

Cases Count: 172

Case Number: 231421

Gender: F

Data Entry Date: 01/08/2007

Weight (kg): 60

Hospitalisation: Admitted to hospital

Age:

Onset Date: 18/06/2007

DOB: 26/07/1949

Outcome: 19/06/2007

Caused or prolonged

Causality: Causality possible

Recovered

Information: History of diabetes, alcholic. Full improvement with fluids, glucose and recommencent

of medication.

Reaction:

Preferred Term

Drug withdrawal syndrome

Severity

inpatient

hospitalisation

Report Description Patient missed usual

venlafaxine 150mg

medication treatment for 4 days and developed nausea, vomiting and dizziness for 48 hours. Blood sugar level found to

be 1.6

Treatment

Ambulance called for drowsiness. Fluid and glucose

given.

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Capsule 150 Milligram

Daily Oral

Stopped: 14/06/2007 Batch: Started: L TERM 0

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Cases Count: 172

Case Number: 231460

Gender: F

Data Entry Date: 02/08/2007

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Drug withdrawal syndrome

Caused or prolonged inpatient

Pneumonia, drug withdrawal syndrome,

dysphagia, muscle

twitching, staring, infection,

nervousness. See attachment.

Dysphagia

Caused or prolonged

inpatient

hospitalisation

hospitalisation

Infection

Caused or prolonged

inpatient

hospitalisation

Muscle twitching

Caused or prolonged

inpatient

hospitalisation

Nervousness

Caused or prolonged

inpatient

hospitalisation

Pneumonia

Caused or prolonged

inpatient

hospitalisation

Staring

Caused or prolonged

inpatient

Started:

hospitalisation

Medicine details:

EFEXOR-XR (Suspected)

Reason:

Capsule Batch: 75 Milligram

Oral **Stopped**: 15/07/2007

0

PUTRAN02



Hospitalisation:

Public Case Detail

Cases Count: 172

Case Number: 231519

Gender: F

Data Entry Date: 05/08/2007 **Weight (kg)**: 63

Age:

Onset Date: 01/10/2002

DOB: 27/04/1978

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Drug dependence Incapacity/disability extreme difficulty coming

off Efexor

Abdominal pain Incapacity/disability

Constipation Incapacity/disability

Diarrhoea Incapacity/disability

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 75 Milligram Daily Oral

Batch: Started: 01/10/2002 Stopped:

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Cases Count: 172

Case Number: 231523

Gender: F

Data Entry Date: 06/08/2007

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

Treatment

Drug exposure during

had been taking Efexor for

cease Efexor

pregnancy
Abortion spontaneous

approximately 2.5 weeks

Report Description

the patient could not confirm whether the miscarriage occured after

stopping or during Efexor

treatment

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 75 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 172

Case Number : 231897

Gender: F

Data Entry Date: 13/08/2007

Weight (kg): 51

Hospitalisation: Admitted to hospital

Age: 80Y

Onset Date: 20/06/2007

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Mania Caused or prolonged

inpatient

Increased energy and activity, increased amount of speech, insomnia,

Stopped:

Stopped:

Venlafaxine ceased. Lithium commenced.

of speech, insomnia, irritability and disinhibition.

Disinhibition Caused or prolonged

inpatient

hospitalisation

hospitalisation

Energy increased Caused or prolonged

inpatient

hospitalisation

Insomnia Caused or prolonged

inpatient hospitalisation

Irritability Caused or prolonged

inpatient hospitalisation

Pressure of speech Caused or prolonged

inpatient hospitalisation

Psychomotor hyperactivity Caused or prolonged

inpatient

hospitalisation

Medicine details:

Batch:

Batch:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason : Depression

Started:

Started:

75 Milligram Daily

Batch: **Started**: 04/06/2007 **Stopped**: 04/07/2007 0

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

GLICLAZIDE (Other drug) Reason : Diabetes mellitus

METFORMIN HYDROCHLORIDE (Other drug) Reason : Diabetes mellitus

Batch: Stopped:

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Medicine details :	
PROPRANOLOL HYDROCHLORIDE (Other drug)	Reason: Essential benign hypertension

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 231946

Gender: M

Data Entry Date: 14/08/2007 Weight (kg): 0

Hospitalisation : Age :

Onset Date : DOB : 31/01/1986

Outcome : Causality : Causality possible

Not yet recovered

Information:

Reaction:					
Preferred Term	Severity	Report Description	Treatment		
Therapy regimen changed	Incapacity/disability	in Aug 07 dose increased to 225mg			
Abasia	Incapacity/disability	so weak that he could not walk			
Asthenia	Incapacity/disability				
Dizziness	Incapacity/disability				
Headache	Incapacity/disability				
Nausea	Incapacity/disability				
Vomiting	Incapacity/disability				

N/	\sim	10	no	40+0	
IV	160		111	detai	

EFEXOR-XR (Suspected) Reason : Depression

Capsule 225 Milligram Daily Oral

Batch: Started: Stopped:

TEMAZEPAM (Other drug) Reason :

Batch: Started: Stopped:

ZYPREXA (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 231986

Gender: F

Data Entry Date: 15/08/2007

Weight (kg): 117

Hospitalisation:

Age:

Onset Date: 10/07/2007

DOB: 04/11/1969

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

drug withdrawal symptoms

like severe nausea, sweating, dizziness,

insomnia

Medicine details:

Drug withdrawal syndrome

EFEXOR-XR (Suspected) Reason : Depression

Capsule 450 Milligram Daily Oral

Batch: **Started**: 08/01/2005 **Stopped**: 07/10/2007

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Cases Count: 172

Case Number: 232096

Gender: F

Data Entry Date: 16/08/2007 **Weight (kg)**: 67

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 18/07/2007 **DOB**: 20/06/1963

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Vision blurred Blurred vision.

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Tablet 37.5 Milligram Daily Oral

Batch: **Started**: 17/07/2007 **Stopped**: 21/07/2007

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Cases Count: 172

Case Number: 232114

Gender: F

Data Entry Date: 16/08/2007

Weight (kg): 0

Hospitalisation:

Age: 42Y

Onset Date: 25/06/2007

DOB:

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term

Report Description

Treatment Efexor ceased.

Muscle twitching

Patient experienced twitching and tingling in

arms and legs, serotonin

syndrome.

Hepatitis chronic active

Liver function test abnormal

Medicine details:

EFEXOR (Suspected)

Reason: Depression

150 Milligram

09/02/2007

Daily

512

126

Batch:

Started:

Severity

Stopped:

Laboratory Investigations:

Range Date Tested Result Details Type

GGT = SGGT = **GGTP**

GGT = SGGT =

3407 25/06/2007

GGTP

GGT = SGGT = 26/07/2007 1632

GGTP

AST = SGOT25/06/2007 465 AST = SGOT 26/07/2007 253

ALT = SGPT 25/06/2007 248

ALT = SGPT 26/07/2007 SAP = ALP25/06/2007 275

SAP = ALP26/07/2007 234

Bilirubin 25/06/2007 28 26/07/2007 Bilirubin 5

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Cases Count: 172

Case Number: 232153

Data Entry Date: 17/08/2007

Weight (kg): 83

Hospitalisation:

Age:

Gender: M

Onset Date: 20/01/2006

DOB: 26/03/1939

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Efexor-XR ceased.

Micturition disorder

Delayed start to urinate and very slow urination, dry mouth, emotional lability, nightmares, libido

decreased and erection

failure.

Affect lability

Dry mouth

Erectile dysfunction

Libido decreased

Nightmare

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Capsule

75 Milligram

150 Milligram

Daily

Oral

Batch:

Started: 10/01/2006

Stopped: 29/01/2006

ZYLOPRIM (Other drug)

Reason: Gout

Oral

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Tablet

Batch:

Started:

Daily

Stopped:

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Cases Count: 172

Case Number: 232167 Gender: F

Data Entry Date: 17/08/2007 Weight (kg): 0

Hospitalisation: Age:

Onset Date: DOB: 19/12/1956

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred Term Liver function test abnormal Malaise	Severity	F	Report Desc	cription	Treatment	
Maiaioo						
Medicine details :						
EFEXOR-XR (Suspected)		Re	eason : Depres	sion		
Capsule		300 Milligram	Daily		Oral	
Batch :	Started :			Stopped :		
DIAZEPAM (Other drug)		Re	eason :			
		5 Milligram				
Batch :	Started :			Stopped :		
GLUCOSAMINE HYDROCHLORIDE (Other drug)		Re	eason :			
		1 Gram				
Batch :	Started :			Stopped :		0
LOSEC (Other drug)		Re	eason :			
		40 Milligram				
Batch :	Started :			Stopped :		0
TEMAZEPAM (Other drug)		Re	eason :			
		10 Milligram				
Batch :	Started :			Stopped :		

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Hospitalisation:

Public Case Detail

Cases Count: 172

Case Number: 232170

Gender: F

Data Entry Date: 17/08/2007 **Weight (kg)**: 0

Age:

Onset Date: 15/05/2007 **DOB**: 30/08/1959

Outcome: 04/06/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Pruritus Patient experienced an itch all over her body, couldn't

function, had memory loss.

Amnesia

Medicine details:

EFEXOR (Suspected) Reason :

Tablet 150 Milligram Daily Oral

Batch: Started: 08/05/2007 Stopped:

KALMA (Suspected) Reason :

Tablet 0.5 Milligram Daily Oral

Batch: **Started**: 08/05/2007 **Stopped**: 02/06/2007

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Cases Count: 172

Gender: F

Age:

Case Number: 232330

Data Entry Date: 21/08/2007 **Weight (kg)**: 67

Hospitalisation :

Onset Date: 20/07/2007 **DOB**: 01/05/1960

Outcome : Causality : Causality probable

Recovered

Information:

Reaction:

Preferred TermSeverityReport DescriptionTreatmentGrand mal convulsionCaused or prolongedPatient experiencedCeased Efexor.

Grand mal convulsion Caused or prolonged Patient experienced inpatient probable tonic-clonic

hospitalisation seizure.

Medicine details:

EFEXOR (Suspected) Reason : Depression

Tablet 75 Milligram Daily Oral

Batch: **Started**: 10/06/2007 **Stopped**: 20/07/2007

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Cases Count: 172

Case Number: 232454

Gender: M

Data Entry Date: 24/08/2007 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Rash Caused or prolonged Gradual onset of rash on

inpatient both lower limbs over 4 hospitalisation days. Rash consistent with

leucocytoclastic vasculitis.

Leukocytoclastic vasculitis Caused or prolonged

inpatient

hospitalisation

Medicine details:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason : Depression

75 Milligram Daily

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 232466

Gender: F

Data Entry Date: 24/08/2007 **Weight (kg)**: 62

Hospitalisation: Age:

Onset Date : DOB : 27/03/1942

Outcome: 21/08/2007 Causality: Causality possible

Recovered

Information: Normal LFTs 3 weeks prior to starting Prexige.

Reaction:

Preferred Term Severity Report Description Treatment

Hepatic function abnormal markedly raised/abnormal

liver function tests

Medicine details:

EFEXOR-XR (Suspected) Reason:

75 Milligram Daily

Batch: **Stopped**: 14/08/2007

Prexige (Suspected) Reason : Osteoarthritis

Tablet 200 Milligram Daily Oral

Batch: **Started**: 15/09/2006 **Stopped**: 14/08/2007

ALDACTONE (Other drug) Reason :

100 Milligram

Batch: Started: Stopped:

PANADOL (Other drug) Reason :

500 Milligram

Batch: Started: Stopped:

QVAR AUTOHALER (Other drug) Reason :

Batch: Started: Stopped:

SOMAC (Other drug) Reason : Other diseases of esophagus

40 Milligram Daily

Batch: Started: Stopped: 14/08/2007

XANAX (Other drug) Reason : Anxiety neurosis

0.5 Milligram Daily

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 232515

Gender: F

Data Entry Date: 27/08/2007

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

pre-treatment: 110/70 and

since treatment 200/120

Medicine details:

Blood pressure increased

EFEXOR-XR (Suspected)

Reason: Depression

Capsule

300 Milligram

Daily

Oral

Batch:

Started: 01/06/2001

Stopped:

ongoing

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Cases Count: 172

Case Number : 232520

Gender: F

Data Entry Date: 27/08/2007 Weight (kg): 0

Hospitalisation : Age :

Onset Date: 24/07/2007 **DOB**: 26/08/1952

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Therapy regimen changed dose increased from 150mg to 187.5mg daily

Blood pressure increased

Headache

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 187 Milligram Daily Oral

Batch: Started: Stopped:

PARIET (Other drug) Reason :

Batch: Started: Stopped:

TEMAZEPAM (Other drug) Reason :

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Blood pressure 24/07/2007 L arm 185/95, R arm

200/100

Blood pressure 31/07/2007 R arm 140/75

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Cases Count: 172

Case Number: 232644

Data Entry Date: 28/08/2007 Weight (kg): 0

Hospitalisation: Age: 25Y

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information: The patient has been taking Efexor on and off for 4 years

Reaction	:
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Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Incapacity/disability	"barely functioning" since dropping the dose of Efexor from 150 mg to 75 mg	
Drug withdrawal syndrome	Incapacity/disability	after ceasing drug experienced drug withdrawal syndrome with uncontrolled crying, aggravated depression, had a "melt down"	
Drug exposure during pregnancy	Incapacity/disability	patient has reduced dose since discovering she was pregnant down to 75mg, she is now 10 weeks pregnant	
Drug withdrawal syndrome	Incapacity/disability	since reducing her dose of Efexor from 150mg to 75mg she has experienced worsening depression and is "barely functioning"	
Depression	Incapacity/disability	when dose reduced her depression worsened	

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 75 Milligram Daily Oral

Batch: Started: Stopped: ongoing

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Cases Count: 172

Gender: F

Weight (kg): 0

Case Number : 232662

Data Entry Date: 29/08/2007

Hospitalisation: Admitted to hospital **Age**:

