

Cases Count: 49

Case Number: 242267

Gender: M

Data Entry Date: 25/06/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 25Y

Onset Date: 28/05/2008

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term
Suicidal ideation

Severity Report Description

**Treatment** 

Suicidal thoughts.

Ceased Cymbalta

Medicine details:

Cymbalta (Suspected)

Reason: Depression

Capsule

60 Milligram

Daily

Oral

Batch :

Started: 23/05/2008

**Stopped**: 29/05/2008

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Cases Count: 49

**Case Number: 243132** 

Gender: F

Data Entry Date: 22/07/2008 Weight (kg): 0

**Hospitalisation**: Required a visit to the doctor Age:

**Onset Date: DOB:** 20/11/1986

Outcome: Causality: Causality possible

Not yet recovered

**Information:** Patient sensitive to many pain relievers.

Reaction:

Preferred Term Severity Report Description Treatment

Nausea Nausea, diarrhoea and blotchy rash reported.

Diarrhoea

Rash macular

Medicine details:

**Duloxetine hydrochloride (Suspected)** Reason : Pain

Capsule 1 Dose Unspec Daily Oral

**Batch**: **Started**: 24/06/2008 **Stopped**: 24/06/2008

Pregabalin (Other drug) Reason : Pain

Capsule 1 Dose Unspec Daily Oral

Batch: Started: Stopped:

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Cases Count: 49

Gender: F

Case Number: 243248

**Data Entry Date**: 28/07/2008 **Weight (kg)**: 0

Hospitalisation: Age: 57Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Blood pressure increased		On 17 June 2008, after starting duloxetine therapy, the patient's blood pressure went up to 180/125. The event of increased blood pressure was considered serious other by the company physician. On an unknown date in June 2008, for the first few days of duloxetine therapy, the patient experienced nausea which then subsided. On an unknown date in June 2008, nine days after starting duloxetine therapy, the patient experienced headache.	Duloxetine was decreased to 30 mg daily.
Headache			
Nausea			

Medicine details:

Duloxetine hydrochloride (Suspected) Reason : Depression

Capsule 60 Milligram Daily Oral

Batch: Started: 17/06/2008 Stopped:

Pregabalin (Other drug) Reason :

Batch: Started: Stopped:

QUETIAPINE (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 49

**Case Number: 243526** 

Gender: F Weight (kg): 0

**Data Entry Date:** 05/08/2008

**Hospitalisation:** 

Age:

Onset Date: 23/07/2008

**DOB:** 04/05/1956

Outcome: 24/07/2008

Causality: Causality probable

Recovered

Information: Previous similar reaction to Luvox.

Reaction:

**Preferred Term** Severity **Report Description** 

**Treatment** 

**Palpitations** 

Palpitations, dilated pupils,

trouble swallowing,

lethargy, difficult feeling.f

Dysphagia

Lethargy

Mydriasis

Medicine details:

Cymbalta (Suspected)

Reason: Depression

Tablet

**Tablet** 

60 Milligram

1 time

Oral

Batch:

Started: 23/07/2008

Stopped: 23/07/2008

Reason: Other diseases of esophagus

**NEXIUM (Other drug)** 

40 Milligram

Daily

Oral

Batch:

Started:

Stopped:

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Cases Count: 49

**Case Number : 243660** 

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 13/07/2008 DOB: 02/06/1950

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Reflux oesophagitis Within 2 days of taking Ceased Cymbalta, Lexotan.

Cymbalta had severe reflux, severe epigastric pain and flatulence. On day 10 had nausea, day 12 woke with headache. Stopped taking Cymbalta. Day 13 extreme attacks of

rage and severe headache, all previous symptoms still present. Symptoms starting to settle by has self-harmed due to rage, significant suicidal

ideation.

Abdominal pain upper

Anger

Flatulence

Headache

Intentional self-injury

Nausea

Suicidal ideation

Medicine details:

Cymbalta (Suspected) Reason : Depression

Capsule 30 Milligram Daily Oral

**Batch**: **Started**: 11/07/2008 **Stopped**: 22/07/2008

BACLOFEN (Other drug) Reason :

30 Milligram Daily Oral

Batch: Started: Stopped:

FENAC (Other drug) Reason :

100 Milligram Daily Oral

Batch: Started: Stopped:

IMURAN (Other drug) Reason :

50 Milligram Daily Oral

Batch: Started: Stopped:

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Medicine details :					
MESASAL (Other drug)	Reason:				
		2.2 Gram	Daily		Oral
Batch :	Started :			Stopped :	
NEXIUM (Other drug)		Reason :			
		40 Milligram	Daily		Oral
Batch :	Started :			Stopped :	
PANADEINE FORTE (Other drug)		F	Reason :		
		1 Dose Uns	spec As necess	ary	
Batch :	Started :			Stopped :	
PANAMAX (Other drug)	NAMAX (Other drug) Reason :				
		1 Gram	As necess	ary	
Batch :	Started :			Stopped :	
PREDNISOLONE (Other drug)		F	Reason :		
		5 Milligram	Daily		Oral
Batch :	Started :			Stopped :	
PREMARIN (Other drug)		F	Reason :		
		925 Milligram	Daily		Oral
Batch :	Started :			Stopped :	
TEMAZE (Other drug)		F	Reason :		
		10 Milligram	Daily		Oral
Batch :	Started :			Stopped :	
THYROXINE SODIUM (Other drug)		Reason :			
		50 Microgran	n Daily		Oral
Batch :	Started :			Stopped :	
VALIUM (Other drug)		F	Reason :		
		5 Milligram	Daily		Oral
Batch :	Started :			Stopped :	

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Cases Count: 49

Gender: M

Nil

Case Number: 243796

**Data Entry Date**: 13/08/2008 **Weight (kg)**: 80

Hospitalisation: Age:

**Onset Date**: 04/07/2008 **DOB**: 10/08/1961

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Urine flow decreased Patient complained of passing small amount of urine only seems to occur

urine only seems to occur during middle of day.

