

Cases Count: 28

Case Number: 231669

Gender: U

Data Entry Date: 08/08/2007

Weight (kg): 78

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 03/07/2007

DOB: 28/05/1965

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction: **Preferred Term**

Severity

Report Description

Treatment

Dyspnoea

Shortness of breath and

Faverin ceased.

chest tightness causing

more anxiety.

Chest discomfort

Medicine details:

FAVERIN (Suspected)

Reason: Depression

Tablet

50 Milligram

Daily

Oral

Batch:

Started: 25/06/2007

Stopped: 04/07/2007

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Cases Count: 28

Case Number: 231721

Gender: F

Data Entry Date: 09/08/2007

Weight (kg): 0

Hospitalisation:

Age: 99U

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Changed to another selective

serotonin reuptake inhibitor.

Irritability

Caused or prolonged

inpatient hospitalisation Patient suffered from depression with bipolar component. She was in hospital for suicidal

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 approvabile.

irritable and angry while being treated with Luvox.

Anger

Caused or prolonged

inpatient hospitalisation

Medicine details:

LUVOX (Suspected) Reason: Depression

Tablet 200 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 28

Case Number: 231799

Gender: F

Data Entry Date: 10/08/2007

Weight (kg): 0

Hospitalisation:

Age: 66Y

Onset Date :

DOB:

Outcome:

Causality: Causality probable

Recovered

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:

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Cases Count: 28

Case Number: 232042

Gender: M

Data Entry Date: 15/08/2007

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 24/04/2007

DOB: 09/04/1973

Outcome:

Abnormal sleep-related event

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description Trea

TreatmentCeased Stilnox

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.

Amnesia

Tablet

Tablet

Medicine details:

LUVOX (Interaction)

Reason:

100 Milligram D

Daily

Oral

Batch :

Batch:

Started:

L TERM

Stopped:

STILNOX (Interaction)

Reason:

10 Milligram

Daily

Oral

Stopped: 17/05/2007

0

MULTIVITAMINS (Other drug)

Reason:

Batch :

Started:

Started: 24/04/2007

Stopped:

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Cases Count: 28

Case Number: 232055

Gender: M

Data Entry Date: 16/08/2007

Weight (kg): 35

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 29/05/2007

DOB: 16/11/1997

Outcome: 04/06/2007

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term

Severity

Treatment

Treated with analgesics.

Nausea

Patient experienced nausea for 24 hours and

Report Description

chronic headache for 48

hours.

Headache

Medicine details:

LUVOX (Suspected)

Reason:

25 Milligram

Daily

Oral

Batch:

Tablet

Started: 28/05/2007

Stopped: 01/06/2007

Page 5 of 29



Cases Count: 28

Case Number: 232057

Gender: M

Data Entry Date: 16/08/2007

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 28/06/2007

DOB: 27/03/1958

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Ceased Luvox

Dizziness

Patient experienced lightheadedness and

feeling detached, 'spaced-out' while being

treated with Luvox for

anxiety.

Dissociation

Medicine details:

LUVOX (Suspected) Reason : Anxiety neurosis

Tablet 25 Milligram Daily Oral

Batch: Started: 27/06/2007 Stopped:

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Cases Count: 28

Case Number: 233509

Gender: F

Data Entry Date: 18/09/2007 **Weight (kg)**: 65

Hospitalisation : Age :

Onset Date: 18/06/2007 **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 Tonic clonic seizure. Also Supportive. Phenytoin.

inpatient found to be in renal failure. hospitalisation

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

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Cases Count: 28

Case Number: 233976

Data Entry Date: 03/10/2007 Weight (kg): 0

Hospitalisation: Age: 78Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

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:

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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 :	

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Hospitalisation:

Public Case Detail

Cases Count: 28

Gender: M

Age:

Case Number : 234139

W I I (/) 70

Data Entry Date: 08/10/2007 **Weight (kg)**: 70

Onset Date: 07/09/2007 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 Increasing confusion and

inpatient agitation, decreased hospitalisation 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:

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Cases Count: 28

Case Number: 234222

Gender: F

Data Entry Date: 10/10/2007

Weight (kg): 0

Hospitalisation:

Age: 33Y

Onset Date : 12/08/2007

7 DOB:

Outcome:

Recovered

Causality: Causality probable

Information:

Reaction:

Preferred Term

Batch:

Severity Report Description

Treatment

Bruxism

Patient experienced nocturnal teeth grinding

Fluvoxamine ceased.

(bruxism).