Onset Date: 06/08/2007 DOB: 09/05/1924

Outcome : Causality : Causality possible

Not yet recovered

Information:

Reaction:			
Preferred Term	Severity	Report Description	Treatment
Parkinsonism	Caused or prolonged inpatient hospitalisation	EPSE - Parkinsonism features, cogwheel rigidity, tremor at rest, mask-like face and low mobility.	Cease risperidone and venlafaxine, just observation.
Cogwheel rigidity	Caused or prolonged inpatient hospitalisation		
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation		
Masked facies	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine details	s:		
RISPERIDONE (Suspected)	Reason:	
Batch :	Started :	Stopped :	
VENLAFAXINE HYDROCH	LORIDE (Suspected)	Reason :	
Batch :	Started :	Stopped :	
AMIODARONE HYDROCHI	ORIDE (Other drug)	Reason: Otr&nos disord of heart rhythm	
Batch :	Started :	Stopped :	
ASPIRIN (Other drug)		Reason: Chron isch heart dis no hyper	
Batch :	Started :	Stopped :	
FRUSEMIDE (Other drug)		Reason: Congestive heart failure	
Batch :	Started :	Stopped :	
GLYCERYL TRINITRATE (Other drug)	Reason: Chron isch heart dis no hyper	
Batch :	Started :	Stopped :	

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Medicine details :				
METOPROLOL TARTRATE (Other drug)		Reason: Chron isch heart dis no hyper		
Batch :	Started :	Stopped :		
OMEPRAZOLE (Other drug)		Reason: Other diseases of esophagus		
Batch :	Started :	Stopped :		
PERINDOPRIL (Other drug)		Reason : Chron isch heart dis no hyper		
Batch :	Started :	Stopped: 0		
SIMVASTATIN (Other drug)		Reason : Chron isch heart dis no hyper		
Batch :	Started :	Stopped :		
SLOW-K (Other drug)		Reason:		
Batch :	Started :	Stopped :		
TEMAZEPAM (Other drug)		Reason:		
Batch :	Started :	Stopped :		
THYROXINE SODIUM (Other drug) Reason : Myxedema				
Batch :	Started :	Stopped :		

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Cases Count: 172

Case Number: 232918

Gender: F

Data Entry Date: 03/09/2007 Weight (kg): 0
Hospitalisation: Age: 47Y

Onset Date: 20/07/2007 DOB:

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Convulsion A patient receiving Efexor experienced a seizure,

vomiting and loss of consciousness for 10

minutes

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

Capsule 75 Milligram Daily Oral

Batch: **Started**: 11/06/2007 **Stopped**: 20/07/2007 0

HYPNODORM (Other drug) Reason :

Batch: Started: Stopped: 0

MOGADON (Other drug) Reason :

Oral

Batch: Started: Stopped: 0

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Cases Count: 172

Case Number: 232974

Gender: F

Data Entry Date: 04/09/2007

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age:

Onset Date: 01/06/2006

DOB: 28/11/1966

Outcome: 02/03/2007

Causality: Causality possible

Recovered with sequelae

Information:

Reaction:

Preferred Term Severity **Treatment**

Drug exposure during pregnancy

Congenital anomaly / birth defect

Drug exposure during

Report Description

pregnancy. See

attachment. This patient is the mother and is related to case 232986 involving

the neonate.

Medicine details:

EFEXOR-XR (Suspected) Reason:

> 150 Milligram Daily

Batch: Started: 01/09/2004 Stopped:

Seretide 125/25 MDI (Suspected) Reason:

> Alternate days Inhalation

Batch: Started: 01/09/2002 Stopped:

FOLIC ACID (Other drug) Reason:

Oral

Oral

Started: 01/06/2006 Stopped: 31/03/2007 Batch:

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Cases Count: 172

Case Number: 232986

Gender: F

Data Entry Date: 04/09/2007 Weight (kg): 0

Hospitalisation: Admitted to hospital Age:

Onset Date: 09/07/2007 DOB: 02/03/2007

Outcome: 10/07/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hernia congenital Congenital anomaly / Congenital diaphragmatic surgical correction birth defect hernia. See attachment.

hernia. See attachment. Related to case 232974

involving the mother.

Medicine details:

Seretide 125/25 MDI (Suspected)

EFEXOR-XR (Suspected) Reason :

150 Milligram Daily Intrauterine

Batch: Started: Stopped:

Batch: Started: Stopped:

FOLIC ACID (Other drug) Reason :

Batch: Started: Stopped:

Reason:

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Cases Count: 172

Gender: F

Case Number: 232988

Data Entry Date: 04/09/2007 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 28/11/1966

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Abortion spontaneous

Drug exposure during

pregnancy

Ectopic pregnancy

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 150 Milligram Daily Oral

Batch: Started: LTERM Stopped: 0

Seretide MDI Nos (Other drug) Reason :

Inhalation

Batch: Started: Stopped:

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Cases Count: 172

Case Number : 233347

Gender: F

Data Entry Date: 13/09/2007

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 42Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Suicide attempt Caused or prolonged

inpatient hospitalisation twice within a month

Agitation Caused or prolonged

inpatient

hospitalisation

Mania Caused or prolonged

inpatient

hospitalisation

Pruritus Caused or prolonged

inpatient

hospitalisation

Restlessness Caused or prolonged

inpatient

hospitalisation

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Oral

Batch: Started: Stopped: 0

VALIUM (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 233349

Data Entry Date: 13/09/2007 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome : Causality : Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Therapy regimen changed 5 days after dose increase

from 37.5 to 75mg Efexor

XR

Atrial fibrillation

Rash pruritic

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 75 Milligram Daily Oral

Batch: Started: Stopped:

CARTIA (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 233757

Gender: M

Data Entry Date: 25/09/2007

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction: **Preferred Term**

pregnancy

Severity

Report Description

Treatment

Drug exposure during

Congenital anomaly / birth defect

Congenital "lung problems" and drug exposure during

Stopped:

pregnancy. See attachment.

Pulmonary malformation

Congenital anomaly /

birth defect

Medicine details:

EFEXOR-XR (Suspected)

Reason:

Batch:

Started:

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Cases Count: 172

Case Number: 233877 Gender: F

Data Entry Date: 28/09/2007 **Weight (kg)**: 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Cerebrovascular accident Stroke. See attachment.

Medicine details:

EFEXOR-XR (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 233916

Gender: M

Data Entry Date: 02/10/2007

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age:

Onset Date: 26/06/2007

DOB: 15/03/1957

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity

Report Description Treatment

Hallucination

Agitation

Caused or prolonged

Patient experienced hallucinations,

Ceased tramadol and

inpatient hospitalisation

hyperreflexia, tremors, agitation and sweating,

likely serotonin syndrome.

venlofaxine, started risperidone.

Caused or prolonged

inpatient

hospitalisation

Confusional state

Caused or prolonged

inpatient

hospitalisation

Hyperhidrosis

Caused or prolonged

inpatient

hospitalisation

Hyperreflexia

Caused or prolonged

inpatient

hospitalisation

Hypomania

Caused or prolonged

inpatient

hospitalisation

Serotonin syndrome

Caused or prolonged

inpatient

hospitalisation

Tremor

Caused or prolonged

inpatient

hospitalisation

Medicine details:

TRAMADOL HYDROCHLORIDE (Suspected)

VENLAFAXINE HYDROCHLORIDE (Suspected)

Reason:

Intravenous

Injection Batch:

Started: 25/06/2007

1 time

Stopped: 25/06/2007

TRAMAL (Suspected)

Reason: Pain Daily

200 Milligram

100 Milligram

Stopped: 26/06/2007

Batch:

Batch:

Started: 17/06/2007

Started :

Reason: Depression

150 Milligram

Daily

L TERM

Stopped: 26/06/2007

0

0

0

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Medicine details: ATENOLOL (Other drug) Reason: 0 L TERM Stopped: Started: Batch: **CLONIDINE HYDROCHLORIDE (Other drug)** Reason: Pain 0 Batch: Started: Stopped: **DILTIAZEM HYDROCHLORIDE (Other drug)** Reason: L TERM Stopped: 0 Batch: Started: **ENDONE** (Other drug) Reason: Pain Tablet 10 Milligram Oral Daily Started: 12/06/2007 **Stopped**: 20/06/2007 Batch: SPIRONOLACTONE (Other drug) Reason: Batch: Started: L TERM Stopped:

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Cases Count: 172

Case Number: 234221

Hospitalisation: Admitted to hospital **Age**: 33Y

Onset Date: 25/07/2007 DOB:

Outcome: 10/08/2007 Causality: Causality probable

Recovered

Information: Other drugs taken: Blackmore's Breast Feeding Tabs and Probiotic 8.

Reaction:

Preferred Term Severity Report Description Treatment

Bruxism Caused or prolonged Patient experienced Venlafaxine ceased.

inpatient

inpatient nocturnal teeth grinding hospitalisation (bruxism) also some teeth grinding during the day.

teeth grinding

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

Capsule 262.5 Milligram Total Oral

Batch: **Started**: 24/07/2007 **Stopped**: 06/08/2007

AMOXYCILLIN SODIUM (Other drug) Reason : Otr&nos infec¶sit diseases

Batch: Started: Stopped:

CIPRAMIL (Other drug) Reason : Depression

Batch: Started: Stopped:

DIFLUCAN (Other drug) Reason : Moniliasis

Batch: Started: Stopped: 0

PARACETAMOL (Other drug) Reason : Headache

Batch: Started: Stopped:

SEROQUEL (Other drug) Reason :

Batch: Started: Stopped:

TEMTABS (Other drug) Reason : Specific disorders of sleep

Batch: Started: Stopped:

XANAX (Other drug) Reason : Anxiety neurosis

Batch: Started: Stopped:

ZOPICLONE (Other drug) Reason : Specific disorders of sleep

Batch: Started: Stopped:

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Reaction:

Public Case Detail

Cases Count: 172

Case Number: 234228 Gender: F

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

Hospitalisation : Age :

Onset Date: DOB: 04/12/1985

Outcome : Causality : Causality possible

Unknown

Information: Patient was not cortisol deficient. History of spondyloarthropathy and narcolepsy.

Preferred Term	Severity	Report Description	Treatment
Hypoglycaemia		Patient developed postprandial hypoglycaemia.	
Medicine details :			
AZATHIOPRINE (Suspected)		Reason :	
Batch :	Started :	Stopped :	
DEXAMPHETAMINE SULPHATE (S	uspected)	Reason :	
Batch :	Started :	Stopped :	
Humira (Suspected)		Reason :	
Injection		1 Dose Unspec	
Batch :	Started :	Stopped :	0
VENLAFAXINE HYDROCHLORIDE	(Suspected)	Reason :	
Batch :	Started :	Stopped :	

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Cases Count: 172

Case Number: 234351

Gender: M

Data Entry Date: 15/10/2007

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Agitation

Caused or prolonged

inpatient hospitalisation

at

Agitation and confusion after taking himself off Efexor XR "recently".

Confusional state

Caused or prolonged

inpatient

hospitalisation

Drug withdrawal syndrome

Caused or prolonged

inpatient

hospitalisation

Medicine details:

EFEXOR-XR (Suspected)

Reason:

300 Milligram

Batch :

Started:

Stopped:

0

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Cases Count: 172

Case Number: 234466 Gender: F

Data Entry Date: 17/10/2007 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date : DOB : 10/07/1967

Outcome : Causality : Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Blood pressure increased

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

Milligram Daily Oral

Batch: Started: Stopped:

DUCENE (Other drug) Reason :

Batch: Started: Stopped:

ORAL CONTRACEPTIVE NOS (Other drug) Reason :

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Blood pressure 130/90 to 206/130

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Cases Count: 172

Case Number: 234569

Gender: M

Data Entry Date: 18/10/2007

Weight (kg): 3.2

Hospitalisation:

Age:

Onset Date: 25/09/2007

DOB: 25/09/2007

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Convulsion neonatal

Caused or prolonged inpatient

? seizure activity at 4.5 hours of age associated with back arching, cycling

and jitteriness.

Drug exposure during

Caused or prolonged

hospitalisation

inpatient

hospitalisation

Feeling jittery

pregnancy

Caused or prolonged

inpatient

hospitalisation

Opisthotonus

Caused or prolonged

inpatient

hospitalisation

Infant retrieved to Flinders Medical Centre Level Three NICU. 1 x dose of Intravenous

Intravenous fluids commenced.

Phenobarb given.

Medicine details:

EFEXOR (Suspected)

Reason:

1 time

1 time

Oral

Batch:

Tablet

Tablet

Started: 01/01/2004

Stopped:

OLANZAPINE (Suspected)

Reason:

Oral

Batch:

Started: 01/01/2004

Stopped:

Laboratory Investigations:

Type Albumin Range

Date Tested Result

Details

MRI Of head performed 28/9/07, Study

within normal limits.

EEG performed. This is a normal EEG with the child in the sleeping state.

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Cases Count: 172

Case Number: 234856

Gender: F

Data Entry Date: 29/10/2007 Weight (kg): 0

Hospitalisation: Age: 50Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Myodesopsia

Vitreous detachment

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 150 Milligram Daily Oral

Batch: Started: Stopped: 0

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Cases Count: 172

Case Number: 235174

Gender: M

Data Entry Date: 12/11/2007

Weight (kg): 0

Hospitalisation:

Age: 56Y

Onset Date: 30/10/2007

DOB:

Outcome:

Causality: Causality probable

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Blood pressure increased

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

Capsule 75 Milligram Daily Oral

Batch: **Started**: 30/10/2007 **Stopped**: 31/10/2007

LIPEX (Other drug) Reason :

Oral

Batch: Started: Stopped:

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Cases Count: 172

Case Number : 235196

Gender: M

Data Entry Date: 12/11/2007

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date: 30/10/2007

DOB:

Causality: Causality possible

Outcome:

Unknown

Ulikilowi

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Chills

Dizziness

Eye pain

Fatigue

Hyperhidrosis

Nausea

Palpitations

Presyncope

Tremor

Medicine details:

EFEXOR-XR (Suspected) Reason:

Oral

Batch: Started: 29/10/2007 Stopped:

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Cases Count: 172

Gender: F

Case Number: 235206

Data Entry Date: 13/11/2007 Weight (kg): 51.5

Hospitalisation: Admitted to hospital Age:

Onset Date:

DOB: 11/01/1967

Outcome: 15/09/2007 Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Hypotension Life threatening Recurrent hypotension

secondary to GE fluid loss. Near total colectomy. Exacerbated by hypotension and bradycardia. Most likely due to combination of

Sporanox and Efexor.