Medicine details:

Duloxetine hydrochloride (Suspected) Reason : Depression

Capsule 60 Milligram Daily Oral

Batch: Started: 02/07/2008 Stopped:

QUETIAPINE (Suspected) Reason :

Tablet 900 Milligram Daily Oral

Batch: Started: 27/06/2008 Stopped:

LITHIUM CARBONATE (Other drug) Reason :

Batch: Started: Stopped:

SEREVENT ACCUHALER (Other drug) Reason :

Batch: Started: Stopped:

THIAMINE (Other drug) Reason :

Batch: Started: Stopped:

Vitamins and Minerals Combination (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 49

**Case Number: 243896** 

Gender: F

**Data Entry Date**: 18/08/2008 **Weight (kg)**: 0

Hospitalisation: Age: 58Y

**Onset Date**: 23/07/2008 **DOB**:

Outcome: Causality: Causality possible

Unknown

Information: The patient medical history included: depression, anxiety, irritability and suicidal

ideation.

Reaction:

Preferred Term Severity Report Description Treatment

Suicidal ideation Gastrointestinal problems Diazepam

like diarrhoea and nausea, headache, increase in suicidality and rage.

Aggression

Diarrhoea

Headache

Nausea

Medicine details:

Cymbalta (Suspected) Reason : Otr mus rheum,fibrosit&myalgia

Capsule 30 Milligram Daily Oral

**Batch**: **Started**: 12/07/2008 **Stopped**: 22/07/2008

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Cases Count: 49

Gender: F

**Case Number: 243897** 

**Data Entry Date**: 18/08/2008 **Weight (kg)**: 0

Hospitalisation: Treated in Accident/Emergency Depar Age: 26Y

**Onset Date**: 09/07/2008 **DOB**:

Outcome : Causality : Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Serotonin syndrome
Serotonin syndrome,
severe nausea, dizziness,
drowsiness, blurred vision,
constipation, tingling in
hands and feet, sore throat

felt weak

Asthenia

Constipation

Dizziness

Nausea

Oropharyngeal pain

Paraesthesia

Somnolence

Vision blurred

Medicine details:

Cymbalta (Suspected)Reason : Otr mus rheum,fibrosit&myalgiaCapsule30 MilligramDailyOral

Batch: Started: 09/07/2008 Stopped:

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Cases Count: 49

Case Number: 244006 Gender: F

**Data Entry Date**: 21/08/2008 **Weight (kg)**: 0

**Hospitalisation:** Age: 60Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Delirium Delirious and sweating.

Hyperhidrosis

Medicine details:

AMITRIPTYLINE HYDROCHLORIDE (Suspected) Reason : Depression

Batch: Started: Stopped: 0

Cymbalta (Suspected) Reason : Depression

Capsule 60 Milligram 1 time Oral

Batch: Started: Stopped:

LOVAN (Suspected) Reason : Depression

Batch: Started: Stopped:

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Cases Count: 49

Case Number: 244236

Gender: F

Data Entry Date: 28/08/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

**Preferred Term** 

Severity Report Description

**Treatment** 

Constipation

Experieicing constipation

problems

Medicine details:

Cymbalta (Suspected)

Reason:

60 Milligram

Batch :

Started:

Stopped:

0

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Cases Count: 49

Case Number: 244346

Gender: M

**Data Entry Date:** 03/09/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 58Y

Onset Date: 15/07/2008

DOB:

Outcome:

Causality: Causality possible

Information:

Unknown

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Transient ischaemic attack

Transient ischaemic attack

Medicine details:

Cymbalta (Suspected)

Reason: Depression

Capsule

60 Milligram

Daily

Oral

Batch:

Started:

Stopped:

0

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Cases Count: 49

Gender: F

Case Number: 244666

**Data Entry Date**: 16/09/2008 **Weight (kg)**: 120

Hospitalisation : Age :

**Onset Date**: 29/07/2008 **DOB**: 01/07/1951

Outcome: 30/07/2008 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Swollen tongue Life threatening Swollen tongue 2-3 hours

after ingestion lasting 15

hours.

Medicine details:

Cymbalta (Suspected) Reason :

Capsule 60 Milligram 1 time Oral

Batch: Started: 29/07/2008 Stopped:

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Cases Count: 49

Case Number: 244977

Onset Date: 14/08/2008

Information:

Gender: M

Age:

**Data Entry Date**: 30/09/2008 **Weight (kg)**: 85

**Hospitalisation**: Required a visit to the doctor

**DOB**: 10/03/1956

Outcome : Causality : Causality possible

Not yet recovered

-

Reaction:

Preferred Term Severity Report Description Treatment

Diarrhoea Diarrhoea, faintness, dizziness, vague feeling.

