	3tarted: 15/11/2006 10.0 Milligra 3tarted: 01/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
Batch: Abilify (Suspected) Tablet Batch:	3tarted: 15/11/2006 10.0 Milligra 3tarted: 01/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet 3atch:	3tarted: 15/11/2006 10.0 Milligra 3tarted: 01/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet 3atch:	3tarted: 15/11/2006 10.0 Milligra 3tarted: 01/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet 3atch:	3tarted: 15/11/2006 10.0 Milligra 3tarted: 01/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
Batch: Abilify (Suspected) Tablet Batch: Laboratory Investigation	3tarted: 15/11/2006 10.0 Milligra 3tarted: 01/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet 3atch:	3tarted: 15/11/2006 10.0 Milligra 3tarted: 01/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet 3atch:	3tarted: 15/11/2006 10.0 Milligra 3tarted: 01/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	
3atch: Abilify (Suspected) Tablet 3atch:	3tarted: 15/11/2006 10.0 Milligra 3tarted: 01/11/2006	Reason: am Daily	Stopped: Unspecified schizophre Oral	



Date 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 Detai

veaction Detai	_	-	
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

3atch: **3tarted**: 02/01/2007 **3topped**: 22/01/2007 discontinued

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation		filgrastim, gentamicin/Timentin

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)			Reason:	Depression		
Tablet	100.0	Milligram	Daily		Oral	
3atch:	Started:	l	_ TERM	Stopped:	31/01/2007	0

Laboratory Investigations:

Date	Туре	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.



Date 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 Detai

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)			Reason:	Depression			
Tablet	100.0	Milligram	Daily		Oral		
3atch:	Started:	L	TERM	Stopped:	31/01/2007	0	

Laboratory Investigations:

Date	Туре	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.

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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:
 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 Detai

Neaction Detai			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		2 blood transfusions, ongoing doses of filgrastim.
	Caused or prolonged inpatient hospitalisation		

	ed					

FAVERIN (Suspected)		Reason:	Depression	
3atch:	Started:		Stopped:	15/01/2007

Laboratory Investigations:

Date	Туре	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	



Date 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:14/03/2007Weight:0.00Hospitalisation:Required a visit to the doctorAge:65Y

Onset Date: 19/01/2007 DOB:

Outcome: Recovered 29/01/2007 Causality: Causality probable

Reaction Detai

todotion Botal		<u> </u>	
Preferred Term Severity		Report Description	Treatment
Confusional state		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.
Amnesia			
Somnolence			

Medicine Details:

ASCORBIC ACID (Other drug)		Reason	: Unspec vitam	in deficien states	
Tablet	1.0	Gram E	aily	Oral	
3atch:	Started:	L TERM	Stopped:		Continuing.
Movox (Suspected)	₹eason:				
Tablet	50.0 N	Milligram E	aily	Oral	
3atch:	3tarted: 05/0	1/2007	Stopped:	21/01/2007	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Etoh - nil, coffee 1 x 1/daily and tea 4 x 5/daily.



Date 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 Detai

Preferred Term	Severity	Report Description	Treatment
Paradoxical drug reaction		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.
Energy increased			
Euphoric mood			

Medicine Details:

STILNOX (Interaction)		Reason: Specific diso	rders of sleep
Tablet	10.0 Milligram	As necessary	Oral
3atch:	Started:	Stopped:	15/02/2007
LUVOX (Interaction)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
3atch:	Started: 15/01/2007	Stopped:	
ATIVAN (Other drug)		Reason:	
3atch:	Started: 15/02/2007	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date 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 Reported: 11/04/2007 Hospitalisation: Onset Date: Outcome: Not yet recove	Seq: 1	Gender: M Weight: 0.00 Age: 99U DOB: Causality: Causality possible			
Reaction Detai					
Preferred Term	Severity	Report Des	scription	Treatment	
Hypoaesthesia	N	lumbness in left side c ethargy, malaise	of face and leg,		
Lethargy Malaise	110	etrialgy, maiaise			
Medicine Details: LUVOX (Suspected) Tablet	200.0	Reason: Milligram Daily	Depression / Oral		
Batch:	Started:		Stopped:	0	
Laboratory Investigation					
Date Type	Range Date Test	ted Result		Details	
Additional Information:					



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

Report I	Detail
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Case Number:227710Seq:1Gender:MReported:18/04/2007Weight:75.00Hospitalisation:Required a visit to the doctorAge:21

Onset Date: 04/02/2007 DOB: 01/02/1986

Outcome: Recovered 06/02/2007 Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Throat tightness		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
Confusional state		urodumess and sidired speech.	
Dizziness			
Dysarthria			
Nausea			
Somnolence			

M	led	lici	ne	Deta	ils:
	CU			Dota	113.