Bradycardia Life threatening

Medicine details:

EFEXOR (Suspected) Reason: Depression

> 75 Milligram Daily Oral

Started: L TERM **Stopped**: 15/09/2007 Batch:

SPORANOX (Suspected) Reason: Moniliasis

100 Milligram Capsule Daily Oral

Batch: Started: L TERM Stopped: 15/09/2007 0

BUSCOPAN (Other drug) Reason:

Batch: Started: Stopped:

CODEINE PHOSPHATE (Other drug) Reason:

Batch: Started: Stopped:

LOMOTIL (Other drug) Reason:

Batch: Started: Stopped:

PREMARIN (Other drug) Reason:

Started: Stopped: 0 Batch:

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Cases Count: 172

Case Number: 235329 Gender: M

Data Entry Date: 15/11/2007 **Weight (kg)**: 0

Hospitalisation: Age: 44Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Narcolepsy	Severe	11 motorcycle accidents, nearly lost his toe, on numerous occasions has fallen asleep and left things cooking on the stove, he is always falling over and slurs, wets the bed in his sleep, he can fall asleep in mid sentence.	
Abnormal behaviour	Severe		
Dysarthria	Severe		
Enuresis	Severe		
Fall	Severe		
Somnolence	Severe		

Medicine details	:						
ALCOHOL (Suspected)		Reason:					
Batch :	Started :		Stopped :				
EFEXOR (Suspected)		Reason :					
Batch :	Started :		Stopped :	0			
STILNOX (Suspected)		Reason :					
	;	30 Milligram Daily					
Batch :	Started :	L TERM	Stopped :				
XANAX (Suspected)		Reason :					
Batch :	Started :		Stopped :				

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Cases Count: 172

Case Number: 235439

Gender: M

Data Entry Date: 20/11/2007

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome : Causalit

Causality: Causality possible

Treatment

Unknown

Information:

Reaction:

Preferred Term Severity Report Description

Weight decreased

approximately 40 kg lost over a 12 month period

Drug withdrawal syndrome

vivid dreams when ceasing

use

Anorexia

Suicidal ideation

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Milligram

Daily

Batch: Started:

Stopped:

Oral

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Patient experienced an

Cases Count: 172

Ceased venlafaxine and started

on Ziprazidone.

Case Number: 235493

Gender: F

Data Entry Date: 21/11/2007 Weight (kg): 70

Hospitalisation: Age: 47Y

Onset Date: DOB:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Electrocardiogram QT Caused or prolonged

prolonged inpatient

hospitalisation

increased QT interval, was anxious, tense, somewhat flat.

Caused or prolonged Anxiety

inpatient hospitalisation

Medicine details:

RISPERIDONE (Suspected) Reason:

> 6 Milligram Daily

Batch: Started: 06/09/2007 Stopped:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason:

> 375 Milligram Daily

Batch: Started: Stopped:

METFORMIN HYDROCHLORIDE (Other drug) Reason:

> 500 Milligram Daily

Stopped: Batch: Started:

SIMVASTATIN (Other drug) Reason:

40 Milligram

Stopped: Batch: Started:

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Hospitalisation:

Public Case Detail

Cases Count: 172

Case Number: 235569

Gender: M

Data Entry Date: 22/11/2007 **Weight (kg)**: 78

Age:

Onset Date: 18/11/2007 **DOB**: 11/09/1951

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Suicidal ideation Life threatening severe suicidal ideation,

not previously identified prior to commencement. Reaction ceased after ceasing medication.

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 75 Milligram Daily Oral

Batch: **Started**: 18/10/2007 **Stopped**: 18/11/2007

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Cases Count: 172

Case Number: 235589

Gender: U

Data Entry Date: 23/11/2007 **Weight (kg)**: 70

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 14/11/2007 **DOB**: 03/05/1973

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Convulsion Convulsions after taking

Efexor.

Medicine details:

EFEXOR (Suspected) Reason : Depression

75 Milligram Daily Oral

Batch: **Started**: 13/11/2007 **Stopped**: 15/11/2007

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Cases Count: 172

Case Number: 235658

Gender: F

Data Entry Date: 26/11/2007

Weight (kg): 0

Hospitalisation:

٨٥

Onset Date: 18/10/2007

Age: 46Y

Outcome:

DOB:

Causality: Causality possible

Not yet recovered

Information: Patient was gradually improving after ceasing Efexor

Reaction:

Preferred Term Severity

Report Description

Treatment

Migraine

Caused or prolonged

cluster migraines

inpatient hospitalisation

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Daily

Capsule

75 Milligram

Oral

Batch :

Started: 10/09/2007

Stopped: 27/10/2007

10/2007

PERINDOPRIL (Other drug)

Reason:

Batch:

Started:

Stopped:

Laboratory Investigations:

Type

Range

Date Tested Result

Details

Other data

CT and lumbar puncture results normal

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Cases Count: 172

Case Number: 235799

Gender: M

Data Entry Date: 30/11/2007

Weight (kg): 85

Hospitalisation:

Age: 37Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Yawning

Excessive yawning . 6 hours after taking Efexor.

Reduction in libido.

Libido decreased

Medicine details:

EFEXOR (Suspected)

Reason:

150 Milligram

Daily

Oral

Batch:

Capsule

Started:

Stopped:

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Cases Count: 172

Case Number: 235807

Gender: F

Data Entry Date: 03/12/2007

Weight (kg): 0

Hospitalisation:

Age: 51Y

Onset Date: 29/03/2007

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Dizziness

Dry mouth

Hypertension

Tachycardia

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Oral

Batch:

Started: 28/03/2007

Stopped: 29/03/2007

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Cases Count: 172

Case Number: 235827

Gender: F

Data Entry Date: 03/12/2007 **Weight (kg)**: 62

Age:

Hospitalisation :
Onset Date :

DOB: 26/06/1970

Outcome : Causality : Causality possible

Not yet recovered

Information: 235827 is a seq of 235217.

Reaction:

Preferred Term Severity Report Description Treatment

Weight increased Weight Gain

Medicine details:

EFEXOR (Suspected) Reason : Depression

Batch: **Started**: 06/12/2006 **Stopped**: 0

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Cases Count: 172

Case Number: 235873

Gender: F

Data Entry Date: 04/12/2007

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dehydration Caused or prolonged

inpatient

hospitalisation

Diarrhoea Caused or prolonged

inpatient hospitalisation

Nausea Caused or prolonged

inpatient hospitalisation

Vomiting Caused or prolonged

inpatient .

hospitalisation

Medicine details:

EFEXOR-XR (Suspected) Reason :

75 Milligram Daily Oral

Batch: Started: 16/11/2007 Stopped:

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Cases Count: 172

Case Number: 235995

Gender: F

Data Entry Date: 06/12/2007

Weight (kg): 0

Hospitalisation:

Age: 67Y

Onset Date: 25/10/2007

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Palpitations

Patient developed sleep disturbances, dizy, lightheaded, itchy skin, joint pain, palpitations, leg

cramps, lack of alertness

and memory loss.

Arthralgia

Disturbance in attention

Dizziness

Memory impairment

Muscle spasms

Pruritus

Medicine details:

EFEXOR (Suspected)

Reason:

150 Milligram

Daily

Oral

Capsule Batch:

Started:

Stopped:

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Cases Count: 172

Case Number: 236057

Gender: F

Data Entry Date: 07/12/2007

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 15/09/2007

Information:

DOB: 13/08/1984

Outcome:

Causality: Causality possible

Recovered

INCOOVER

Reaction:

Preferred Term

Report Description

Treatment

Abortion spontaneous

The patient was applying

Zorac cream for

approximately 12 days.

Medicine details:

EFEXOR (Suspected)

Reason: Depression

Batch:

Started:

Severity

Stopped :

Zorac (Suspected)

Reason: Other acne of sebaceous glands

Cream

1 Dose Unspec Daily

Topical

Batch :

Started: 15/07/2007

Stopped: 15/08/2007

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Cases Count: 172

Case Number : 236196

Gender: F

Data Entry Date: 12/12/2007 **Weight (kg)**: 0

Hospitalisation: Age: 48Y
Onset Date: 24/10/2007 DOB:

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Menorrhagia

Preferred Term Severity Report Description Treatment

Patient has found her periods have recently gone from every 28/7 to every 31/7 in past 2 months.

Adverse event: Started Efexor and 3 days later had a heavy period (with clotting and flooding) that lasted for 10 days. When she increased the dose of Efexor to one capsule, 2 days later the heavy bleeding recurred and was just fading by date of call (23/11/07). She went to her GP, who told her she?d probably need a D&C immediately. Ultrasound of her uterus showed proliferative changes, but no fibroids, polyps or tumours. He referred her to her gynaecologist.

Follow-up: Mrs L attended her gynaecologist on 26/11/07 who apparently was not interested in linking venlafaxine with the bleeding issue. She said he attributed her symptoms solely to perimenopause. The last bleed indeed may have been a period, as she had lost count of when they were due. She said she forgot to tell the gynae she takes fish oil.

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

1 Dose Unspec Daily

Batch: Started: 22/10/2007 Stopped:

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Cases Count: 172

Case Number: 236334

Gender: F

Data Entry Date: 17/12/2007

Weight (kg): 0

Hospitalisation:

Age: 27Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

Report DescriptionHer doctor advised to stop

Treatment

Drug withdrawal syndrome

Efexor for 3 days and then start Zoloft. The patient stopped taking Efexor on 11-Dec-2007, and on 13-Dec-2007 started experiencing suicidal thoughts, electric shock feeling all over the body, lack of concentration, crying, feeling angry. It has been advised to contact her doctor immediately. The patient has not recovered yet and the product has been permanently withdrawn.

Obsessive-compulsive disorder

However the patient reported that for the last 2 months Efexor has not been helping her, and experiencing also an obsessive behaviour.

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Reaction:

Preferred Term

Drug effect decreased

Severity

Report Description

Treatment

The patient has been on Efexor for 2 years, the initial dose was 150mg/day, but about 11 months ago was reduced to 75mg/day due to pregnancy. The patient took Efexor during the pregnancy and delivered a normal new born, who is now 2-month-old. After the delivery the patient went back to 150mg/day. However the patient reported that for the last 2 months Efexor has not been helping her, and experiencing also an obsessive behaviour. Her doctor advised to stop Efexor for 3 days and then start Zoloft. The patient stopped taking Efexor on 11-Dec-2007, and on 13-Dec-2007 started experiencing suicidal thoughts, electric shock feeling all over the body, lack of concentration, crying, feeling angry. It has been advised to contact her doctor immediately. The patient has not recovered yet and the product has been

permanently withdrawn.

Drug exposure during pregnancy

Medicine details:	Medicine d	etails:
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EFEXOR-XR (Suspected)

Reason:

150 Milligram

Oral

0

Batch :

Started:

Stopped :

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Cases Count: 172

Gender: F

Case Number : 236357

Data Entry Date: 17/12/2007 **Weight (kg)**: 55

Hospitalisation: Age:

Onset Date: 02/11/2007 **DOB**: 29/04/1967

Outcome: Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dystonia Caused or prolonged Severe dystonic reaction -

inpatient 4 weeks after starting hospitalisation Efexor-XR. Swallowing, speech, breathing

difficulties.

Dysarthria Caused or prolonged

inpatient hospitalisation

Dysphagia Caused or prolonged

yspnagia Caused or prolonged inpatient

hospitalisation

Dyspnoea Caused or prolonged

inpatient hospitalisation

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 150 Milligram Daily Oral

Batch: **Started**: 01/10/2007 **Stopped**: 02/11/2007

CAMPRAL (Other drug) Reason :

Batch: Started: Stopped:

MULTI-B (Other drug) Reason :

Batch: Started: Stopped:

NATRILIX (Other drug) Reason :

Batch: Started: Stopped:

SERETIDE ACCUHALER NOS (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 236411

Gender: F

Data Entry Date: 19/12/2007

Weight (kg): 0

Hospitalisation:

Age: 32Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Abnormal labour

Preferred Term Severity **Report Description**

Treatment

The patient had been taking Efexor XR during her pregnancy and was expected to deliver the

baby in a

short time (drug exposure

during pregnancy).

Reporter's follow-up report indicated that the pregnanc ended on 24-Nov-2007 and the male baby was born prematurely at 38 weeks of gestation. The

birth weight

of the baby was 4.2 Kg. No complications with respect to baby. Delivered by Cesarean Section due to failure of progress (abnormal labour) on 24-Nov-2007. Some blood loss during Cesarean Section (1.5

litres) due to uterine tear (uterine injury) on

24-Nov-2007. There were

no problems with

child delivered by

caesarian because labour was not progressing, mother experienced uterine tear during delivery

Drug exposure during

EFEXOR-XR (Suspected)

pregnancy

Uterine injury

Medicine details:

Reason: Depression

150 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 236533

Gender: U

Data Entry Date: 27/12/2007

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Colectomy

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

487 Milligram

Daily

Oral

Batch:

Started:

Stopped:

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Cases Count: 172

Gender: F

Case Number : 236570

Data Entry Date: 31/12/2007 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date: **DOB**: 12/06/1949

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Drug ineffective the patient was receiving efexor and cipramil

concomitently, when cipramil was withdrawn and efexor dose was increased she experienced depression, anxiety, suicidal ideation and crying. She felt as thought the efexor was not treating

her depression

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

150 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 236672

Gender: F

Data Entry Date: 07/01/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date: 28/12/2007 DOB:

Causality: Causality possible Outcome:

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Caused or prolonged **Pancreatitis** Patient who had

commenced taking Efexor inpatient hospitalisation XR approximately 6 weeks

prior, developed

pancreatitis

Medicine details:

EFEXOR-XR (Suspected) Reason:

Oral

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 236765

Gender: F

Data Entry Date: 08/01/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

1100pitalioation .