Disturbance in attention

Dizziness

Medicine details:

Cymbalta (Suspected) Reason :

60 Milligram 1 time

**Batch**: **Started**: 14/08/2008 **Stopped**: 14/08/2008

DUCENE (Other drug) Reason :

5 Milligram Daily

Batch: Started: Stopped:

MICARDIS (Other drug) Reason :

40 Milligram Daily

Batch: Started: Stopped:

NEXIUM (Other drug) Reason :

20 Milligram Daily

Batch: Started: Stopped:

PANAMAX (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 49

**Case Number : 245096** 

Gender: F

**Data Entry Date**: 02/10/2008 **Weight (kg)**: 0

**Hospitalisation**: Required a visit to the doctor Age:

Onset Date: 29/08/2008 DOB: 12/09/1948

Outcome: 02/09/2008 Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Pruritus Felt itchy all over, and had Drug ceased

a feeling of "pins and needles" down the side of

her face.

Paraesthesia

Medicine details :

Cymbalta (Suspected) Reason : Otr mus rheum,fibrosit&myalgia

Capsule 60 Milligram Daily Oral

**Batch**: **Started**: 26/08/2008 **Stopped**: 29/08/2008 0

INDERAL (Other drug) Reason:

40 Milligram Daily

Batch: Started: Stopped:

MAREVAN (Other drug) Reason :

3 Milligram Daily Oral

Batch: Started: Stopped:

MURELAX (Other drug) Reason :

30 Milligram Daily Oral

Batch: Started: Stopped:

TRAMAL SR (Other drug) Reason :

200 Milligram Daily Oral

Batch: Started: Stopped:

VALIUM (Other drug) Reason :

15 Milligram Daily

Batch: Started: 29/08/2008 Stopped:

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Cases Count: 49

**Case Number: 245100** 

Gender: F

**Data Entry Date**: 02/10/2008 **Weight (kg)**: 0

Hospitalisation: Age: 45Y

**Onset Date**: 02/09/2008 **DOB**:

Outcome: Causality: Causality possible

hours, confusion.

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Delirium Caused or prolonged Delirium, memory loss 24

inpatient hospitalisation

Amnesia Caused or prolonged

inpatient hospitalisation

Confusional state Caused or prolonged

inpatient hospitalisation

**Medicine details:** 

Duloxetine hydrochloride (Interaction) Reason :

Capsule 60 Milligram Daily Oral

Batch: Started: 15/03/2008 Stopped:

TRAMADOL HYDROCHLORIDE (Interaction) Reason : Migraine

Injection 1 Dose Unspec 1 time Intravenous

Batch: Started: Stopped:

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Cases Count: 49

Gender: F

Age:

**Case Number: 245121** 

**Data Entry Date**: 03/10/2008 **Weight (kg)**: 57

Hospitalisation :

Onset Date: 02/09/2008 DOB: 11/11/1976

Outcome: 06/09/2008 Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Abdominal pain upper Stomach pain, nausea, dry Ceased cymbalta

retching, headache, dizzy, fainting, "groggy" on the first day, the second day arms, legs and body felt "heavy", prickly skin, "sand paper" skin, swollen lips and tongue, raised dry skin. 4 days of feeling

"unwell".

Dizziness

Dry skin

Lip swelling

Nausea

Paraesthesia

Retching

Swollen tongue

Syncope

Medicine details:

Cymbalta (Suspected) Reason :

Capsule 60 Milligram 1 time Oral

**Batch**: **Started**: 02/09/2008 **Stopped**: 02/09/2008

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Cases Count: 49

**Case Number: 245178** 

Gender: F

**Data Entry Date**: 07/10/2008

Weight (kg): 0

**Hospitalisation:** 

Age: 25Y

Onset Date: 28/07/2008

DOB:

Outcome:

Causality: Causality possible

Oxazepam

Recovered

Information:

Reaction:

Somnolence

Preferred Term Severity

Report Description Treatment

Felt drowsy, went to sleep and when she woke "everything was hurting", severe joint pain, aching all over - shoulders, back, arms and legs. She also had "lockjaw" and was grinding her teeth - for

grinding her teeth - for several hours without

abating.

Arthralgia

Bruxism

Myalgia

Trismus

Medicine details:

Cymbalta (Interaction) Reason : Depression

Capsule 60 Milligram 1 time Oral

**Batch**: **Started**: 28/07/2008 **Stopped**: 28/07/2008 0

PROZAC (Interaction) Reason: Depression

20 Milligram Daily

Batch: Started: Stopped: 24/07/2008

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palpitations and vomiting.

Cases Count: 49

**Case Number: 245186** 

Gender: F

**Data Entry Date**: 07/10/2008 **Weight (kg)**: 0

Hospitalisation: Age: 16Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Palpitations Caused or prolonged Patient experienced

inpatient

hospitalisation

Dizziness Caused or prolonged

inpatient hospitalisation

Hallucination Caused or prolonged

inpatient hospitalisation

Vomiting Caused or prolonged

inpatient hospitalisation

Medicine details :

Cymbalta (Suspected) Reason : Depression

Capsule 60 Milligram 1 time Oral

**Batch**: **Started**: 06/08/2008 **Stopped**: 06/08/2008 0

MICROGYNON 50 (Other drug) Reason :

Batch: Started: 27/07/2008 Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Calcium 2.20 - 2.60 07/08/2008 2.30

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Cases Count: 49

Case Number: 245258

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Chest pain

Two to three weeks after begining treatment, the patient experienced chest

patient experienced chest pain and tachycardia.