Daily

Medicine details:

LUVOX (Suspected) Reason : Depression

Started: 10/08/2007

Tablet 50 Milligram

Stopped: 12/08/2007

Oral

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Cases Count: 28

Case Number : 235048

Gender: M

Data Entry Date: 06/11/2007 **Weight (kg)**: 0

Hospitalisation: Admitted to hospital **Age**: 50Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

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. a patient receiving Stilnox Physical assault 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

		letai	

LUVOX (Suspected) Reason : Depression

100 Milligram Daily Oral

Batch: Started: Stopped: 0

STILNOX (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 28

Case Number: 235801

Gender: M

Data Entry Date: 30/11/2007 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

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:

Stopped:

LUVOX (Suspected)

Reason:

Tablet

50 Milligram Daily

Oral

Batch:

Stopped:

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Cases Count: 28

Case Number: 236456

Gender: F

Data Entry Date: 20/12/2007

Onset Date: 18/06/2007

Weight (kg): 0

Hospitalisation:

Age: 20Y

DOB:

Outcome: 19/06/2007

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

International normalised ratio

Increased INR. Epistaxis and?intramuscular

Vitamin K, cessation of fluvoxamine.

haematoma.

increased **Epistaxis**

Haematoma

Medicine details:

FLUVOXAMINE MALEATE (Interaction)

Reason: Depression

Tablet

Oral

Batch:

Stopped: 19/06/2007

WARFARIN SODIUM (Interaction)

Reason: Peptic ulcer nos w/o ment perf

Tablet

Oral

Batch:

Started: 07/05/2007

Started:

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

0

to 2.1.

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Cases Count: 28

Case Number: 236854

Gender: M

Data Entry Date: 10/01/2008

Onset Date: 23/06/2007

Weight (kg): 0

Hospitalisation:

Age: 55Y

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description Treatment

Hypersensitivity

Allergic reaction, urticaria, shortness of breath,

administered.

Fluvoxamine ceased, loratidine

heaviness of limbs.

Dyspnoea

Urticaria

Medicine details:

FLUVOXAMINE MALEATE (Suspected)

Reason: Depression

Tablet Batch: 0.5 Dose Unspec Daily

Started: 18/06/2007

Oral

Stopped: 23/06/2007

0

ATENOLOL (Other drug)

Reason:

Batch:

Started: Stopped:

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Batch:

Public Case Detail

Cases Count: 28

Case Number: 237174

Gender: F

Data Entry Date: 22/01/2008 **Weight (kg)**: 0

Hospitalisation: Admitted to hospital **Age**: 68Y

Onset Date: 15/12/2007 **DOB**:

Outcome: Causality: Causality possible

Recovered

inpatient hospitalisation

Started:

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

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

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

Stopped:

0

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Cases Count: 28

Case Number: 237204

Gender: F

Data Entry Date: 22/01/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 11/10/1969

Outcome: 12/01/2008 Causality: Causality probable

Recovered

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

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Cases Count: 28

Case Number: 238983

Gender: M

Data Entry Date: 14/03/2008

Weight (kg): 0

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 28/02/2008

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:

Reason:

50 Milligram

Daily

Oral

Oral

Batch :

Started: 28/02/2008

Stopped: 29/02/2008

VITAMIN B COMPLEX (Other drug)

Batch :

Started:

Stopped:

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Hospitalisation:

Public Case Detail

Cases Count: 28

Case Number: 240597

Gender: M

Data Entry Date: 05/05/2008 **Weight (kg)**: 0

Age:

Onset Date : De

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:

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Cases Count: 28

Case Number: 240752

Gender: M

Data Entry Date: 08/05/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age:

Onset Date: 27/03/2008

DOB: 15/02/1983

Outcome: 27/03/2008

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Luvox discontinued. Clozapine

inpatient

hospitalisation

Caused or prolonged

withheld and re-introduced.

0

Medicine details:

CLOPINE (Interaction)

Drug level increased

Reason: Unspecified schizophrenia

Drug level increased.

Tablet 700 Milligram Oral

Batch:

Started: 30/01/2007

Started: 15/03/2008

Stopped:

LUVOX (Interaction)

Batch:

Serum drug level

Reason:

Oral

Tablet

50 Milligram

Daily

Daily

Stopped: 27/03/2008

Discontinued.

Laboratory Investigations:

Type

Date Tested Result

Details

Clozapine serum level increased to

2220.