DOB:

Outcome:

Onset Date:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Self esteem decreased

Suicidal feelings, feeling worthless and helpless, fuzzy in the head in the first 2 weeks of Efexor XR

treament. Also

experienced becoming more nervous and anxious. Recovered in Dec 2007.

Anxiety

Feeling abnormal

Nervousness

Suicidal ideation

Medicine details:

EFEXOR-XR (Suspected)

Reason:

37.5 Milligram

Daily

Oral

Batch :

Started :

Stopped:

0

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Cases Count: 172

Case Number: 236871 Gender: M

Data Entry Date: 10/01/2008 Weight (kg): 0

Hospitalisation: Age:

Onset Date: 23/11/2007 **DOB**: 04/02/1961

Outcome: Causality: Causality possible

Recovered

Information:

VENLAFAXINE HYDROCHLORIDE (Suspected)

ASCORBIC ACID (Other drug)

Reaction:

Preferred Term Severity **Report Description Treatment**

Hyponatraemia Hyponatraemia Venlafaxine decreased o

37.5mg for 3 days then ceased. Slat tabs commenced.

Frusemide ceased. started on salt tabs 1 tds and sodium

bicarbonate 840 tds. Medicine details: FRUSEMIDE (Suspected) Reason: 20 Milligram Daily Batch: Started: Stopped: 21/11/2007 SPIRONOLACTONE (Suspected) Reason: Oral

Reason:

Reason:

Tablet 25 Milligram Daily

Batch: Started: Stopped: 24/11/0207

75 Milligram Daily

Batch: Started: Stopped: 23/11/2007

Batch: Started: Stopped:

CIPROFLOXACIN (Other drug) Reason:

Stopped: Batch: Started:

CLINDAMYCIN HYDROCHLORIDE (Other drug) Reason:

Started: Batch: Stopped:

ENOXAPARIN (Other drug) Reason:

Batch: Started: Stopped:

OXYCONTIN (Other drug) Reason:

Batch: Started: Stopped:

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PANTOPRAZOLE (Other drug)

Reason:

Batch:

Started :

Stopped:

Laboratory Investigations :								
Туре	Range	Date Tested	Result	Details				
Sodium	(137-1)	15/11/2007	129					
Sodium	(137-1)	16/11/2007	129					
Sodium	(137-1)	19/11/2007	126					
Sodium	(137-1)	21/11/2007	126					
Sodium	(137-1)	23/11/2007	126					
Sodium	(137-1)	24/11/2007	125					
Sodium	(137-1)	24/11/2007	125					
Sodium	(137-1)	25/11/2007	126					
Sodium	(137-1)	26/11/2007	130					
Sodium	(137-1)	27/11/2007	134					

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Cases Count: 172

Case Number : 236875

Gender: F

Data Entry Date: 10/01/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: The patient had previously used Zoloft before and experienced similar adverse effects.

Reaction:

Preferred Term Severity Report Description Treatment

Burning sensation Incapacity/disability Face and head burned,

stomach pain, diarrhoea, anxiety increased, cold sweats, pulse increased, dizziness, tremors. Patient "was in bed for 2 days".

Abdominal pain upper Incapacity/disability

Anxiety Incapacity/disability

Cold sweat Incapacity/disability

Diarrhoea Incapacity/disability
Dizziness Incapacity/disability

Heart rate increased Incapacity/disability

Tremor Incapacity/disability

Medicine details:

EFEXOR-XR (Suspected) Reason:

75 Milligram Total Oral

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 236900

Gender: M

Data Entry Date: 11/01/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

Report Description Treatment

Neuroleptic malignant

Caused or prolonged inpatient

Hyperthermia, muscle rigidity, CK rise. Suspected

hospitalisation

neuroleptic malignant syndrome. See

attachment.

Blood creatine phosphokinase

increased

syndrome

Caused or prolonged

inpatient

hospitalisation

Hyperthermia Caused or prolonged

inpatient hospitalisation

Muscle rigidity Caused or prolonged

inpatient hospitalisation

Medicine details:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 236932	Gender: F

Data Entry Date: 14/01/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

R	e	a	C	ti	0	n	:

Preferred Term Severity Report Description Treatment

Burning sensation Patient experienced an intense burning sensation in head and profuse

sweating, twitching of the right hand and a numb

nose.

Hyperhidrosis Hypoaesthesia Muscle twitching

Medicine details:

EFEXOR-XR (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 237055

Gender: F

Data Entry Date: 17/01/2008

Weight (kg): 0

Hospitalisation:

Age: 20Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Report Description

Treatment

Abortion spontaneous

drug exposure had been 8 weeks and patient had

been pregnant for 8 weeks

Drug exposure during

pregnancy

Medicine details:

EFEXOR-XR (Suspected)

Reason:

75 Milligram

Daily

Oral

Batch:

Started:

Severity

Stopped:

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Cases Count: 172

Case Number : 237056	Gender: F
	Gender.

Data Entry Date: 17/01/2008 Weight (kg): 0

Hospitalisation: Age: 66Y

Onset Date: 08/01/2008 **DOB**:

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Chest discomfort Dyspnoea	Severity	Report Description		ription	Treatment	
Madiaina dataila .						
Medicine details :						
EFEXOR-XR (Suspected)		Rea	ison :			
		75 Milligram	Daily		Oral	
Batch :	Started :			Stopped :		0
AVAPRO (Other drug)		Rea	ison :			
Batch :	Started :			Stopped :		
CELEBREX (Other drug)		Rea	ison :			
Batch :	Started :			Stopped :		
NORVASC (Other drug)		Rea	ison :			
Batch :	Started :			Stopped :		
VITAMIN NOS (Other drug)		Rea	ison :			
Batch :	Started :			Stopped :		

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Cases Count: 172

Case Number: 237110

Gender: M

Data Entry Date: 21/01/2008 Weight (kg): 0

Age: 69Y **Hospitalisation:**

Onset Date: DOB:

Outcome: Causality: Causality possible

Not yet recovered

Information: patient is overweight and has a history of familial hypercholesterolaemia

Reaction:

Preferred Term Severity **Report Description Treatment**

Blood cholesterol increased Caused or prolonged

inpatient

hospitalisation

Patient receiving Efexor XR for approximately 12 years experiencd

triglycerides increased and cholesterol increased,

pancreatitis.

Blood triglycerides increased Caused or prolonged

inpatient

hospitalisation

Caused or prolonged **Pancreatitis**

inpatient

hospitalisation

Medicine details:

CARBAMAZEPINE (Suspected) Reason:

400 Milligram

Started: Stopped: Batch:

EFEXOR-XR (Suspected) Reason:

> 450 Milligram Oral Daily

Started: Stopped: Batch:

ZYPREXA (Suspected) Reason:

> 5 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result **Details Biochemistry** 3.9-5.5 mmol/L 04/01/2008 29.7 cholesterol **Biochemistry** 3.9-5.5 mmol/L 06/01/2008 31.9 cholesterol **Biochemistry** 0.5-1.5 mmol/L 04/01/2008 107 **Triglycerides** 0.5-1.5 mmol/L 06/01/2008 **Biochemistry** 86.2 **Triglycerides**

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Cases Count: 172

Case Number: 237245

Gender: M

Data Entry Date: 23/01/2008

Weight (kg): 0

Hospitalisation:

Age: 37Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Hyperhidrosis

Preferred Term

Severity

150 Milligram

Report Description Treatment

Patient had severe, intolerable sweating on all Dosage reduced

doses of Efexor.

Medicine details:

EFEXOR-XR (Suspected)

Reason:

Daily

Oral

Batch:

Capsule

Started: 15/05/2007

Stopped:

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Cases Count: 172

Case Number: 237541

Gender: M

Data Entry Date: 04/02/2008 **Weight (kg)**: 0

Hospitalisation: Age: 73Y
Onset Date: DOB:

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Urinary hesitation after taking Efexor for 2-3 weeks the patient

experienced suicidal thoughts, urinary hesitancy and rising BGL. After dose was increased to 150mg daily the suicidal ideation resolved but other symptoms are ongoing

Blood glucose increased occasional increase to 8-9

mmolL

Suicidal ideation

Medicine details:

EFEXOR-XR (Suspected) Reason:

75 Milligram Daily Oral

Batch: Started: Stopped: ongoing

LIPITOR (Other drug) Reason :

80 Milligram

Batch: Started: Stopped: 0

TEMAZE (Other drug) Reason :

20 Milligram

Batch: Started: Stopped:

ZESTRIL (Other drug) Reason :

20 Milligram

Batch: Started: Stopped:

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Cases Count: 172

Gender: F

Case Number : 237863

Data Entry Date: 13/02/2008 **Weight (kg)**: 39

Hospitalisation: Age: 99u

Onset Date: 10/01/2008 DOB:

Outcome: 30/01/2008 Causality: Causality possible

Recovered

Information: poor temporal relationship

Reaction:

Feeling abnormal

Preferred Term Severity Report Description Treatment

"Completely drugged", eyesight went blurred, confusion, "jaw constantly clamped shut", "muscle seizures/muscle cramps right through my body", weight loss of about 10 kg,

"shaking

uncontrollably/shaking all though", nausea for 3 days, "without any sleep at all", profuse sweating, constant diarrhoea/"can no longer eat without the food going straight through".

Cogwheel rigidity

Confusional state

Diarrhoea

Hyperhidrosis

Insomnia

Muscle twitching

Nausea

Tremor

Trismus

Vision blurred

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

37.5 Milligram Total Oral

Batch: **Started**: 09/01/2008 **Stopped**: 10/01/2008 0

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Cases Count: 172

Case Number: 237864

Gender: M

Data Entry Date: 13/02/2008 Weight (kg): 0

Hospitalisation: Age: 99u

DOB: **Onset Date:**

Causality: Causality possible Outcome:

Not yet recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Drug withdrawal syndrome Efexor XR dosage was

reduced and the patient experienced withdrawal symptoms such as suicidal ideation and extreme

dizziness.

Therapeutic response Patient experienced a

decreased subtherapeutic effect on

450 mg daily Efexor XR. Efexor XR dosage was reduced and the patient experienced withdrawal symptoms such as suicidal ideation and extreme

dizziness. See attachmen

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

> 450 Milligram Daily Oral

Batch: Started: Stopped: 0

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Cases Count: 172

Case Number: 237930

Data Entry Date: 15/02/2008 Weight (kg): 0

Hospitalisation : Age :

Onset Date: 14/10/2007 **DOB**: 02/08/1923

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hyponatraemia Nausea, vomiting,

hyponatreamia, SIADH.

Medication withheld.

Inappropriate antidiuretic hormone secretion

Medicine details: **VENLAFAXINE HYDROCHLORIDE (Suspected)** Reason: 75 Milligram Daily Batch: Started: 10/07/2007 Stopped: 14/10/2007 **ASPIRIN** (Other drug) Reason: 100 Milligram Oral Batch: Started: Stopped: ATENOLOL (Other drug) Reason: 50 Milligram Oral Batch: Started: Stopped: **ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)** Reason: 20 Milligram Batch: Started: Stopped: FELODIPINE (Other drug) Reason: 5 Milligram Started: Stopped: Batch: Fosamax Plus Once Weekly (Other drug) Reason: Started: Stopped: Batch: **OXAZEPAM (Other drug)** Reason: Batch: Started: Stopped: Rosuvastatin (Other drug) Reason: 10 Milligram Started: Stopped: Batch: **TELMISARTAN** (Other drug) Reason: Batch: Started: Stopped:

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Medicine details:

VENTOLIN ROTACAPS (Other drug)

Reason:

Batch :

Started :

Stopped:

Details

Laboratory Investigations:

Type Range

Date Tested Result

Sodium

13/10/2007 118

Serum osmolality

13/10/2007

264

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Cases Count: 172

Case Number: 238259

Gender: F

Data Entry Date: 25/02/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 14/02/2008

DOB: 01/11/1933

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Hallucination

Dizziness

Caused or prolonged

Hallucinations, dizziness, nausea, tinnitus, blurred vision, hyponatraemia.

Both medicines suspected of contributing were ceased. IV fluids and electrolytes were

inpatient hospitalisation

given.

Caused or prolonged

inpatient

hospitalisation

Hyponatraemia

Caused or prolonged

inpatient

hospitalisation

Nausea

Caused or prolonged

inpatient

hospitalisation

Tinnitus

Caused or prolonged

inpatient

hospitalisation

Vision blurred

Caused or prolonged

inpatient

hospitalisation

Medicine details:

ATACAND PLUS 16/12.5 (Suspected)

Reason:

1 Dose Unspec Daily

Oral

Batch:

Started:

Stopped:

VENLAFAXINE HYDROCHLORIDE (Suspected)

Reason:

Daily

Oral

Started: 14/02/2008

Stopped: 15/02/2008

Batch:

0

Laboratory Investigations:

Type

Range

Date Tested Result

75 Milligram

Details

Sodium

Upon admission sodium level was 121 mmol/L,

Chloride

chloride was 80 mmol/L,

Potassium

potassium was 3.3 mmol/L

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Cases Count: 172

Case Number: 238260 Gender: F

Data Entry Date: 25/02/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome : Causality : Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Convulsion Convulsions

Medicine details:

EFEXOR-XR (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 238274

Gender: F

Data Entry Date: 25/02/2008 **Weight (kg)**: 0

Hospitalisation: Required a visit to the doctor **Age**: 50Y

Onset Date : DOB :

Outcome: Causality: Causality probable

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Drug withdrawal syndrome Patient experienced withdrawal effects, has

tried a few times to lower dose, developes palpitations, anxious

feelings.