Tachycardia

**Medicine details:** 

Cymbalta (Suspected) Reason :

Batch: Started: Stopped:

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**Cases Count: 49** 

Gender: F

**Case Number: 245315** 

**Data Entry Date**: 10/10/2008 **Weight (kg)**: 65

Hospitalisation: Age:

**Onset Date**: 29/05/2008 **DOB**: 27/08/1940

Outcome : Causality : Causality possible

Recovered with sequelae

Information:

Reaction:			
Preferred Term	Severity	Report Description	Treatment
Hypertension	Incapacity/disability	Patient had a prior history of hypertension for several years. Recent hospital admission dates 15/04/08 to 29/04/08. Cymbalta was commenced by psychiatrist on 23/05/08 for management of resistant depression. Upon introduction of Cymbalta the patient's blood pressure was further elevated.	The Atacand dose was increased to 32mg daily on the 03/06/08. The patient was initiated on prazosin 2mg 10/06/08 for one dose only (profound hypotension- not continued). The patient was commenced on Zanidip 10mg daily, and the dose was increased to 20mg daily before 27/06/08. The patient remains on Cymbalta

Medicine details :					
Cymbalta (Suspected)	Reason: Depression				
Tablet		60 Milligram	Daily		Oral
Batch :	Started: 23	/05/2008		Stopped :	
ASPIRIN (Other drug)	Reason :				
Tablet		100 Milligram	Daily		Oral
Batch :	Started :			Stopped :	
ATACAND (Other drug)		Rea	ason :		
Tablet		16 Milligram	Daily		Oral
Batch :	Started :			Stopped :	
CHLORVESCENT (Other drug)		Rea	ason :		
Tablet	1 Dose Unspec 2 times			Oral	
Batch :	Started: 19/04/2008		Stopped :	Stopped :	
DIAZEPAM (Other drug)	Reason :				
Tablet		1 Milligram	2 times		Oral
Batch :	Started :			Stopped :	
LIPEX (Other drug)	Reason :				
Tablet		40 Milligram	Daily		Oral
Batch :	Started :			Stopped :	
NICORETTE PATCH (Other drug)	Reason :				
Patch, dermal		10 Milligram	Daily		Transdermal
Batch :	Started: 16	/04/2008		Stopped :	

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Medicine details: OSTELIN 1000 (Other drug) Reason: 25 Microgram Oral Capsule Daily **Started**: 29/04/2008 Stopped: Batch: PARACETAMOL (Other drug) Reason: Tablet 1 Gram As necessary Oral Batch: Started: Stopped: PREDNISOLONE (Other drug) Reason: Tablet 4 Milligram Oral Daily Started: Stopped: Batch: Seretide 250/50 Accuhaler (Other drug) Reason: Inhalation Inhalation 2 Dose Unspec 2 times Started : Stopped: Batch: SPIRIVA (Other drug) Reason: Inhalation 18 Microgram Daily Inhalation Batch: Started: Stopped: TRITACE (Other drug) Reason: 10 Milligram Oral Capsule Daily Batch: Started: Stopped:

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Cases Count: 49

Case Number: 245388

Gender: F

**Data Entry Date:** 13/10/2008

Weight (kg): 60

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 01/09/2008

**DOB**: 20/01/1966

Outcome:

Causality: Causality possible

Not yet recovered

Information: DOCI report.

Reaction:

**Preferred Term** 

Severity **Report Description**  **Treatment** 

Urinary hesitation

Urine hesitancy and poor

Ceased Cymbalta, back to

sleep for 2 weeks.

previous SSRI.

Insomnia

Medicine details:

Cymbalta (Suspected)

Reason: Depression

**Tablet** 

60 Milligram

Daily

Oral

Batch:

Started: 16/08/2008

Stopped: 15/09/2008



Cases Count: 49

Case Number: 245421

Gender: F

**Data Entry Date: 14/10/2008** 

Weight (kg): 0

Hospitalisation: Admitted to hospital

**Age:** 99U

**Onset Date:** 

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

**Preferred Term** Severity **Report Description** 

**Treatment** 

Delirium

Caused or prolonged

inpatient

hospitalisation

Patient experienced mirgraine and was prescribed tramadol hcl,

the patient ended up delirious and completley off the planet, she did not know her children, who she was and where she

was.

Migraine

Caused or prolonged

inpatient hospitalisation

Medicine details:

Cymbalta (Interaction) Reason: Depression

60 Milligram Oral Capsule Daily

Batch: Started: 15/07/2008 Stopped: 0

TRAMADOL HYDROCHLORIDE (Interaction) Reason: Migraine

Stopped: Batch: Started:

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Cases Count: 49

Case Number: 245464

Gender: F

**Data Entry Date**: 15/10/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tremor Caused or prolonged One week after beginning Ceased Duloxetine.

inpatient treatment, the patient started feeling shaky, could walk property could not talk

and was feeling dopey.

Aphasia Caused or prolonged

inpatient hospitalisation

Feeling abnormal Caused or prolonged

inpatient .

hospitalisation

Gait disturbance Caused or prolonged

inpatient hospitalisation

Medicine details:

Cymbalta (Suspected) Reason :

Capsule 60 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 49

Gender: F

**Case Number : 245561** 

**Data Entry Date**: 17/10/2008 **Weight (kg)**: 60

Hospitalisation : Age :

**Onset Date**: 08/10/2008 **DOB**: 09/08/1968

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Anxiety Caused or prolonged anxiety, stiff neck, painful diazepam 2.5 mg orally 8 hourly

inpatient neck, paraesthesiae down hospitalisation both arms, fear of death,

generalised hyperreflexia,

insomnia

Fear of death Caused or prolonged

inpatient

hospitalisation

Hyperreflexia Caused or prolonged

inpatient hospitalisation

Tiospitalisation

Insomnia Caused or prolonged

inpatient hospitalisation

Musculoskeletal stiffness Caused or prolonged

inpatient

hospitalisation

Neck pain Caused or prolonged

inpatient hospitalisation

Paraesthesia Caused or prolonged

inpatient

hospitalisation

Serotonin syndrome Caused or prolonged

inpatient

hospitalisation

**Medicine details:** 

Cymbalta (Suspected) Reason : Pain

Capsule 30 Milligram 1 time Oral

**Batch**: **Started**: 08/10/2008 **Stopped**: 08/10/2008 0

CELEBREX (Other drug) Reason :

Batch: Started: Stopped:

PANADEINE (Other drug) Reason :

Batch: Started: Stopped:

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**Laboratory Investigations:** 

Туре Range Date Tested Result Details

Magnetic Resonance Imaging MRI was performed with negative results.