Range

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Cases Count: 28

Case Number: 241791

Gender: F

Data Entry Date: 11/06/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 21/05/2008

DOB: 18/11/1961

Outcome: 21/05/2008

Causality: Causality possible

Recovered with sequelae

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

Bruxism

Severe grinding of teeth leading to dameged 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:

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Cases Count: 28

Case Number: 241935

Gender: F

Data Entry Date: 13/06/2008 Weight (kg): 0

Hospitalisation : Age :

Onset Date : 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:

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Cases Count: 28

Case Number: 242105

Gender: F

Data Entry Date: 19/06/2008

Weight (kg): 95.5

Hospitalisation: Required a visit to the doctor

Age:

Onset Date :

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,

Halved Lovox dose.

hypotensive episodes.

Hypotension

Medicine details:

LUVOX (Suspected)

Reason: Depression

Tablet

50 Milligram

Daily

Oral

Batch:

Started: 15/10/2007

Stopped: 15/05/2008

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Cases Count: 28

Case Number: 242435

Gender: M

Age:

Data Entry Date: 27/06/2008 **Weight (kg)**: 100

Hospitalisation: Required a visit to the doctor

DOB: 05/01/1952

Outcome : Causality : Causality possible

Recovered

Information:

Onset Date: 30/05/2008

Reaction:

Preferred Term Severity Report Description Treatment

Headache Was on Luvox 100mg 2 Ceased Voxam daily, chnaged over to

Voxam 100mg end of May, developed head which had to cease medication.

Therapeutic response unexpected with drug

substitution

Medicine details:

Voxam (Suspected) Reason : Depression

Tablet 200 Milligram Daily Oral

Batch: Started: 30/05/2008 Stopped:

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Cases Count: 28

Case Number: 243599

Gender: F

Age:

Data Entry Date: 07/08/2008 **Weight (kg)**: 66

Hospitalisation: Required a visit to the doctor

Onset Date: 22/07/2008 **DOB**: 13/10/1948

Outcome: 23/07/2008 Causality: Causality certain

Recovered

Information: Cert (Timing)

Reaction:

Preferred Term Severity Report Description Treatment

Throat irritation Burning down throat on

ingestion.

Medicine details:

FAVERIN (Suspected) Reason :

Tablet 50 Milligram Daily Oral

Eutroxsig (Other drug) Reason :

100 Microgram Daily Oral

Batch: Started: Stopped:

PARIET (Other drug) Reason :

20 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 28

Case Number: 245787

Gender: F

Data Entry Date: 23/10/2008

Weight (kg): 42

Hospitalisation:

Age: 23Y

Onset Date: 15/02/2008

DOB:

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Abdominal pain

Incapacity/disability

Abdominal pain and

Withdrawal of fluvoxamine.

nausea.

Nausea

Incapacity/disability

Medicine details:

FLUVOXAMINE MALEATE (Suspected)

Reason: Depression

Tablet

100 Milligram

Daily

Oral

Batch:

Started: 01/08/2007

Stopped: 12/08/2008

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Cases Count: 28

Case Number: 246087

Gender: F

Data Entry Date: 10/11/2008 Weight (kg): 68

Hospitalisation: Age:

Onset Date: 17/09/2008 **DOB**: 06/06/1931

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:			
Preferred Term Severity		Report Descriptio	n Treatment
Diarrhoea		Severe diarrhoea	
Medicine details :			
LUVOX (Suspected)		Reason :	
Batch :	Started : 17/09/2008	Sto	pped: 19/09/2008
COUMADIN (Other drug)		Reason :	
Batch :	Started :	Sto	pped :
LANOXIN (Other drug)		Reason :	
Batch :	Started :	Sto	pped :
NORVASC (Other drug)		Reason :	
Batch :	Started :	Sto	pped :

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Cases Count: 28

Case Number : 246877

Gender: M

Age:

Data Entry Date: 08/12/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

DOB: 12/08/1988

Outcome: 26/09/2008

Onset Date: 17/03/2008

Causality: Causality possible

Death, maybe drug

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 Treatment was not stopped. abdominal pain, weight

loss from 85kg to 70kg, poor quality of sleep, nightmares, headaches developed a rash and

completed suicide.

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

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Cases Count: 28

Case Number: 247920

Gender: M

Data Entry Date: 22/01/2009 Weight (kg): 0

Age:

Hospitalisation:

Outcome:

Onset Date: 15/11/2008

DOB: 13/08/1965 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Pulmonary embolism Caused or prolonged Patient experienced a

inpatient

pulmonary embolism whilst hospitalisation being treated with Clopine.

Ceased fluvoxamine.

Medicine details:

CLOPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 350 Milligram Oral Daily

Batch: Started: Stopped:

FLUVOXAMINE MALEATE (Suspected) Reason:

> 100 Milligram Daily Oral

Batch: Started: Stopped:

LITHIUM CARBONATE (Other drug) Reason:

Stopped: Batch: Started:

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

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