



Public Case Detail

Cases Count: 28

Case Number : 231669

Data Entry Date : 08/08/2007

Gender : U

Hospitalisation : Required a visit to the doctor

Weight (kg) : 78

Onset Date : 03/07/2007

Age :

DOB : 28/05/1965

Outcome :
Recovered

Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Shortness of breath and chest tightness causing more anxiety.	Faverin ceased.
Chest discomfort			

Medicine details :			
FAVERIN (Suspected)		Reason : Depression	
Tablet	50 Milligram	Daily	Oral
Batch :	Started : 25/06/2007	Stopped :	04/07/2007

Public Case Detail

Cases Count: 28

Case Number : 231721

Data Entry Date : 09/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term

Severity

Report Description

Treatment

Irritability

Caused or prolonged inpatient hospitalisation

Patient suffered from depression with bipolar component. She was in hospital for suicidal behaviour and was switched from paroxetine to LUVOX 200-250mg daily on an unknown date. Her behaviour changed and she became very irritable and angry while being treated with Luvov.

Changed to another selective serotonin reuptake inhibitor.

Anger

Caused or prolonged inpatient hospitalisation

Medicine details :

LUVOX (Suspected)

Reason : Depression

Tablet

200 Milligram

Daily

Oral

Batch :

Started :

Stopped :

Public Case Detail

Cases Count: 28

Case Number : 231799

Data Entry Date : 10/08/2007

Hospitalisation :

Onset Date :

Outcome :

Recovered

Gender : F

Weight (kg) : 0

Age : 66Y

DOB :

Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Patient experienced suicidal tendencies while being treated with Luvox.	LUVOX was ceased and Avanza was started.

Medicine details :			
LUVOX (Suspected)		Reason : Depression	
Tablet	200 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 28

Case Number : 232042

Data Entry Date : 15/08/2007

Hospitalisation :

Onset Date : 24/04/2007

Outcome :
Recovered

Gender : M

Weight (kg) : 0

Age :

DOB : 09/04/1973

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Abnormal sleep-related event		Patient thought he was going mad. Had conversations with wife, wouldn't remember. They would fight over it. He opened bills, put them away somewhere and forgot to pay them. Probably drove in his sleep - no recollection - but car often had been moved overnight and windows rolled down.	Ceased Stilnox
Amnesia			

Medicine details :

LUVOX (Interaction)		Reason :	
Tablet	100 Milligram	Daily	Oral
Batch :	Started :	L TERM	Stopped :
STILNOX (Interaction)		Reason :	
Tablet	10 Milligram	Daily	Oral
Batch :	Started : 24/04/2007	Stopped : 17/05/2007	0
MULTIVITAMINS (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 28

Case Number : 232055

Data Entry Date : 16/08/2007

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 35

Onset Date : 29/05/2007

Age :

DOB : 16/11/1997

Outcome : 04/06/2007

Causality : Causality probable

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Nausea		Patient experienced nausea for 24 hours and chronic headache for 48 hours.	Treated with analgesics.
Headache			

Medicine details :			
LUVOX (Suspected)	Reason :		
Tablet	25 Milligram	Daily	Oral
Batch :	Started : 28/05/2007	Stopped : 01/06/2007	

Public Case Detail

Cases Count: 28

Case Number : 232057

Data Entry Date : 16/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 28/06/2007

Age :

DOB : 27/03/1958

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Dizziness		Patient experienced lightheadedness and feeling detached, 'spaced-out' while being treated with Luvox for anxiety.	Ceased Luvox
Dissociation			

Medicine details :

LUVOX (Suspected)	Reason : Anxiety neurosis		
Tablet	25 Milligram	Daily	Oral
Batch :	Started : 27/06/2007	Stopped :	

Public Case Detail

Cases Count: 28

Case Number : 233509

Data Entry Date : 18/09/2007

Gender : F

Hospitalisation :

Weight (kg) : 65

Onset Date : 18/06/2007

Age :

DOB : 03/10/1957

Outcome :

Causality : Causality possible

Recovered

Information: past history: hypertension and migraines.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	Tonic clonic seizure. Also found to be in renal failure.	Supportive. Phenytoin.
Renal failure	Caused or prolonged inpatient hospitalisation		

Medicine details :

FLUVOXAMINE MALEATE (Suspected)

Reason : Depression

100 Milligram Daily

Batch :

Started : 15/01/2007

Stopped : 18/06/2007

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatinine		18/06/2007	181 micromol/L	
Creatinine		20/06/2007	374	

Case Number : 233976

Data Entry Date : 03/10/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 78Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed		increased dose from 100 mg to 200mg	
Disorientation		she could not finish a sentence without forgetting what she was trying to say	
Dysarthria		staggering and slurring of speech	
Confusional state			
Memory impairment			