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Cases Count: 49

Case Number: 246073

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Oedema

Preferred Term Severity Report Description Treatment

Urinary retention Caused or prolonged inpatient

hospitalisation

One week after beginning duloxetine, the patient experienced urinary retention and swelling

(oedema) in his legs, trunk

and hands.

Medicine details :

Cymbalta (Suspected) Reason: Depression

Capsule 60 Milligram Daily Oral

Lyrica (Other drug) Reason :

Batch: Started: Stopped:

Norspan Nos (Other drug) Reason :

Drug delivery system, transder Transdermal

Batch: Started: Stopped:

SEROQUEL (Other drug) Reason :

Batch: Started: Stopped:

VALIUM (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 49

**Case Number : 246092** 

Gender: M

**Data Entry Date :** 10/11/2008

Weight (kg): 0

**Hospitalisation:** 

Age:

Onset Date: 16/09/2008

**DOB**: 04/08/1930

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description Treatm

Treatment

Mania

Patient experienced manic symptoms and his

Duloxetine dose was decreased

creatinine clearance level

to 30mg on 16/09/2008.

was 32.

Creatinine renal clearance

decreased

**Medicine details:** 

Cymbalta (Suspected) Reason :

Capsule 60 Milligram Daily Oral

**Batch**: **Started**: 02/09/2008 **Stopped**: 15/09/2008 0

ZYPREXA (Suspected) Reason :

2.5 Milligram

Batch: Started: Stopped: Contin

Bicor (Other drug) Reason :

Batch: Started: Stopped:

CLOPIDOGREL (Other drug) Reason :

Batch: Started: Stopped:

EPILIM (Other drug) Reason :

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Creatinine clearance Prior to taking Duloxetine creatinine

clearance levels:32

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Cases Count: 49

Case Number: 246094 Gender: F

**Data Entry Date**: 10/11/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dizziness Caused or prolonged Patient experienced severe inpatient dizziness and nausea.

inpatient hospitalisation

Nausea Caused or prolonged

inpatient hospitalisation

Medicine details :

Cymbalta (Suspected) Reason :

Batch: Started: Stopped:

Escitalopram (Other drug) Reason :

Batch: Started: Stopped:

VENLAFAXINE HYDROCHLORIDE (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 49

Case Number: 246138

Gender: M

**Data Entry Date:** 11/11/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

**Age:** 19Y

Onset Date: 01/08/2008

DOB:

Outcome:

Causality: Causality probable

Not yet recovered

Information:

Reaction:

**Preferred Term** Severity **Report Description** 

**Treatment** 

Suicidal ideation

Increasing thoughts of self harm. Want's to kill himself before he hurts anybody. Increasing thoughts of

wanting to killl/harm other

Medication ceased on 11/9/08. Patient referred by CATT team (11/9/08)

people. Headaches, aggression, twitching.

Aggression Headache

Homicidal ideation

Medicine details:

Cymbalta (Suspected) Reason: Depression

> 60 Milligram Daily

Batch: Started: 01/08/2008 Stopped: 12/09/2008

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Cases Count: 49

**Case Number : 246145** 

Hospitalisation: Age: 55Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hypotension Two hours after taking Duloxetine was discontinued.

duloxetine, the patient experienced severe postural hyoptension and fainting which lasted for approximately three hours.

Presyncope

Medicine details:

Cymbalta (Suspected) Reason : Depression

30 Milligram Daily Oral

Batch: Started: Stopped: 0

DIAZEPAM (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 49

**Case Number: 246173** 

Gender: F

**Data Entry Date: 12/11/2008** 

Weight (kg): 0

**Hospitalisation:** 

**Age:** 99U

**Onset Date:** 

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Abortion spontaneous

**Preferred Term** Severity **Treatment** 

The patient took duloxetine hydrochloride (Cymbalta) for an unknown indication. The patient became pregnant. The exposure period was during trimester one. When the patient was diagnosed as pregnant, duloxetine was

**Report Description** 

discontinued. On an unknown date after discontinuation of duloxetine, the patient lost

the pregnancy

(miscarriage).

Drug exposure during

pregnancy

**Medicine details:** 

Cymbalta (Suspected)

Reason:

Daily

60 Milligram

Started:

Batch:

Stopped:

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Cases Count: 49

**Case Number: 246188** 

Gender: F

**Data Entry Date:** 12/11/2008 Weight (kg): 86

Hospitalisation: Admitted to hospital Age: 60Y

Onset Date: 06/10/2008 DOB:

Outcome: Causality: Causality possible

Not yet recovered

Information: Seafood allergy, nil known drug allergies.

Reaction:

**Preferred Term Report Description Treatment** Severity

Vertigo Caused or prolonged Vertigo, vomiting -

inpatient continuous, and abdominal hospitalisation

pain, nausea, diarrhoea possible GI bleeding (dark

motion), felt unwell.