Anxiety

Palpitations

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

Capsule 75 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 238283

Gender: F

Data Entry Date: 26/02/2008

Weight (kg): 0

Hospitalisation: Required a visit to the doctor

Age: 30Y

Onset Date:

DOB:

Outcome:

Causality: Causality probable

Not yet recovered

Information:

Reaction:

Preferred Term Severity

Report Description

Stopped:

Treatment

Drug withdrawal syndrome

When patient withdraws from Efexor she develops

Cannot stop Efexor or reduce dose.

agitation, palpitations, butterfly feeling in head.

Agitation

Feeling abnormal

Palpitations

Medicine details:

EFEXOR (Suspected) Reason: Anxiety neurosis

75 Milligram Daily

Batch: **Started**: 30/01/2005

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Cases Count: 172

Case Number: 238329

Gender: M

Data Entry Date: 27/02/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age:

Onset Date: 02/01/2008

DOB: 29/01/1952

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Tr

Treatment

Blood creatine phosphokinase

Life threatening

Delirium, narcoleptic malignant syndrome.

Aciclovir, ceftriaxone and vancomycin. Transfered to Royal Adelaide Hospital.

increased

Life threatening

Coma Delirium

Life threatening

Neuroleptic malignant

Life threatening

syndrome

Medicine details:

EFEXOR (Suspected) Reason: Otr spec symp psychopathol nec

150 Milligram Daily

Batch: Started: Stopped:

CELEBREX (Other drug) Reason : Otr&unsp vertebrogen pain synd

Capsule 200 Milligram Daily Oral

Batch: Started: Stopped:

KEFLEX (Other drug) Reason: Otr&nos infec¶sit diseases

Batch: Started: 31/12/2007 Stopped:

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Cases Count: 172

Case Number: 238350

Gender: F

Data Entry Date: 27/02/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: 21/02/2008 DOB: 21/04/1983

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Serotonin syndrome Incapacity/disability Likely Serotonin Sydrome Withdrawal of medication; Low

-Agitation, dilated pupils, dose benzodiazapine

sweats

Agitation Incapacity/disability
Hyperhidrosis Incapacity/disability
Mydriasis Incapacity/disability

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

Capsule 75 Milligram Daily Oral

Batch: **Started**: 14/02/2008 **Stopped**: 22/02/2008 0

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Cases Count: 172

Case Number: 238352

Gender: M

Data Entry Date: 27/02/2008 Weight (kg): 0

Hospitalisation: Age: 99u

DOB: **Onset Date:**

Causality: Causality possible Outcome:

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Caused or prolonged Intentional self-injury Self harm (hitting his head

inpatient

hospitalisation

aggression.

Aggression Caused or prolonged inpatient

hospitalisation

Agitation Caused or prolonged

inpatient hospitalisation

Medicine details:

EFEXOR-XR (Suspected) Reason:

> 150 Milligram Daily Oral

against walls), agitation,

Batch: Started: Stopped: 0

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Cases Count: 172

Case Number: 238370

Gender: F

Data Entry Date: 28/02/2008

Weight (kg): 0

Hospitalisation:

Age: 39Y

Onset Date: 15/01/2008

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Neurological symptom

Experienced Neurological symptoms: tremor, chilling,

difficulty in walking, twitching, eye rolling and

sweating.

Chills

Eye rolling

Gait disturbance

Hyperhidrosis

Muscle twitching

Tremor

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Capsule

75 Milligram

Daily

Oral

Batch:

Started:

Stopped:

4 days

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Cases Count: 172

Case Number: 238429 Gender: F

Data Entry Date: 29/02/2008 **Weight (kg)**: 0

Hospitalisation: Age: 32Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: Taking Fluoxetine 40mg per day at the same time.

Reaction:

Preferred Term Severity Report Description Treatment

Depression Worsening of depression Stilnox ceased.

symptoms when Stilnox

was introduced.

Insomnia

Medicine details:

STILNOX (Interaction) Reason: Specific disorders of sleep

Tablet 1 Dose Unspec Daily Oral

Batch: Started: Stopped:

VENLAFAXINE HYDROCHLORIDE (Interaction) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 238527

Gender: M

Data Entry Date: 03/03/2008

Weight (kg): 75

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 02/11/2007

DOB: 13/11/1945

Outcome:

Causality: Causality possible

Not yet recovered

Severity

1101 701 1000

Information:

Reaction:

Preferred Term

Report Description

Treatment

Off all medication

Bruxism

Developed 24 hour bruxism following the increase of Venlafaxine from 75 to 150mg nocte.

Medicine details :

VENLAFAXINE HYDROCHLORIDE (Suspected)

Reason: Depression

150 Megabecquer Daily

Batch:

Started: 26/10/2007

Stopped: 02/11/2007

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Cases Count: 172

Case Number : 238746

Gender: F

Data Entry Date: 10/03/2008 **Weight (kg)**: 0

Hospitalisation: Age: 84Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information: 84-year-old with history of myocardial ischaemia and mild cognitive disorder. Stated to

be first report of Interaction with ECT at 75mg daily dose of Efexor.

Reaction:

Preferred TermSeverityReport DescriptionTreatmentCardiac arrestLife threateningCardiac Arrest during ECT for severe depression,Previous ECT courses on Efexor without event.

while on Efexor

spontaneous reversion to

normal rhythm odes of Cardiac spontaneous reversion to

Cardiac arrest Life threatening Two episodes of Cardiac

Arrest during ECT for severe depression, while

on Efexor

Bradycardia Life threatening 1. bradycardia requiring atropine and ephedrine; 2.

spontaneous reversion to

normal rhythm

normal rhythm

Medicine details:

EFEXOR (Suspected) Reason: Depression

75 Milligram Daily Oral

Batch: Started: Stopped: 0

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Cases Count: 172

Case Number: 238766

Gender: F

Data Entry Date: 11/03/2008 Weight (kg): 0

Hospitalisation: Age: 99u

DOB: **Onset Date:**

Causality: Causality possible Outcome:

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Caused or prolonged Agitation Agitation, hyperactivity and "other symptoms".

inpatient hospitalisation

Psychomotor hyperactivity Caused or prolonged

inpatient hospitalisation

Medicine details:

EFEXOR-XR (Suspected) Reason:

Oral Capsule

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 238880

Gender: M

Data Entry Date: 13/03/2008 **Weight (kg)**: 100

Hospitalisation: Required a visit to the doctor

DOB: 01/08/1969

Age:

Outcome: 20/02/2008 Causality: Causality probable

Recovered

Information:

Onset Date: 15/02/2008

Reaction:

Preferred Term Severity Report Description Treatment

Paraesthesia Hot/cold pins and needles skin of arms. "Not with it"

feeling. Felt lousy.

Feeling abnormal

Feeling of body temperature

change Malaise

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

75 Milligram Daily

Batch: **Started**: 14/02/2008 **Stopped**: 19/02/2008

Seretide 250/25 MDI (Other drug) Reason : Asthma

2 Dose Unspec Daily

Batch: Started: Stopped:

VENTOLIN (Other drug) Reason : Asthma

As necessary

Batch: Started: Stopped:

ZOTON (Other drug) Reason : Other diseases of esophagus

30 Milligram Daily

Batch: Started: Stopped:

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Cases Count: 172

Gender: M

Case Number: 238952

Data Entry Date: 14/03/2008 **Weight (kg)**: 0

Hospitalisation: Age: 26Y

Onset Date: 29/02/2008 **DOB**:

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Suicidal ideation Experienced insomnia, "life not worth living - Suicidal

ideation", anorgasmic, funny dreams and lost

weight.

Abnormal dreams

Anorgasmia

Insomnia

Weight decreased

Medicine details:

EFEXOR-XR (Suspected) Reason :

75 Milligram Oral

Batch: Started: 15/02/2008 Stopped: Contin

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Cases Count: 172

Gender: F

Case Number: 238964

Data Entry Date: 14/03/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Not yet recovered

Information:

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	vч	V.	\mathbf{v}	

Preferred Term Severity Report Description Treatment

Convulsion

Experienced whole body convulses, constant diarrhoea, paraesthesia (tingling in fingers and toes), and involuntary movement in arms and

legs.

Diarrhoea

Dyskinesia

Paraesthesia

Medicine details:

EFEXOR-XR (Suspected) Reason :

Capsule Oral

Batch: Started: 01/02/2008 Stopped:

DIAFORMIN (Other drug) Reason :

Batch: Started: Stopped:

SERC (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 239110

Gender: F

Data Entry Date: 19/03/2008

Weight (kg): 65

Hospitalisation:

Age:

Onset Date: 12/02/2008

DOB: 30/07/1929

Outcome: 18/03/2008

Causality: Causality possible

Recovered with sequelae

Information:

Reaction:

Severity

Report Description

Treatment

Preferred Term Confusional state

Caused or prolonged inpatient

Doctor doubled dose of venlafaxine on 12th Feb 2008 to 150mg daily.

Patient became

2nd March 2008, commence Olanzapine, restrict fluids

Hospitalise. Cease venlafaxine

hospitalisation

increasingly confused during the ensuing days. Admitted to St Vincents Hospital in Darlinghust with

hyponatraemia and acute delirium 1st March 2008.

Delirium

Caused or prolonged

inpatient

hospitalisation

Hyponatraemia

Caused or prolonged

inpatient

hospitalisation

Medicine details:

VENLAFAXINE HYDROCHLORIDE (Suspected)

Reason:

Daily

Oral

Batch: unknown

Started: 12/02/2008

Stopped: 01/03/2008

0

LIPITOR (Other drug)

Reason:

Reason:

Oral

Batch:

Tablet

Started:

Stopped:

0

MICARDIS (Other drug)

80 Milligram

20 Milligram

40 Milligram

150 Milligram

Oral

Batch:

Started:

Stopped:

0

OMEPRAZOLE (Other drug)

Reason:

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Type

Range

Date Tested Result

Details

Electrolytes

Sodium 129 on 29th Feb, 121 on 1st march [Normal >135], normal thereafter.

EEG non specific changes for delirium.

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Cases Count: 172

Case Number: 239111

Gender: F

Data Entry Date: 19/03/2008

Weight (kg): 60

Hospitalisation:

Age: 61Y

Onset Date: 20/02/2008

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Irritability

Irritability manifesting as swearing. Reaction occurred after dose was increased from 150mg to 225 mg daily. The event

resolved after Efexor XR

was reduced.

Medicine details:

EFEXOR-XR (Suspected) Reason: Obsessive compulsive neurosis

Capsule 225 Milligram Daily Oral

Batch: Started: 10/12/2006 Stopped: 0

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Cases Count: 172

Case Number: 239161

Gender: F

Data Entry Date: 20/03/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Dystonia

Caused or prolonged

Severe dystonic reaction.

inpatient hospitalisation

Medicine details:

EFEXOR-XR (Suspected)

Reason:

Capsule

225 Milligram Oral

Batch:

Started:

Stopped:

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Cases Count: 172

Gender: M

Case Number: 239163

Data Entry Date: 20/03/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: History of alcohol and drug abuse.

Reaction:

Preferred Term Severity Report Description Treatment

Aggression Taking venlafaxine that was not prescribed for him

and committed violent act

and rape.

Intentional drug misuse

Sexual abuse

Medicine details:

EFEXOR (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case Number : 239352

Gender: F

Data Entry Date: 31/03/2008 **Weight (kg)**: 95

Hospitalisation: Admitted to hospital Age:

Onset Date: 04/03/2008 **DOB**: 01/11/1952

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Depressed mood Caused or prolonged

inpatient hospitalisation Gradual worsening of depressed mood over the past six weeks, to the point of feeling suicidal and at risk of harming herself.

Medicine details:

ACETYLCYSTEINE (Suspected) Reason: Unspecifid affective psychosis

Batch: Started: Stopped:

EFEXOR (Suspected) Reason: Unspecifid affective psychosis

375 Milligram Daily

Batch: Started: Stopped: 0

LITHIUM CARBONATE (Suspected) Reason : Unspecifid affective psychosis

Tablet 900 Milligram Daily Oral

Batch: Started: Stopped: 0

VALIUM (Suspected) Reason : Unspecifid affective psychosis

10 Milligram Daily

Batch: Started: Stopped:

ZYPREXA (Suspected) Reason: Unspecifid affective psychosis

30 Milligram Daily

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 239424

Gender: M

Data Entry Date: 31/03/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date :

DOB: 30/09/1947

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Nightmare

Whilst taking Efexor XR experienced nightmares. Since stopping Efexor XR, experienced suicidal thoughts, felt depressed.

Depression

Suicidal ideation

Withdrawal syndrome

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Capsule

75 Milligram

Daily

Oral

Batch:

Started: 01/09/2007

Stopped: 08/03/2008

PUTRAN02 Page 96 of 186



Cases Count: 172

Case Number : 239626

Gender: M

Data Entry Date: 07/04/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date :

DOB: 31/12/1948

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Withdrawal syndrome Incapacity/disability Discontinuation symptoms, Restarted Efexor XR.

physical shaking, anxiety, hysteria, very fearful, "out of sorts", unable to focus mentally, "melting down". The events started 2 days after missing the capsules.

Anxiety Incapacity/disability
Conversion disorder Incapacity/disability
Fear Incapacity/disability
Feeling abnormal Incapacity/disability
Mental impairment Incapacity/disability

Tremor Incapacity/disability

Medicine details:

EFEXOR-XR (Suspected) Reason:

Capsule 150 Milligram Daily Oral

Batch : Started : Stopped :

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Cases Count: 172

Case Number: 239767 Gender: U

Data Entry Date: 10/04/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Psychotic disorder

Reporter had a patient who became psychotic when using combinations of quetiapine and aripiprazole

quetiapine and aripiprazole and withdrawing from

Efexor.