Medicine details :

LUVOX (Suspected)	Reason : Anxiety neurosis
200 Milligram Daily Oral	
Batch :	Started :
	Stopped : ongoing
STILNOX (Suspected)	Reason : Specific disorders of sleep
Milligram Daily Oral	
Batch :	Started : L TERM
	Stopped : 14/09/2007 0
CELEBREX (Other drug)	Reason :
100 Milligram	
Batch :	Started :
	Stopped :
DI-GESIC (Other drug)	Reason :
Batch :	Started :
	Stopped :
FISH OIL NOS (Other drug)	Reason :
	Oral
Batch :	Started :
	Stopped :
Lyrica (Other drug)	Reason :
75 Milligram 2 times Oral	
Batch :	Started :
	Stopped : 0
NEXIUM (Other drug)	Reason :
20 Milligram	
Batch :	Started :
	Stopped :

Medicine details :

OROXINE (Other drug)

Reason :

100 Microgram

Oral

Batch :

Started :

Stopped :

0

Panadol Osteo (Other drug)

Reason :

Oral

Batch :

Started :

Stopped :

PLAQUENIL (Other drug)

Reason :

200 Milligram

Oral

Batch :

Started :

Stopped :

Case Number : 234139

Data Entry Date : 08/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 70

Onset Date : 07/09/2007

Age :

DOB : 15/02/1923

Outcome : 20/09/2007

Causality : Causality probable

Recovered

Information: Patient medical history: Alzheimer's dementia/multi-infarct dementia.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation	Increasing confusion and agitation, decreased mobility, globally increased tone and clonus of ankles bilaterally, mild dehydration, cogwheeling.	
Agitation	Caused or prolonged inpatient hospitalisation		
Clonus	Caused or prolonged inpatient hospitalisation		
Cogwheel rigidity	Caused or prolonged inpatient hospitalisation		
Dehydration	Caused or prolonged inpatient hospitalisation		
Hypertonia	Caused or prolonged inpatient hospitalisation		
Mobility decreased	Caused or prolonged inpatient hospitalisation		

Medicine details :

FLUVOXAMINE MALEATE (Suspected)		Reason : Anxiety neurosis	
Tablet	50 Milligram	Daily	Oral
Batch :	Started : 24/08/2007	Stopped : 10/09/2007	
ASPIRIN (Other drug)		Reason : Chron isch heart dis no hyper	
	100 Milligram	Daily	
Batch :	Started : L TERM	Stopped : 0	
GALANTAMINE HYDROBROMIDE (Other drug)		Reason : Unspecified psychosis	
	24 Milligram	Daily	
Batch :	Started : L TERM	Stopped :	
PERINDOPRIL (Other drug)		Reason : Essential benign hypertension	
	5 Milligram	Daily	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 28

Case Number : 234222

Data Entry Date : 10/10/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 12/08/2007

Age : 33Y

Outcome :

DOB :

Recovered

Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Bruxism		Patient experienced nocturnal teeth grinding (bruxism).	Fluvoxamine ceased.

Medicine details :			
LUVOX (Suspected)		Reason : Depression	
Tablet	50 Milligram	Daily	Oral
Batch :	Started : 10/08/2007	Stopped : 12/08/2007	

Public Case Detail

Cases Count: 28

Case Number : 235048

Data Entry Date : 06/11/2007
Hospitalisation : Admitted to hospital
Onset Date :
Outcome :
 Recovered

Gender : M
Weight (kg) : 0
Age : 50Y
DOB :
Causality : Causality possible

Information: There was no alcohol or other substances found in his blood.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Abnormal behaviour		a patient receiving Stilnox and Luvox drove his car to a motel room, barricaded himself inside and was increasingly confused. When the police arrived he assaulted them. Now recovered and no memory of event.	
Physical assault		a patient receiving Stilnox and Luvox drove his car to a motel room, barricaded himself inside and was increasingly confused. When the police arrived he assaulted them. Now recovered and no memory of event.	
Amnesia		patient could not recall the events	
Aggression			
Confusional state			

Medicine details :

LUVOX (Suspected)	Reason : Depression
100 Milligram	Daily
	Oral
Batch :	Started :
	Stopped : 0
STILNOX (Suspected)	Reason :
Batch :	Started :
	Stopped :

Public Case Detail

Cases Count: 28

Case Number : 235801

Data Entry Date : 30/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Aggression	Caused or prolonged inpatient hospitalisation	Patient took Luvox for three weeks. He went drinking for a few hours and five hours later when he returned home to his family, he behaved violently, abusively and was totally out of character. He was eventually controlled by police and was hospitalised.	Luvox was discontinued.
Aggression	Caused or prolonged inpatient hospitalisation		
Personality change	Caused or prolonged inpatient hospitalisation		