Abdominal pain Caused or prolonged

inpatient

hospitalisation

Caused or prolonged Diarrhoea

inpatient

hospitalisation

Faeces discoloured Caused or prolonged

inpatient

hospitalisation

Malaise Caused or prolonged

inpatient

hospitalisation

Nausea Caused or prolonged

inpatient

hospitalisation

Caused or prolonged Vomiting

inpatient

hospitalisation

Medicine details:

**Duloxetine hydrochloride (Suspected)** Reason: Depression

> 60 Milligram Daily

Started: 06/10/2008 Batch: Stopped: 06/10/2008

LIPITOR (Other drug) Reason: Othr&unspec metabolic diseases

> 10 Milligram Daily

Started: Batch: Stopped:

Micardis Plus (Other drug) Reason: Essential benign hypertension

1 Dose Unspec Daily

Started: Stopped: 09/10/2008 Batch:

NORVASC (Other drug) Reason: Essential benign hypertension

> Daily 2.5 Milligram

Batch: Started: Stopped:

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Cases Count: 49

Case Number: 246272

Gender: M

**Data Entry Date**: 14/11/2008 **Weight (kg)**: 0

Hospitalisation: Age: 90Y

**Onset Date**: 10/09/2008 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hyponatraemia Caused or prolonged Hyponatreamia IV rehydration with nornal

inpatient saline.

hospitalisation

Medicine details:

Cymbalta (Suspected) Reason : Depression

Capsule 30 Milligram Daily Oral

Batch: Started: 01/09/2008 Stopped: 10/09/2008

LACTULOSE (Other drug) Reason :

Batch: Started: Stopped:

METAMUCIL (Other drug) Reason :

Batch: Started: Stopped:

MIRTAZAPINE (Other drug) Reason :

Batch: Started: Stopped:

OSTELIN 1000 (Other drug) Reason :

Batch: Started: Stopped:

OXAZEPAM (Other drug) Reason :

Batch: Started: Stopped:

**Laboratory Investigations:** 

Type Range Date Tested Result Details

Sodium 114, 115. 55.

Serum osmolality 243
Urine osmolality 394

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Cases Count: 49

Cymbalta ceased.

**Case Number : 246295** 

Gender: F

**Data Entry Date**: 17/11/2008 **Weight (kg)**: 0

**Hospitalisation**: Required a visit to the doctor Age:

**Onset Date**: 03/10/2008 **DOB**: 04/11/1945

Outcome: 06/10/2008 Causality: Causality probable

Recovered

Information: Reactions to Efexor XR - nightmares, Keflex - rash and Doloxene - facial swelling.

DOCI report.

Reaction:

Preferred Term Severity Report Description Treatment

Palpitations
Patient commenced
Cymbalta and felt heart
palpitation that day,

continued for the next 3 days on Cymbalta with

continued palpitations.

Medicine details:

Cymbalta (Suspected) Reason : Depression

30 Milligram Daily

**Batch: Started:** 03/10/2008 **Stopped:** 06/10/2008

CARTIA (Other drug) Reason :

1 Dose Unspec

Batch: Started: Stopped:

Crestor (Other drug) Reason :

10 Milligram

Batch: Started: Stopped:

FERRO-GRADUMET (Other drug) Reason :

1 Dose Unspec

Batch: Started: Stopped:

OROXINE (Other drug) Reason : Myxedema

150 Milligram Daily

Batch: Started: Stopped:

PANADEINE FORTE (Other drug) Reason :

4 Dose Unspec

Batch: Started: Stopped:

**QUININE (Other drug)** Reason : Pain in limb

300 Milligram Daily

Batch: Started: Stopped:

TAMOXIFEN CITRATE (Other drug) Reason :

20 Milligram

Batch: Started: Stopped:

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Cases Count: 49

**Case Number: 246530** 

Gender: F

**Data Entry Date**: 25/11/2008

Weight (kg): 0

**Hospitalisation:** Admitted to hospital

**Age:** 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: DOCI report.

Reaction:

Preferred Term Severity Report Description Treatment

Dehydration Caused or prolonged

inpatient

Patient experienced dehydration and hepatic

hospitalisation function abnormal.

Hepatic function abnormal Caused or prolonged

inpatient hospitalisation

**Medicine details:** 

Cymbalta (Suspected) Reason :

Capsule 60 Milligram 1 time Oral

Batch: Started: Stopped:

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Cases Count: 49

**Case Number: 246531** 

Gender: F

**Data Entry Date: 25/11/2008** 

Weight (kg): 0

**Hospitalisation:** 

Age:

Onset Date: 15/08/2008

**DOB**: 02/07/1975

Outcome:

Causality: Causality possible

Recovered

Information: DOCI report.

Reaction:

**Preferred Term** Severity **Report Description** 

**Treatment** 

Anorgasmia

Patient experienced anorgasmia, nausea and Cymbalta discontinued.

weight gain.

Nausea

Weight increased

Medicine details:

Cymbalta (Suspected) Reason: Depression

Capsule 30 Milligram Daily Oral

**Stopped**: 22/08/2008 Batch: A358906 exp 12/09 Started: 01/08/2008 0

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Cases Count: 49

**Case Number: 246533** 

Gender: F

Data Entry Date: 25/11/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: DOCI reporot.

Reaction:

Preferred Term

Severity

**Report Description** 

Treatment

Hyponatraemia

Patient experienced hyponatraemia and went

Duloxetine discontinued.

into delirium.