Medicine details:

Aripiprazole (Suspected) Reason :

Batch: Started: Stopped:

EFEXOR (Suspected) Reason :

Batch: Started: Stopped:

QUETIAPINE (Suspected) Reason :

Batch: Started: Stopped:

PUTRAN02 Page 98 of 186



Cases Count: 172

Case Number: 239831

Gender: M

Data Entry Date: 11/04/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 01/03/2008

DOB: 20/06/1924

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Photosensitivity reaction

Photosensitive drug reaction, eczematous rash - affecting face, hands and

Wet dressings, betamethazone bd, 10% WSP in aqueous

cream, hydrocortisone to face.

legs

Eczema

Medicine details:

METFORMIN HYDROCHLORIDE (Suspected)

Reason: Diabetes mellitus

Daily

Daily

Tablet

1 Gram

Oral

Batch :

Batch:

Started: 07/02/2008

Stopped:

VENLAFAXINE HYDROCHLORIDE (Suspected)

Reason :

150 Milligram

Stopped:

BRICANYL (Other drug)

Reason:

2 Dose Unspec Daily

Batch:

Started: L TERM

Stopped:

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)

Reason:

20 Milligram Daily

Batch:

Started :

Started:

L TERM Stopped:

IRBESARTAN (Other drug)

Reason: Essential benign hypertension

150 Milligram

Daily

Batch :

Started :

L TERM

Stopped:

Symbicort Turbuhaler 400/12 (Other drug)

Reason:

Batch :

Started :

Stopped:

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Cases Count: 172

Case Number: 239945

Gender: M

Data Entry Date: 14/04/2008

Weight (kg): 105

Hospitalisation: Required a visit to the doctor

Age:

Onset Date: 25/02/2008

DOB: 24/05/1955

Outcome:

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Nausea

Patient experienced severe nausea, headache,

dizziness, moderate

agitation.

Agitation

Dizziness

Headache

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Capsule

75 Milligram

Daily

Oral

Batch:

Started: 25/02/2008

Stopped: 29/02/2008

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Cases Count: 172

Case Number: 239974

Gender: F

Data Entry Date: 15/04/2008

Weight (kg): 0

Hospitalisation:

Age: 33Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

pregnancy

Preferred TermDrug exposure before

Severity

Report Description Treatment

Drug exposure during

pregnancy

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Capsule

37.5 Milligram

Daily

Oral

Batch:

Started: 15/08/2007

Stopped:

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Cases Count: 172

Gender: F

Case Number: 239975

Data Entry Date: 15/04/2008 Weight (kg): 0

Hospitalisation: Age:

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

Causality: Causality possible Outcome:

Reason:

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Caused or prolonged Body temperature decreased

inpatient hospitalisation Temperature did not stablisise for 48 hours following birht - kept dropping. Had in-utero exposure to Efexor XR.

Drug exposure during Caused or prolonged

pregnancy inpatient hospitalisation

Medicine details: **EFEXOR-XR** (Suspected)

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 240354

Gender: M

Data Entry Date: 24/04/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 75Y

Onset Date: 28/01/2008

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Inappropriate antidiuretic hormone secretion

Caused or prolonged inpatient

SIADH and confusion.

Venlafaxine and ramipril ceased. Fluid restriction.

Confusional state

Caused or prolonged

inpatient

hospitalisation

hospitalisation

Medicine details:

RAMIPRIL (Suspected) Reason:

2.5 Milligram

Daily

Oral

Batch:

Started:

Stopped:

VENLAFAXINE HYDROCHLORIDE (Suspected)

Reason: 75 Milligram Daily

Oral

Batch:

Started:

Stopped:

AMPICILLIN (Other drug)

Reason: 100 Milligram

6.3 Milligram

Daily

Daily

Oral

Batch:

Started:

Stopped:

CARVEDILOL HYDROCHLORIDE (Other drug)

Reason:

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Type Sodium Range

Date Tested Result

Details

Se Na = 120 urine Na 71 and Se OSM =

251 urine OSM 424.

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Cases Count: 172

Case Number: 240428 Gender: F

Data Entry Date: 29/04/2008 **Weight (kg)**: 0

Hospitalisation: Age: 40Y
Onset Date: 01/10/2004 DOB:

Outcome : Causality : Causality possible

Not yet recovered

Information:

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Reaction:

Preferred Term

Hypersensitivity

Severity

Incapacity/disability

Report Description

- 1. Increased skin sensitivity, gradually becoming worse and worse. Patient now reacts to many cosmetics, suncreams and moisturisers - skin breaks out in rashes, and itchy red sores, hair follicles become inflammed and infected. 2. Increased skin oiliness and acne (face, forehead, back, shoulders) - patient never had skin problems before commencing
- adolescence. 3. Worsening depression and anhedonia - patient is finding it harder and harder to combat depressive symptoms and has gained weight due to becoming more anhedonic and inactive.

venlafaxine even during

4. Patient is unable to stop taking venlafaxine completely. She has gradually tapered her daily dose from 75 mg/day to approx 18 mg/day (half a 37.5 mg capsule) over the last 4 years and has tried on three separate occasions to stop the drug completely. Each time she has suffered shaking, nervousness, agitation, anxiety, headaches and had to start taking the drug again in order to be able to function normally at work. The longest period she went without the drug was 6 days and she experienced the symptoms above throughout the 6 days.

Treatment

The skin problem is greatly exacerbating the depression and has resulted in the patient not being able to leave the house on occasions and she is developing social phobia.

Acne Incapacity/disability Agitation Incapacity/disability Anhedonia Incapacity/disability Anxiety Incapacity/disability Depression Incapacity/disability Headache Incapacity/disability Nervousness Incapacity/disability Tremor Incapacity/disability Weight increased Incapacity/disability Withdrawal syndrome Incapacity/disability

PUTRAN02 Page 105 of 186 Medicine details:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason : Depression

Capsule 18.7 Milligram 1 time Oral

Batch: Started: 01/06/1999 Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Other data Negative RAS tests (no dust mite

allergy)

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Cases Count: 172

Case Number: 240434

Gender: M

Data Entry Date: 29/04/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date: DOB:

Outcome: Causality: Causality possible

Not yet recovered

Information: Dose of Efexor XR was not decreased gradually before commencing Edronax.

Reaction:

Preferred Term Severity **Report Description Treatment**

Suicidal ideation Switched from Efexor XR

to Edronax. Experienced suicidal thoughts,

aggression toward his wife

and dizzy spells.

Edronax ceased and Xanax commenced until he is able to

see his doctor again.

Aggression

Dizziness

Medicine details:

EDRONAX (Suspected) Reason:

> 8 Milligram Daily

Started: 15/04/2008 Batch: Stopped:

EFEXOR-XR (Suspected) Reason:

> 150 Milligram Daily

Batch: Started: Stopped: 15/04/2008

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Cases Count: 172

Case Number: 240535

Gender: M

Data Entry Date: 02/05/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Severity

Information:

Reaction:

Preferred Term

Report Description

Treatment

Alcohol abuse

Started binge drinking and

Dose increased to 150mg once

acting irrationally -

threatens to leave partner and breaks windows.

daily.

Oral

Aggression

Thinking abnormal

Medicine details:

EFEXOR-XR (Suspected)

Reason:

Daily

Capsule 150 Milligram

Batch: Started: 01/04/2008

Stopped:

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Cases Count: 172

Case Number: 240791 Gender: F

Data Entry Date: 10/05/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Dizziness Patient has been stabilized

on Efexor 150mg for a period of time, however after taking one tablet she has developed signs of dizziness, which has not occurred since starting the

Efexor.

Medicine details:

EFEXOR (Suspected) Reason :

Capsule 150 Milligram Daily Oral

Batch: 70274A Started: Stopped:

LEVLEN ED (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 240807

Gender: F

Data Entry Date: 12/05/2008 Weight (kg): 0

Hospitalisation: Age: 19Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: Patient had a past ilness of bactereamia infection which she was treated for with

antibiotics close to when she experienced lockjaw.

Reaction:

Preferred Term Severity Report Description Treatment

Dyspnoea Caused or prolonged Experienced lcok jaw,

inpatient difficulty breathing due to hospitalisation anxiety, anxiety,

bacteraemia and muscle

tension.

Anxiety Caused or prolonged

inpatient

hospitalisation

Muscle tightness Caused or prolonged

inpatient

hospitalisation

Trismus Caused or prolonged

inpatient hospitalisation

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

Capsule 75 Milligram Daily Oral

Batch: **Started**: **Stopped**: 30/04/2008 0

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Cases Count: 172

Case Number: 240810

Gender: F

Data Entry Date: 12/05/2008

Onset Date: 15/01/2008

Weight (kg): 0

Hospitalisation:

Age: 48Y

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Suicidal ideation

Preferred Term Severity

Report Description Treatment

paranoia, hot flushes, Efexor XR helped with anxiety but not with hot and cold sweats and palpitation, discontinuation symptoms such as increased anxiety after reducing to 75 mg daily, "sick feeling in the stomach", stomach upset, "felt a bit sick before she ate food", felt

"Funny head", dizziness,

suicidal/suicidal thoughts.

Anxiety

Dizziness

Drug ineffective

Hot flush

Malaise

Nausea

Palpitations

Paranoia

Withdrawal syndrome

Medicine details:

EFEXOR-XR (Suspected) Reason: Anxiety neurosis

Capsule 75 Milligram Oral Daily

Batch: Started: Stopped: 15/01/2008

RISPERIDONE (Other drug) Reason:

2 Milligram

Batch: Started: Stopped:

VALIUM (Other drug) Reason:

Tablet 5 Milligram Oral

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 240920

Gender: F

Data Entry Date: 15/05/2008 Weight (kg): 0

Hospitalisation: Treated in outpatient department only. **Age**: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Palpitations and ventricular Efexor XR stopped and digoxin

fibrillation. commenced.

Ventricular fibrillation

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

Capsule 150 Milligram Daily Oral

Batch: Started: Stopped: 0

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Cases Count: 172

Case Number: 241027

Gender: M

Data Entry Date: 19/05/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Outcome:

DOB:

Onset Date: 15/05/2008

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Withdrawal syndrome

Stopped taking Efexor XR 2 days ago and "feels ready to pass out",

vomiting and sweating.

Hyperhidrosis

Presyncope

Vomiting

Medicine details:

EFEXOR-XR (Suspected)

Reason:

150 Milligram

Oral

Capsule Batch:

Started: 15/01/2008

Daily

Stopped: 07/05/2008

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Cases Count: 172

Case Number: 241030

Gender: M

Data Entry Date: 20/05/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date: DOB:

Causality: Causality certain Outcome:

Recovered

Information: Cert:rechall

Voluntarily stopped Efexor XR temporarily and the same events recurred.

Reaction:

Preferred Term Severity **Report Description Treatment**

Withdrawal syndrome Patient forgot a dose of No treatment, events resolved Efexor XR and when missed dose of Efexor XR

experienced headaches and hypertension of 220/110 mmHg.

was taken.

Headache Hypertension

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

Capsule 300 Milligram Oral Daily

Batch: Started: Stopped: Contin

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Cases Count: 172

Case Number : 241486

Gender: F

Data Entry Date: 03/06/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Neuroleptic malignant Neuroleptic malignant

syndrome syndrome.

Medicine details:

EFEXOR-XR (Suspected) Reason :

Capsule Oral

Batch: Started: Stopped:

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Cases Count: 172

Gender: M

Case Number : 241863

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

Hospitalisation: Age:

Onset Date : DOB : 04/09/1949

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Drug withdrawal syndrome

No libido since on Efexor

XR and drug withdrawal

increased again

syndrome including mind not with body, vivd dreams, nausea, can not sleep, lack of balance, response time

decreased and vertigo.

Abnormal dreams

Balance disorder

balance disorder

Dissociation

Hypokinesia

Insomnia

Loss of libido

Nausea

Vertigo

Medicine details:

EFEXOR-XR (Suspected) Reason :

Capsule 150 Milligram Daily Oral

Batch: Started: 02/06/2008 Stopped:

EFEXOR-XR (Suspected) Reason:

Capsule 150 Milligram Daily Oral

Batch: Started: L TERM Stopped: 22/05/2008 0

EFEXOR-XR (Suspected) Reason:

Capsule 75 Milligram Daily Oral

Batch: **Started**: 23/05/2008 **Stopped**: 29/05/2008

MOCLOBEMIDE (Suspected) Reason :

Oral

Batch: Started: 01/06/2008 Stopped:

MICARDIS (Other drug) Reason :

80 Milligram

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 241899

Gender: F

Data Entry Date: 16/06/2008 **Weight (kg)**: 50

Age:

Hospitalisation: Admitted to hospital **Onset Date**: 13/04/2008

DOB: 02/05/1988

Outcome : Causality : Cau

Causality: Causality possible

Recovered

Information: Possible overdose denied by patient.

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Reaction.			
Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Life threatening	Serotonin syndrome, chest pain, developed tonic clonic seizures.	Intubated and ventilated, midazolam for seizures, supportive care.
Chest pain	Life threatening		
Clonus	Life threatening		
Encephalopathy	Life threatening		
Grand mal convulsion	Life threatening		
Hyperreflexia	Life threatening		
Hypertonia	Life threatening		
Nystagmus	Life threatening		
Pyrexia	Life threatening		

Medicine details:

Batch:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason:

Started:

Stopped :

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Cases Count: 172

Case Number : 241900

Gender: F

Data Entry Date: 16/06/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

Suicide attempt

Tried to hang herself. Also her periods have stopped.

Amenorrhoea

Medicine details:

EFEXOR (Suspected)

Reason:

Tablet

Oral

Batch :

Started:

Stopped:

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Cases Count: 172

Case Number: 241902

Gender: M

Data Entry Date: 16/06/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date: 04/06/2008

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term

Self-injurious ideation

Severity

Report Description

Treatment

Thoughts of "harming

Daily

himself".