Medicine details :			
ALCOHOL (Suspected)		Reason :	
Batch :	Started :	Stopped :	
LUVOX (Suspected)		Reason :	
Tablet	50 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 28

Case Number : 236456

Data Entry Date : 20/12/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/06/2007

Age : 20Y

Outcome : 19/06/2007

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
International normalised ratio increased		Increased INR. Epistaxis and ? intramuscular haematoma.	Vitamin K, cessation of fluvoxamine.
Epistaxis			
Haematoma			

Medicine details :

FLUVOXAMINE MALEATE (Interaction)	Reason : Depression
Tablet	Oral
Batch :	Started :
	Stopped : 19/06/2007 0
WARFARIN SODIUM (Interaction)	Reason : Peptic ulcer nos w/o ment perf
Tablet	Oral
Batch :	Started : 07/05/2007
	Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
International normalised ratio				INR prolongation 6.1. Unsure oif outcome but INR decreased with Vit K to 2.1.

Public Case Detail

Cases Count: 28

Case Number : 236854

Data Entry Date : 10/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 23/06/2007

Age : 55Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hypersensitivity		Allergic reaction, urticaria, shortness of breath, heaviness of limbs.	Fluvoxamine ceased, loratidine administered.
Dyspnoea			
Urticaria			

Medicine details :

FLUVOXAMINE MALEATE (Suspected)	Reason : Depression
Tablet	0.5 Dose Unspec Daily Oral
Batch :	Started : 18/06/2007 Stopped : 23/06/2007 0
ATENOLOL (Other drug)	Reason :
Batch :	Started : Stopped :

Public Case Detail

Cases Count: 28

Case Number : 237174

Data Entry Date : 22/01/2008

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 15/12/2007

Age : 68Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information: Medica history: High blood pressure, severe depression and anxiety

Reaction :

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation	Patient felt nauseated, was sweating, and suffered from severe headaches.	Treated with Valium, Panadeine Forte and something for nausea.
Headache	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine details :

LUVOX (Suspected)		Reason :	
Tablet	50 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
AVAPRO (Other drug)		Reason : Essential benign hypertension	
Tablet			Oral
Batch :	Started :	Stopped :	
BETALOC (Other drug)		Reason : Essential benign hypertension	
Tablet	50 Milligram	Daily	Oral
Batch :	Started :	Stopped :	0

Public Case Detail

Cases Count: 28

Case Number : 237204

Data Entry Date : 22/01/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome : 12/01/2008

DOB : 11/10/1969

Recovered

Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Chest pain		Chest pain radiating to left arm, migraine, uncontrollable sobbing and laughter.	
Crying			
Inappropriate affect			
Migraine			
Speech disorder			
Visual impairment			

Medicine details :			
Movox (Suspected)	Reason : Depression		
Tablet	50 Milligram	1 time	Oral
Batch :	Started : 03/01/2008	Stopped : 11/01/2008	0

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Electrocardiography				normal

Public Case Detail

Cases Count: 28

Case Number : 238983

Data Entry Date : 14/03/2008

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date : 28/02/2008

Age :

DOB : 06/01/1977

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Gastrooesophageal reflux disease Akathisia		Acid reflux and restlessness.	

Medicine details :			
LUVOX (Suspected)		Reason :	
	50 Milligram	Daily	Oral
Batch :	Started : 28/02/2008	Stopped :	29/02/2008
VITAMIN B COMPLEX (Other drug)		Reason :	
			Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 28

Case Number : 240597

Data Entry Date : 05/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 02/08/2004

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Autism		Autism, drug exposure during pregnancy.	
Drug exposure during pregnancy			

Medicine details :			
LUVOX (Suspected)		Reason : Depression	
Tablet	400 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 28

Case Number : 240752

Data Entry Date : 08/05/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 27/03/2008

Age :

Outcome : 27/03/2008

DOB : 15/02/1983

Recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug level increased	Caused or prolonged inpatient hospitalisation	Drug level increased.	Luvox discontinued. Clozapine withheld and re-introduced.

Medicine details :

CLOPINE (Interaction)		Reason : Unspecified schizophrenia	
Tablet	700 Milligram	Daily	Oral
Batch :	Started : 30/01/2007	Stopped :	0
LUVOX (Interaction)		Reason :	
Tablet	50 Milligram	Daily	Oral
Batch :	Started : 15/03/2008	Stopped : 27/03/2008	Discontinued.

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level				Clozapine serum level increased to 2220.

Public Case Detail

Cases Count: 28

Case Number : 241791

Data Entry Date : 11/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/05/2008

Age :

Outcome : 21/05/2008

DOB : 18/11/1961

Recovered with sequelae

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Bruxism		Severe grinding of teeth leading to damaged to tooth enamel. Bruxism.	Reduced dose of Luvox.