Delirium

Medicine details:

Cymbalta (Suspected)

Reason:

Capsule

60 Milligram

Oral

Batch :

Started:

Stopped:

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Cases Count: 49

Gender: F

**Case Number : 246648** 

**Data Entry Date**: 26/11/2008 **Weight (kg)**: 0

Hospitalisation: Age:

**Onset Date**: 26/11/2008 **DOB**: 14/04/1951

Outcome: 26/11/2008 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Swollen tongue Caused or prolonged She developed tongue hydrocortisone, phenergan,

inpatient swelling/enlargement, considered cogentin but hospitalisation tightness in the jaw and symptoms resolved

neck at about 0900.

Muscle tightness Caused or prolonged

inpatient hospitalisation

Medicine details :

Abilify (Suspected) Reason :

Tablet 2 Milligram 1 time Oral

Batch: Started: Stopped:

Cymbalta (Suspected) Reason :

Tablet 60 Milligram 1 time Oral

Batch: Started: Stopped: 0

PROCHLORPERAZINE MALEATE (Suspected) Reason :

Injection 12.5 Milligram 3 times Intravenous

**Batch**: **Started**: 25/11/2008 **Stopped**: 26/11/2008

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Weight (kg): 0

Cases Count: 49

**Case Number: 246690** 

**Data Entry Date: 28/11/2008** 

Gender: F

**Hospitalisation**: Required a visit to the doctor

Age: 60Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Not yet recovered

**Information:** May have a history of mental illness.

Reaction:

Preferred Term Severity Report Description Treatment

Hyperhidrosis Feeling as though half of Withdrawl of duloxetine

her head was numb and not under voluntary control, feeling of heaviness on the chest, excessive sweating, thought she was having a heart attack, feeling of wanting to harm others.

Chest discomfort

Paraesthesia

Violence-related symptom

Medicine details:

Cymbalta (Suspected) Reason : Depression

Tablet 60 Milligram Daily Oral

Batch: Started: Stopped:

CEPHALEXIN (Other drug) Reason :

500 Milligram Daily

Batch: Started: Stopped:

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Cases Count: 49

**Case Number: 246695** 

Gender: M

**Data Entry Date**: 28/11/2008

Weight (kg): 0

**Hospitalisation:** 

**Age:** 99u

Onset Date: 15/10/2008

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Sexual abuse

Preferred Term

Severity

**Report Description** 

**Treatment** 

Patient raped someone.

Medicine details:

Cymbalta (Suspected)

Reason: Depression

Batch:

Started: 23/07/2008

Stopped:

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Cases Count: 49

Gender: M

Age:

**Case Number: 246743** 

**Data Entry Date**: 02/12/2008 **Weight (kg)**: 90

Data Entry Date: 02/12/2008 weight (kg): 90

Onset Date: 16/10/2008 DOB: 15/09/1954

Outcome: 06/11/2008 Causality: Causality probable

Recovered

Hospitalisation: Required a visit to the doctor

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Tremor Tremors, skin prickling Phenergan, Panadol Osteo

amd stinging, sweating, headache, feeling cold, abdominal churning.

Abdominal discomfort

Feeling cold
Headache
Hyperhidrosis
Paraesthesia

Medicine details:

Cymbalta (Suspected) Reason : Depression

120 Milligram Daily

Batch: Started: 30/09/2008 Stopped:

TRAMAL (Suspected) Reason :

400 Milligram Daily

Batch: Started: Stopped:

ENDONE (Other drug) Reason :

15 Milligram Monthly

Batch: Started: Stopped:

GABAPENTIN (Other drug) Reason :

900 Milligram Daily Oral

Batch: Started: Stopped:

NEXIUM (Other drug) Reason :

80 Milligram Daily

Batch: Started: Stopped:

VALIUM (Other drug) Reason :

15 Milligram Monthly

Batch: Started: Stopped:

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**Hospitalisation:** 

## **Public Case Detail**

Cases Count: 49

**Case Number: 246745** 

Gender: F

**Data Entry Date**: 02/12/2008 **Weight (kg)**: 70

Age:

Onset Date: 27/10/2008 DOB: 11/04/1969

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Anger Anger

Medicine details:

Cymbalta (Suspected) Reason : Depression

60 Milligram Daily

**Batch**: **Started**: 10/10/2008 **Stopped**: 29/10/2008

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Cases Count: 49

Case Number: 246791 Gender: F

**Data Entry Date**: 03/12/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

v	Δ	2	r	tı	$\boldsymbol{\cap}$	n	•
	C	a	v	LI	v	n	-

Preferred Term Severity Report Description Treatment

Intentional self-injury After switching to

duloxetine the patient slit

her wrists.

Medicine details:

Cymbalta (Suspected) Reason :

Batch: Started: Stopped:

EFEXOR (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 49

Case Number: 246792 Gender: M

**Data Entry Date**: 03/12/2008 **Weight (kg)**: 0

Hospitalisation: Age: 38Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Serotonin syndrome Patient experienced Cymbalta ceased

serotonergic syndrome.