Medicine details:

EFEXOR-XR (Suspected)

Reason:

37.5 Milligram

Oral

Capsule Batch:

Started: 04/06/2008

Stopped: 05/06/2008

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Cases Count: 172

Gender: F

Case Number : 241903

Data Entry Date: 16/06/2008 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date : DOB : 21/05/1980

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Polycystic ovaries Caused or prolonged

inpatient

hospitalisation

"Periods becoming further apart until in May 2006 they stopped altogether", "put on a considerable amount of weight", "her female hormones were shot to pieces", ovarian cysts. Lab test showed polycystic ovarian morphology and high

prolactin levels.

Amenorrhoea Caused or prolonged

inpatient

hospitalisation

Blood prolactin increased Caused or prolonged

inpatient

hospitalisation

Menstruation irregular Caused or prolonged

inpatient

hospitalisation

Weight increased Caused or prolonged

inpatient

hospitalisation

Medicine details:

EFEXOR (Suspected) Reason:

Tablet 150 Milligram Daily Oral

Batch: Started: 15/12/2003 Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Prolactin <20 10/08/2006 170
Thyroid Stimulating 0.40 - 4.00 03/07/2004 0.7

Hormone

Thyroid Stimulating 0.40 - 4.00 10/08/2006 0.5

Hormone

Other data 10/08/2006 130 Oestradoil level

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i aporatory	Investigations	•
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Type Range Date Tested Result Details

Ultrasound 4/9/2006:

Transabdominal and endovaginal examination was performed. The uterus is retroverted and is small in size with a volume of 24cc. No uterine masses are seen. There is a normal central endometrial echo. Endometrial thickness is measured at 5.7 mm. Both ovaries are prominent with a right ovarian volume of 13cc, left 10cc. There are greater than 15 less than 10mm diameter follicles arising from both ovaries, consistent with polycystic ovarian morphology. No dominant follicle is seen on either side. No adnexal masses are seen. There is no free fluid. Both kidnesy are normal in

size and appearance.

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Hospitalisation:

Public Case Detail

Cases Count: 172

Case Number: 241982

Gender: M

Data Entry Date: 17/06/2008 **Weight (kg)**: 85

Age:

Onset Date: 10/06/2008

DOB: 25/07/1955

Outcome :

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

tongue went yellow, dizzy, cessation of medication

light headed marked rise in

liver function test

Dizziness

Hepatic function abnormal

Tongue discolouration

Medicine details:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason : Depression

Capsule 37.5 Milligram Daily Oral

Batch: **Started**: 05/06/2008 **Stopped**: 13/06/2008

Laboratory Investigations:

Type Range Date Tested Result Details

GGT = SGGT = GTT 2844

GGTP

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Cases Count: 172

Case Number: 242026

Gender: F

Data Entry Date: 18/06/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 25Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Hallucination

Preferred Term Severity **Report Description Treatment**

Epilepsy Caused or prolonged

Epilepsy continuing, eyes rolling, consciousness, muscle spasms of hand

Treated with Xanax and lamotrigine.

hospitalisation and feet and hallucinations.

Caused or prolonged Consciousness fluctuating

inpatient

inpatient

hospitalisation

Convulsion Caused or prolonged

inpatient

hospitalisation

Caused or prolonged Eye rolling

> inpatient hospitalisation

Caused or prolonged

inpatient

hospitalisation

Muscle spasms Caused or prolonged

hospitalisation

inpatient

Medicine details:

EFEXOR (Suspected) Reason: Debility&undue fatigue

Tablet 150 Milligram Daily Oral

Started: 15/02/2008 Stopped: Continued. Batch:

TOPAMAX (Suspected) Reason: Migraine

Tablet 50 Milligram Daily Oral

Batch: Started: 15/02/2008 Stopped: 15/03/2008

Yasmin (Other drug) Reason: Contraception

Tablet 1 Dose Unspec Oral

Started: Stopped: 0 Batch:

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Cases Count: 172

Case Number : 242058

Gender: F

Data Entry Date: 19/06/2008 Weight (kg): 0

Hospitalisation: Admitted to hospital Age:

Onset Date: 04/05/2008 DOB: 09/07/1934

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Neuroleptic malignant Caused or prolonged syndrome inpatient

hospitalisation

Neuroleptic malignant stopped: efexor, clopine, benztropine; treated with tachycardic, sweating, bromocriptine.

dystonic, rigidity

Medicine details:

BENZTROPINE MESYLATE (Suspected) Reason :

Batch: **Started**: **Stopped**: 04/05/2008 0

CLOPINE (Suspected) Reason:

Batch: Started: Stopped:

EFEXOR (Suspected) Reason : Depression

Batch: **Started**: **Stopped**: 04/05/2008

TRIMETHOPRIM (Other drug) Reason :

Batch: **Started**: 24/04/2008 **Stopped**: 05/05/2008

Laboratory Investigations:

Type Range Date Tested Result Details

Creatine 04/08/2008 2810

phosphokinase

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Cases Count: 172

Case Number: 242189

Gender: M

Data Entry Date: 24/06/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 71Y

Onset Date: 11/05/2008

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity

Report Description Tre

Treatment

Epistaxis

Caused or prolonged

Epistaxis x 2 episodes,

Pressure and nasal packing.

inpatient hospitalisation brought in by ambulance. Lasting approx 20 minutes.

Medicine details:

VENLAFAXINE HYDROCHLORIDE (Suspected)

Reason : Depression

150 Milligram D

Daily

Oral

Batch:

Started: 06/05/2008

Stopped:

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Cases Count: 172

Case Number: 242249

Gender: F

Data Entry Date: 25/06/2008 Weight (kg): 0

Hospitalisation : Age :

Onset Date : DOB : 14/06/1940

Outcome: Causality: Causality possible

Unknown

Information: Upon reducing dose to 75 mg daily, sleep has improved but suicidal ideation has not

resolved.

Reaction:

Preferred Term Severity Report Description Treatment

Suicidal ideation

Suicidal thoughts, "has not had any sleep". Patient

also had pre-existing

depression

Medicine details:

EFEXOR-XR (Suspected) Reason :

150 Milligram Daily Oral

Batch: **Started**: 15/03/2008 **Stopped**: 15/05/2008 0

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Cases Count: 172

Case Number : 242250

Hospitalisation: Age:

Onset Date: 03/06/2008 DOB: 20/12/1946

Outcome: Causality: Causality possible

Unknown

Information: The patient has seen a neurologist who was unable to provide a diagnosis. Nuclear

MRI, blood tests nos, ECG, ateriogram carotid, electrocardiogram all were normal.

Reaction:

Preferred Term Severity Report Description Treatment

Drug withdrawal syndrome Caused or prolonged

inpatient hospitalisation

efexor was not working so patient decreased dose and experienced asthenia, difficulty instanding,

difficulty instanding, dyspnoea, difficulty forming words, dysphagia, fatigue, coldness of skin, feeling hot, headache, dizziness, muscle contractions, left side weak,left side of face drooping, left leg dragging, numbness and tingling down the left side,

palpitations

Drug ineffective Caused or prolonged

inpatient

hospitalisation

Medicine details:

EFEXOR-XR (Suspected) Reason :

300 Milligram Daily Oral

Batch: **Started**: **Stopped**: 27/05/2008 0

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Cases Count: 172

Case Number: 242409

Gender: F

Data Entry Date: 30/06/2008

Weight (kg): 0

Hospitalisation:

Age: 30Y

Onset Date: 10/06/2008

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Choreoathetosis

Preferred Term Severity

Report Description Treatment

single dopse of phenergan valium (within 12 hrs) followed by

seretonin syndrome, next day stiffness,

choreoathetosis, confusion, sweaty,

paranoid psychosis/mania.

Confusional state

Delusional disorder, persecutory type Hyperhidrosis

Hypertonia

Serotonin syndrome

Medicine details:

EFEXOR (Interaction) Reason: Depression

150 Milligram Daily

Batch: Started: Stopped:

PHENERGAN (Interaction) Reason: Specific disorders of sleep

50 Milligram Daily Oral

Batch: Started: 09/06/2008 Stopped:

PUTRAN02 Page 128 of 186



Cases Count: 172

Case Number: 242413

Gender: M

Data Entry Date: 30/06/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Report Description

Treatment

Electrocardiogram QT

prolonged

Medicine details:

EFEXOR-XR (Suspected)

Reason:

Oral

Batch:

Started:

Severity

Stopped:

Laboratory Investigations:

Type

Other data

Range

Date Tested Result

150 Milligram

Details

QT interval raised to 0.42 ,before it was

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Cases Count: 172

Case Number: 242645

Gender: F

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

Hospitalisation: Required a visit to the doctor Age:

Onset Date: 22/06/2008 DOB: 01/07/1972

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Nausea, vomiting, small Slowly discontinued Efexor. flecks of fresh blood in

some vomit, also in early morning sputum.

Pounding/throbbing frontal headache. BP 130/100.

Haematemesis Headache

Vomiting

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

75 Milligram Daily

Batch: Started: 10/06/2008 Stopped:

IMPLANON IMPLANT (Other drug) Reason : Contraception

68 Milligram Daily

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 242735

Gender: M

Data Entry Date: 09/07/2008 **Weight (kg)**: 0

Hospitalisation: Admitted to hospital Age: 46Y

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information: Seroquel increased to 300mg bd on 29/02/08.

Reaction:

Preferred Term Severity Report Description Treatment

Convulsion Caused or prolonged Seizure

inpatient hospitalisation

. Ture

Medicine details:

EFEXOR-XR (Suspected) Reason :

Capsule 150 Milligram Daily Oral

Batch: Started: Stopped:

SEROQUEL (Suspected) Reason :

Tablet 600 Milligram Daily Oral

Batch: Started: Stopped: 0

ANDROCUR (Other drug) Reason :

25 Milligram Daily Oral

Batch: Started: Stopped:

AUGMENTIN DUO FORTE (Other drug) Reason :

175 Milligram Daily Oral

Batch: Started: 10/06/2008 Stopped:

PARACETAMOL (Other drug) Reason :

1 Gram As necessary Oral

Batch: Started: Stopped:

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Cases Count: 172

Gender: M

Case Number : 242836

Data Entry Date: 11/07/2008 **Weight (kg)**: 0

Hospitalisation: Age: 37Y

Onset Date: 21/03/2008 DOB:

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Withdrawal syndrome Caused or prolonged inpatient

hospitalisation

Tried to take no Efexor from 21/03/2008 but "went haywire". Electrical pulses in his head, vision blurred, difficulty concentrating, felt agitated, hearing amplified reflux vomiting and

reflux vomiting and occasionally panic attacks. Most constant symptom

was sweating.

Medicine details:

EFEXOR-XR (Suspected) Reason: Obsessive compulsive neurosis

Capsule 37.5 Milligram Daily Oral

Batch: **Started**: 15/03/2007 **Stopped**: 21/03/2008

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Cases Count: 172

Case Number:242	969	Gender: U

Data Entry Date: 16/07/2008 Weight (kg): 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality possible

Unknown

Information:

RISPERIDONE (Suspected)

Reaction:				
Preferred Term	Severity	Report Description	Treatment	
Cerebral palsy		Baby was born with cerebral palsy.		
Drug exposure during pregnancy				
Medicine details :				
EFEXOR (Suspected)		Reason:		

Batch: Started: Stopped:

Batch: Started: Stopped:

SYNTOCINON (Suspected) Reason :

Batch: Started: Stopped:

Reason:

PUTRAN02 Page 133 of 186



Cases Count: 172

Case Number: 243017

Gender: F

Data Entry Date: 18/07/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information: patient reports concurrent flu condition

Reaction:

Preferred Term Severity Report Description Treatment

Pain Incapacity/disability
Somnolence Incapacity/disability

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

37.5 Milligram Daily Oral

Batch: Started: 12/07/2008 Stopped:

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Cases Count: 172

Gender: F

Case Number: 243042

Data Entry Date: 21/07/2008 Weight (kg): 0

Age: 99u **Hospitalisation:**

Onset Date: DOB:

Outcome: Causality: Causality possible

Not yet recovered

Information: Past conditions:

Victim of sexual abuse.

The patient has a past history of victim of sexual abuse. The patient had no prior history of depression, or family history of depression. She advised that her depression and anxiety related to workplace violence and sexual harassment by another staff member and resulted in her having to leave the workplace and being antidressants. The patient tsaid that Efexor XR had such an immediate lifting of her mood that she felt

she could cope with life.

Reaction:			
Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Incapacity/disability	Patient experienced withdrawal symptoms, such as brain zaps, dizziness, decreased emotional feelings, nausea, excessive sweating, motion sickness, vomiting, diarrhoea, body spasms, vivid dreams, nightmares, stomach cramps, halluninations, sensitivity to sounds, sudden movement by others causes her to jump, weight gain, swollen hands and feet, fluid retention, menstruation every 2 weeks, headaches, hives and severe welts, hives.	Drug ceased - started - ceased.
Dizziness	Incapacity/disability		
Drug effect decreased	Incapacity/disability		
Emotional disorder	Incapacity/disability		
Fluid retention	Incapacity/disability		
Headache	Incapacity/disability		
Hyperhidrosis	Incapacity/disability		
Hypersensitivity	Incapacity/disability		
Nausea	Incapacity/disability		
Oedema peripheral	Incapacity/disability		
Polymenorrhoea	Incapacity/disability		
Urticaria	Incapacity/disability		
Weight increased	Incapacity/disability		

PUTRAN02 Page 135 of 186 Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule

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

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Cases Count: 172

Gender: F

Case Number: 243104

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

Hospitalisation: Age: 99u

DOB: **Onset Date:**

Causality: Causality possible Outcome:

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Caused or prolonged Drug effect decreased Felt depressed again and dose was increased.

inpatient

hospitalisation

Caused or prolonged Depression

inpatient hospitalisation

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

300 Milligram Daily Oral Capsule

Batch: Started: Stopped: Contin

AVANZA (Other drug) Reason:

Stopped: Batch: Started:

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Cases Count: 172

Gender: F

Case Number : 243198

Data Entry Date: 24/07/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99U

Onset Date : DOB :

Outcome: Causality: Causality certain

Not yet recovered

Information: Patient stopped Efexor XR for 2 days and the condition lessened. When she took her

normal dose on day 2, symptoms worsened.