Movox (Su	spected)		Reason:	Anxiety neuros	sis
Та	olet 2	25.0 Milligram	Daily		Oral
3at	ch: Started:	02/02/2007		Stopped:	05/02/2007

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

Donaut Datail				
Report Detail Case Number: 228521 Reported: 15/05/2007 ospitalisation:	Seq: 1		Gender Weight Age	
Onset Date: Outcome: Unknown			DOB	
eaction Detai Preferred Term	Severity	Penor	Description	Treatment
Hepatitis			ng treated with Luvox.	Treatment
Medicine Details: LUVOX (Suspected)		Reaso	on:	
Tablet	50.0	Milligram	Daily Oral	
3atch:	Started:		Stopped:	
Laboratory Investigation	1S: Range Date Tes	ted Result	Def	ails
	range Date les	teu resuit	Det	alis
Date Type				



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

Case Num	ber: 229830	Seq:	1		Ger	nder: F		
Repor	ted: 18/06/2007				We	ight: 0.00		
ospitalisat	ion: Admitted to	hospital				Age: 77Y		
Onset D	ate:					OOB:		
Outco	me: Recovered				Causality: Causality possible			
eaction D	etai							
Pre	ferred Term	Seve	erity	Report	Description	Treatment		
-all			she	r the 4 years th was plagued b other bizarre b	ne patient took Stilnox, by hallucinations, falls behaviour.	Hospitalised several times for injuries. Ceased Stilnox.		
Abnormal sl	eep-related even	t						
Amnesia								
Hallucinatio	n							
Sleep walkir	ng							
						•		
Medicine EVISTA (Oth			60.0 Mil	Reasc	on:			
	er drug)	Sta	60.0 Mil		on: Stopped:			
EVISTA (Oth	er drug) n:	Sta			Stopped:			
EVISTA (Oth	er drug) n:	Sta		ligram Reaso	Stopped:			
EVISTA (Oth	er drug) n: er drug)		rted:	ligram Reaso	Stopped:			
EVISTA (Oth 3atcl NOTEN (Oth	er drug) n: er drug) n:		rted: 50.0 Mil	ligram Reaso	Stopped: on: Stopped:			
EVISTA (Oth 3atcl NOTEN (Oth 3atcl	er drug) n: er drug) n:		rted: 50.0 Mil rted:	ligram Reasc ligram	Stopped: Stopped:			
EVISTA (Oth 3atcl NOTEN (Oth 3atcl	er drug) n: er drug) n: (Other drug)	Sta	rted: 50.0 Mil rted:	ligram Reaso ligram	Stopped: Stopped:			
EVISTA (Oth 3atcl NOTEN (Oth 3atcl	er drug) n: er drug) n: Cother drug)	Sta	50.0 Mil rted: 2.0 Do	ligram Reaso ligram Reaso se Unspecified	Stopped: Stopped: On: As necessary Stopped:			
EVISTA (Oth 3atcl NOTEN (Oth 3atcl PERIACTIN (er drug) n: er drug) n: Cother drug)	Sta	50.0 Mil rted: 2.0 Do	ligram Reasc ligram Reasc se Unspecified L TERM Reasc	Stopped: Stopped: On: As necessary Stopped:			
EVISTA (Oth 3atcl NOTEN (Oth 3atcl PERIACTIN (er drug) n: er drug) n: Other drug) n:	3ta 3ta	sted: 50.0 Millerted: 2.0 Do	ligram Reasc ligram Reasc se Unspecified L TERM Reasc	Stopped: Stopped: On: As necessary Stopped: On:			
EVISTA (Oth 3atcl NOTEN (Oth 3atcl PERIACTIN (3atcl LIPITOR (Oth 3atcl	er drug) n: er drug) n: Other drug) n: ner drug)	Sta Sta	50.0 Mil rted: 2.0 Do rted: 40.0 Mil	ligram Reaso ligram Reaso se Unspecified L TERM Reaso ligram	Stopped: on: Stopped: on: As necessary Stopped: on: Daily			
EVISTA (Oth 3atcl NOTEN (Oth 3atcl PERIACTIN (3atcl LIPITOR (Oth 3atcl	er drug) n: er drug) n: Other drug) n:	Sta Sta	50.0 Mil rted: 2.0 Do rted: 40.0 Mil	ligram Reaso ligram Reaso se Unspecified L TERM Reaso ligram	Stopped: on: Stopped: on: As necessary Stopped: on: Daily	Details		



Case Number: 229830

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

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

Seq: 1

Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	Admitted to hospital Recovered				C	Weight: Age: DOB: ausality:	
Medicine Deta							
METFORMIN HYDE	ROCHLORIDE (Other drug		Reas				
3atch:		Started:	Milligram L TERM	Daily	Stopped:		
OSTELIN 1000 (Oth		marteu.	Reas		Moppeu.		
COTELIN 1000 (Cil	iei uiug)	20	Dose Unspecified				
3atch:		Started:	L TERM		Stopped:		
DYAZIDE (Other dr			Reas		700 100		
(**************************************	- 3,	1.0	Dose Unspecified				
3atch:		Started:	L TERM		Stopped:		
STILNOX (Suspect	ed)		Reas	on:			
Tablet		10.0	Milligram	Daily		Oral	
3atch:		Started:			Stopped:	15/01/2007	,
Laboratory In	vestigations:						
Additional Inf	ormation:						



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

	229830	Seq: 1				Ge	nder:	F	
Reported:	18/06/2007						eight:		
Hospitalisation:	Admitted to hospi	tal					Age:		
Onset Date:							DOB:		
Outcome:	Recovered					Caus	sality:	Causality possible	
Reaction Detai									
Medicine Deta									
FAVERIN (Suspecte	ea)	400.0	Millionen	Reaso		0	_1		
Tablet			Milligram		Daily	Ora	al	Contin	
3atch:		Started:		L TERM		Stopped:		Contin	
Laboratory Inv	vestigations:								
Laboratory Inv	vestigations:								
Laboratory Inv	vestigations:								
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