**Medicine details:** 

Cymbalta (Suspected) Reason :

Capsule 60 Milligram Daily Oral

Batch: Started: Stopped: 0

Benzodiazepine NOS (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 49

**Case Number: 246793** 

Gender: F

Data Entry Date: 03/12/2008

Outcome:

Weight (kg): 88

Hospitalisation: Required a visit to the doctor

**Age:** 27Y

Onset Date: 30/08/2008

DOB:

\_\_\_\_\_\_

Causality: Causality certain

Recovered

Information: Cert (Rechall)

Reaction:

Preferred Term Severity Report Description Treatment

Mouth ulceration Severe mouth ulcers. Cymbalta ceased

Medicine details:

Cymbalta (Suspected) Reason : Depression

**Batch**: **Started**: 26/08/2008 **Stopped**: 19/09/2008

LEVLEN ED (Other drug) Reason :

Batch: Started: Stopped:

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Reaction:

## **Public Case Detail**

Cases Count: 49

**Case Number : 246795** 

Gender: F

**Data Entry Date**: 03/12/2008 **Weight (kg)**: 102

Hospitalisation : Age :

**Onset Date: DOB:** 16/09/1965

Outcome : Causality : Causality possible

Not yet recovered

Information: Patient History: 2005 - Hypertension

Preferred Term	Severity	Report Descriptio		iption	Treatment	
Hypertension		Hypertension				
Medicine details :						
Cymbalta (Suspected)		Reason : Depression				
Capsule		120 Milligram	Daily		Oral	
Batch :	Started :			Stopped :		
Axit (Other drug)		Rea	son :			
		7.5 Milligram	Daily		Oral	
Batch :	Started :			Stopped :		
COVERSYL (Other drug) Reason :						
		5 Milligram	Daily		Oral	
Batch :	Started :			Stopped :		
DIANE-35 ED (Other drug) Reason :						
		1 Dose Unspec	Daily		Oral	
Batch :	Started :			Stopped :		
Nasalate (Other drug)		Rea	son :			
Cream			Daily		Transdermal	
Batch :	Started :			Stopped :		
OROXINE (Other drug)		Rea	son :			
					Oral	
Batch :	Started :			Stopped :		
PANADEINE FORTE (Other drug)		Rea	son :			
			As necessary	y	Oral	
Batch :	Started :			Stopped :		
PEPPERMINT OIL (Other drug) Reason :						
Batch :	Started :			Stopped :		
SIMETHICONE (Other drug)		Reason :				
		100 Milligram	Daily		Oral	
Batch :	Started :			Stopped :		

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Cases Count: 49

Gender: F

**Case Number: 246865** 

**Data Entry Date**: 08/12/2008 **Weight (kg)**: 82

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 08/10/2008 DOB: 18/09/1948

Outcome: Causality: Causality possible

Unknown

Information: DOCI report.

Reaction:

Dizziness

Preferred Term Severity Report Description Treatment

Nausea Caused or prolonged Patient took one dose of Cymbalta ceased.

inpatient Cymbalta and developed hospitalisation severe nausea, vomiting, bloody diarrhoea and was

extremly dizziy lasting for 3

weeks.

Diarrhoea haemorrhagic Caused or prolonged

inpatient hospitalisation

Caused or prolonged

inpatient hospitalisation

Vomiting Caused or prolonged

inpatient hospitalisation

Medicine details:

Cymbalta (Suspected) Reason : Depression

30 Milligram 1 time

**Batch**: **Started**: 08/10/2008 **Stopped**: 08/10/2008

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Cases Count: 49

**Case Number: 247679** 

Gender: M

Data Entry Date: 13/01/2009

Weight (kg): 0

**Hospitalisation:** Required a visit to the doctor

**Age:** 51Y

Onset Date: 19/12/2009

DOB:

Outcome :

Causality: Causality possible

Cymbalta ceased.

Recovered

Information: DOCI report.

Reaction:

Nausea

Preferred Term Severity

Report Description Treatment

Patient experienced nausea and vomiting and paralysis in legs. Spoke to Dr Douglas: paralysis not

accurate. Patient

complained of decreased

sensation in legs.

Hypoaesthesia

Therapeutic product ineffective for unapproved indication

Vomiting

**Medicine details:** 

Cymbalta (Suspected) Reason : Pain

Capsule 30 Milligram Daily Oral

**Batch**: **Started**: 19/12/2008 **Stopped**: 20/12/2008

AVAPRO (Other drug) Reason :

Tablet 150 Milligram Daily Oral

**Batch**: **Started**: 05/12/2007 **Stopped**: 0

Lyrica (Other drug) Reason :

Capsule 300 Milligram Oral

Batch: Started: 01/03/2007 Stopped:

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Cases Count: 49

Gender: M

**Case Number: 247698** 

**Data Entry Date**: 14/01/2009 **Weight (kg)**: 0

Hospitalisation: Weight (kg): C

**Onset Date**: 14/01/2009 **DOB**: 19/04/1952

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hyponatraemia -presented reduced/ceased cymbalta

inpatient with migraine which may hospitalisation be partly due to low

sodium detected (sodium

level 120)

Migraine Caused or prolonged

inpatient hospitalisation

Medicine details:

Cymbalta (Suspected) Reason :

Tablet 60 Milligram 1 time Oral

**Batch**: **Started**: 15/08/2008 **Stopped**: 0

LIPITOR (Other drug) Reason :

Tablet 40 Milligram 1 time Oral

Batch: Started: Stopped:

MERSYNDOL FORTE (Other drug) Reason :

Tablet As necessary Oral

Batch: Started: Stopped:

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Cases Count: 49

Case Number: 247760

Gender: F

**Data Entry Date:** 19/01/2009

Weight (kg): 0

Hospitalisation: Admitted to hospital

**Age:** 99U

**Onset Date:** 

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

**Preferred Term** 

Severity

**Report Description** 

**Treatment** 

Dystonia

Caused or prolonged

Patient experienced dystonia.

Duloxetine was discontinued

inpatient

hospitalisation

Medicine details:

Cymbalta (Suspected)

Reason:

60 Milligram

Batch:

Daily

Started: Stopped:

Selection Parameters: Date Range: 01/08/2007 To 31/01/2009 Unclear causality excluded GM medicines Only Medicine Names: Duloxetine hydrochloride, Cymbalta

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