Medicine details :			
LUVOX (Suspected)		Reason : Depression	
Tablet	100 Milligram	1 time	Oral
Batch :	Started : 24/01/2008	Stopped :	

Public Case Detail

Cases Count: 28

Case Number : 241935

Data Entry Date : 13/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 11/02/1992

Outcome :

Causality : Causality possible

Unknown

Information: Patient was six to ten weeks pregnant.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous		Spontaneous abortion.	

Medicine details :

LUVOX (Suspected)

Reason : Depression

Tablet

150 Milligram

Daily

Oral

Batch :

Started : 14/01/2008

Stopped :

Public Case Detail

Cases Count: 28

Case Number : 242105

Data Entry Date : 19/06/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 95.5

Onset Date :

Age :

DOB : 06/09/1939

Outcome : 15/05/2008

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Muscle spasms		Severe muscle cramping, hypotensive episodes.	Halved Lovox dose.
Hypotension			

Medicine details :			
LUVOX (Suspected)		Reason : Depression	
Tablet	50 Milligram	Daily	Oral
Batch :	Started : 15/10/2007	Stopped : 15/05/2008	

Public Case Detail

Cases Count: 28

Case Number : 242435

Data Entry Date : 27/06/2008

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 100

Onset Date : 30/05/2008

Age :

DOB : 05/01/1952

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Headache		Was on Luvox 100mg 2 daily, changed over to Voxam 100mg end of May, developed head which had to cease medication.	Ceased Voxam
Therapeutic response unexpected with drug substitution			

Medicine details :			
Voxam (Suspected)	Reason : Depression		
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 30/05/2008	Stopped :	

Public Case Detail

Cases Count: 28

Case Number : 245787

Data Entry Date : 23/10/2008

Gender : F

Hospitalisation :

Weight (kg) : 42

Onset Date : 15/02/2008

Age : 23Y

DOB :

Outcome :

Causality : Causality probable

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Incapacity/disability	Abdominal pain and nausea.	Withdrawal of fluvoxamine.
Nausea	Incapacity/disability		

Medicine details :			
FLUVOXAMINE MALEATE (Suspected)		Reason : Depression	
Tablet	100 Milligram	Daily	Oral
Batch :	Started : 01/08/2007	Stopped :	12/08/2008

Public Case Detail

Cases Count: 28

Case Number : 246087

Data Entry Date : 10/11/2008

Gender : F

Hospitalisation :

Weight (kg) : 68

Onset Date : 17/09/2008

Age :

DOB : 06/06/1931

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Severe diarrhoea	

Medicine details :			
LUVOX (Suspected)		Reason :	
Batch :	Started : 17/09/2008	Stopped :	19/09/2008
COUMADIN (Other drug)		Reason :	
Batch :	Started :	Stopped :	
LANOXIN (Other drug)		Reason :	
Batch :	Started :	Stopped :	
NORVASC (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 28

Case Number : 246877

Data Entry Date : 08/12/2008
Hospitalisation : Admitted to hospital
Onset Date : 17/03/2008
Outcome : 26/09/2008
 Death, maybe drug

Gender : M
Weight (kg) : 0
Age :
DOB : 12/08/1988
Causality : Causality possible

Information: Fatal report. There is a coroner's inquiry ongoing - result to come to the man's mother (who reported this incident).

Reaction :

Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Death	Patient experienced severe abdominal pain, weight loss from 85kg to 70kg, poor quality of sleep, nightmares, headaches developed a rash and completed suicide.	Treatment was not stopped.
Headache	Death		
Nightmare	Death		
Poor quality sleep	Death		
Rash	Death		
Weight decreased	Death		

Medicine details :

LUVOX (Suspected) Reason : Depression
 100 Milligram Daily
Batch : Started : 17/03/2008 Stopped : 26/09/2008

Public Case Detail

Cases Count: 28

Case Number : 247920

Data Entry Date : 22/01/2009

Hospitalisation :

Onset Date : 15/11/2008

Outcome :
Recovered

Gender : M

Weight (kg) : 0

Age :

DOB : 13/08/1965

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism	Caused or prolonged inpatient hospitalisation	Patient experienced a pulmonary embolism whilst being treated with Clopine.	Ceased fluvoxamine.

Medicine details :			
CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	350 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
FLUVOXAMINE MALEATE (Suspected)		Reason :	
	100 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
LITHIUM CARBONATE (Other drug)		Reason :	
Batch :	Started :	Stopped :	
ZUCLOPENTHIXOL DECANOATE (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Selection Parameters : Date Range: 01/08/2007 To 31/01/2009 Unclear causality excluded GM medicines Only Medicine Names: FAVERIN, FLUVOXAMINE MALEATE, LUVOX, Movox, Voxam