Reaction:

Preferred Term Severity Report Description Treatment

Withdrawal syndrome Allergic to Efexor XR, 5 Ceased Efexor XR immediatley.

days of horrendous withdrawal/withdrawal nightmare, experienced excessive sweating, brain zaps and continually, dizziness, motion sickmess, continual nausea, vomiting, diarrhoea, stomach cramps, hallucinations, hyperacusis, nervousness, need to lie down because of withdrawal events she was experiencing.

Hypersensitivity

Medicine details:

EFEXOR-XR (Suspected) Reason: Depression

Capsule 375 Milligram Daily Oral

Batch: Started: Stopped: 15/02/2008

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Cases Count: 172

Case Number : 243229

Gender: F

Data Entry Date: 25/07/2008 Weight (kg): 0

Hospitalisation: Age: 99u

Onset Date : DOB :

Outcome: Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Withdrawal syndrome Developed severe anxiety

symptoms on discontinuation.

Anxiety

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 75 Milligram Daily Oral

Batch : Started : Stopped :

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Cases Count: 172

Case Number: 243239

Gender: M

Data Entry Date: 28/07/2008

Weight (kg): 0

Hospitalisation:

Age: 70Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

Hypertension

Experienced a sudden increase in blood pressure

Therapy discontinued.

Medicine details:

EFEXOR-XR (Suspected)

Reason:

Daily

Oral

Capsule

Batch:

Started :

Stopped :

0

Laboratory Investigations:

Type

Blood pressure

Range

Date Tested Result

225 Milligram

Details

BP increased to 190/125. After discontinuing Efexor-XR, BP returned to

normal of 140/80 but then his diastolic reading went back up to 140/120.

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Cases Count: 172

Case Number: 243274

Gender: F

Data Entry Date: 29/07/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Convulsion

Severity

Report Description

Treatment

Convulsion after increasing Efexor-XR ceased

Efexor-XR from 75mg daily to 150mg daily in June

2008.

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Capsule

150 Milligram

Daily

Oral

Batch:

Started:

Stopped:

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Cases Count: 172

Gender: F

Case Number: 243279

Data Entry Date: 29/07/2008 **Weight (kg)**: 0

Hospitalisation: Required a visit to the doctor Age:

Onset Date: DOB: 10/04/1956

Outcome : Causality : Causality possible

Not yet recovered

Information:

Reaction:			
Preferred Term	Severity	Report Description	Treatment
Hearing impaired	Incapacity/disability	Exprienced funny hearing, nausea, dizziness, blocked ears, sinusitis, flu like symptoms, dry retching. Does not drive a car and could not cope with task because of vomiting.	Stemetil and Maxolon, Antibiotics and antihistamines.
Dizziness	Incapacity/disability		
Eustachian tube obstruction	Incapacity/disability		
Influenza like illness	Incapacity/disability		
Nausea	Incapacity/disability		
Retching	Incapacity/disability		
Sinusitis	Incapacity/disability		

Medicine details:

Vomiting

EFEXOR-XR (Suspected) Reason: Depression

Capsule 75 Milligram Daily Oral

Incapacity/disability

Batch: **Started**: **Stopped**: 05/07/2008 0

ASPIRIN (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case	Number : 243314	Gender:	F
Case	Number : 243314	Gender:	

Weight (kg): 0 **Data Entry Date:** 30/07/2008

Hospitalisation: Age:

Onset Date: 15/12/2007 **DOB**: 15/01/1961

Causality: Causality possible Outcome:

Not yet recovered

Weight decreased

Information:				
Reaction :				
Preferred Term	Severity	Report Description	Treatment	
Serotonin syndrome		Serotonin Syndrome, severe nausea, severe lack of appetite, high fevers, tiredness, mood swings, difficulty swalling, lack of saliva in mouth, anxiety and weight loss.		
Anorexia				
Anxiety				
Aptyalism				
Chills				
Diarrhoea				
Dysphagia				
Fatigue				
Hyperhidrosis				
Mood swings				
Nausea				
Pyrexia				
Tic				
Tremor				

Medicine details :				
EFEXOR-XR (Suspected)	R	eason : Depre	ssion	
Capsule	375 Milligram	Daily	Oral	
Batch :	Started : 15/06/2007		Stopped : 15/07/2008	0
ATENOLOL (Other drug)	R	eason :		
Batch :	Started :		Stopped :	
DUPHASTON (Other drug)	R	eason:		
Batch :	Started :		Stopped :	

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Medicine details :					
LAMOTRIGINE (Other drug)		Reason :	Reason:		
Batch :	Started :		Stopped :		
PARIET (Other drug)		Reason :			
Batch :	Started :		Stopped :		
SANDOMIGRAN (Other drug)		Reason :			
Batch :	Started :		Stopped:		
SEROQUEL (Other drug)		Reason :			
Batch :	Started :		Stopped :		

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Cases Count: 172

Case Number: 243513

Gender: F

Data Entry Date: 05/08/2008

Weight (kg): 0

Hospitalisation:

Age: 22Y

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information: In addition, the daughter has been doctor shopping to obtain sufficient Stilnox.

Reaction:

Preferred Term Severity **Report Description Treatment**

Abnormal sleep-related event Life threatening

Patient now takes up to 14 x at a time, deliberately stays awake to enjoy the "pleasant numbness" it eases the pain of starving herself. She gained weight from all the nocturnal eating (only on nights she took Stilnox), developed the habit of purging after a night where she ate in her sleep.

She has driven three times in her sleep. Patient has taken overdose of Stilnox from 14-32 tablets at a time, found unconscious and taken to hospital, for resuscitation, went all yellow and puffy. Stabbing herself with a knife, she says its to see what she can feel.

Dependence Life threatening Eating disorder Life threatening Intentional self-injury Life threatening Somnambulism Life threatening Suicide attempt Life threatening Weight increased

Medicine details:

EFEXOR (Suspected) Reason: Anxiety neurosis

Life threatening

75 Milligram Daily

Started: 15/04/2008 Batch: Stopped:

STILNOX (Suspected) Reason:

Tablet Oral Milligram Daily

Batch: Started: L TERM Stopped:

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Cases Count: 172

Case Number: 243877

Gender: M

Data Entry Date: 18/08/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Headache

Preferred Term Severity **Report Description**

After increase of Efexor-XR from 75mg, then 150mg to 225 mg daily, patient experienced headache, dizziness, muscle pain, fainting, panic attacks, weight gain,

increased appetite, feeling thirsty, anxiety getting worse and stomach

cramps.

Treatment

Cognitive Behavioural Therapy exercises help. Needs to take Valium.

Abdominal pain upper

Anxiety

Dizziness

Increased appetite

Myalgia

Panic attack

Syncope

Thirst

Weight increased

Medicine details:

EFEXOR-XR (Suspected) Reason: Anxiety neurosis

Capsule 225 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 243907

Gender: M

Data Entry Date: 19/08/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date: 15/03/2006

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Syncope vasovagal

Syncope vasovagal attacks aggravated on Efexor XR

and dizzy spells.

Depression Dizziness

Withdrawal syndrome

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Capsule

75 Milligram

Daily

Oral

Batch:

Started: 15/03/2006

Contin

TAMSULOSIN HYDROCHLORIDE (Other drug)

Reason:

400 Microgram

Batch:

Started:

Stopped:

Stopped:

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Cases Count: 172

Case Number: 243921

Gender: M

Data Entry Date: 19/08/2008

Weight (kg): 0

Hospitalisation:

Age: 18Y

Onset Date:

DOB:

-

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Amnesia

Incapacity/disability

horrible memory loss/memory impairment and an inability to think properly. Can no longer learn anymore as too

discontinued.

Efexor permanently

mentally slow to keep up. Could not cope without

Efexor

Anger Incapacity/disability
Anxiety Incapacity/disability
Learning disorder Incapacity/disability

Mental impairment Incapacity/disability

Medicine details:

EFEXOR-XR (Suspected)

Reason:

Capsule

Oral

Batch :

Started: 10/11/2007

Stopped:

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Cases Count: 172

Case Number: 244452

Gender: M

Age:

Data Entry Date: 08/09/2008 Weight (kg): 68

Hospitalisation: Required a visit to the doctor

DOB: 04/10/1924

Onset Date: 28/07/2008

Outcome: Causality: Causality possible

Not yet recovered

Information: History of GORD.

Reaction:

Preferred Term Severity **Report Description Treatment**

Nausea Nausea, vomiting,

indigestion and epigastric

pain.

Abdominal pain upper

Dyspepsia Vomiting

Medicine details:

EFEXOR (Suspected) Reason: Depression

300 Milligram Capsule Daily Oral

Stopped: 07/08/2008 Started: 01/07/2008 Batch:

ASPIRIN (Other drug) Reason: Acute heart failure, undefined

> 100 Milligram Oral Daily

Batch: Started: L TERM Stopped:

Combigan (Other drug) Reason: Unspecified glaucoma

Batch: Started: Stopped:

Lyrica (Other drug) Reason: Pain

Capsule 150 Milligram Oral Daily

Batch: Started: 01/07/2008 Stopped:

XALATAN (Other drug) Reason: Unspecified glaucoma

Batch: Started: Stopped:

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

Tablet 20 Milligram Daily Oral

Batch: Started: L TERM Stopped: 0

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Cases Count: 172

Case Number: 244605

 $\textbf{Gender}: \ M$

Data Entry Date: 15/09/2008

Weight (kg): 0

Hospitalisation:

Age: 28Y

Onset Date :

DOB:

Outcome :

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Severity Report Description

Treatment

Psychotic disorder

Psychotic episode and

Efexor XR reduced

paranoia.

Paranoia

Medicine details:

EFEXOR-XR (Suspected)

Reason:

225 Milligram

Daily

Oral

Batch :

Started:

Stopped:

Contin

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Cases Count: 172

Gender: F

Case Number: 244696

Data Entry Date: 18/09/2008 **Weight (kg)**: 75

Hospitalisation : Age :

Onset Date: 29/07/2008 **DOB**: 26/05/1971

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Paraesthesia

Felt pins and needles,
generally tingling, became
sweaty, hot inside,
vomiting, dilated pupils.

Thoughts of self harm,

frightened.

Fear

Hyperhidrosis

Mydriasis

Self-injurious ideation

Vomiting

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Tablet 37.5 Milligram 1 time Oral

Batch: **Started**: 29/07/2008 **Stopped**: 29/07/2008

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Cases Count: 172

Gender: F

Case Number : 244775

Data Entry Date: 22/09/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: 08/09/2008 DOB: 31/12/1951

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Withdrawal syndrome Incapacity/disability Drug withdrawal syndrome: felt dizzy/woozy, nausea,

confusion, not mentally alert, exhausted and fatigued in whole body, feeling very anxious and

constipation.

Anxiety Incapacity/disability

Confusional state Incapacity/disability
Constipation Incapacity/disability

Disturbance in attention Incapacity/disability

Dizziness Incapacity/disability

Fatigue Incapacity/disability

Nausea Incapacity/disability

Medicine details:

EFEXOR-XR (Suspected) Reason :

Capsule 75 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 172

Case Number : 244812

Gender: F

Data Entry Date: 23/09/2008 Weight (kg): 0

Hospitalisation: Required a visit to the doctor **Age**: 34Y

Onset Date: 15/04/2008 **DOB**:

Outcome: Causality: Causality certain

Not yet recovered

Information: Cert (rechall)

Reaction:

Preferred Term Severity Report Description Treatment

Malaise Has not felt well, feels Cease Efexor, change to

detached and numb. When Duloxetine she forgets to take it

feelings disappear and she feels more "alive" for about

6 hours.

Hypoaesthesia Indifference

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Tablet 75 Milligram Daily Oral

Batch: Started: 15/03/2008 Stopped:

CALCIUM NOS (Other drug) Reason :

Batch: Started: Stopped:

Detrusitol (Other drug) Reason :

2 Milligram Daily

Batch: Started: Stopped:

FISH OIL NOS (Other drug) Reason :

3 Gram Daily

Batch: Started: Stopped:

Mirtazon (Other drug) Reason :

90 Milligram Daily

Batch: Started: Stopped:

SELENIUM SULPHIDE (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Gender: F

Case Number: 244813

Data Entry Date: 23/09/2008 Weight (kg): 0

Hospitalisation: Required a visit to the doctor **Age:** 34Y

Onset Date: 15/04/2008 DOB:

Outcome: Causality: Causality certain

Not yet recovered

Information: Cert (Rechall)

Reaction:

Dizziness Myalgia

Preferred Term Severity **Report Description Treatment**

Withdrawal syndrome Withdrawal symptoms, like Efexor ceased, changed to duloxetine

pins and needles, dizzy head, muscle anche and

pains.

Paraesthesia Medicine details: EFEXOR-XR (Suspected) Reason: Depression 75 Milligram Tablet Daily Oral Started: 15/03/2008 Stopped: Batch: **CALCIUM NOS (Other drug)** Reason:

Batch: Started: Stopped:

Detrusitol (Other drug) Reason:

2 Milligram Daily

Started: Batch: Stopped:

FISH OIL NOS (Other drug) Reason:

> 3 Gram Daily

Batch: Started: Stopped:

Mirtazon (Other drug) Reason:

> 4 Milligram Daily

Batch: Started: Stopped:

SELENIUM SULPHIDE (Other drug) Reason:

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 244832

Gender: M

Data Entry Date: 24/09/2008

Weight (kg): 0

Hospital is at ion:

Age:

Onset Date: 01/07/2008

DOB: 30/12/1983

Outcome:

Causality: Causality probable

Not yet recovered

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Insomnia and neck pain

Ceased Efexor, temazepam

Neck pain

Medicine details:

EFEXOR-XR (Suspected)

Reason: Anxiety neurosis

Tablet

75 Milligram

Daily

Oral

Batch:

Started: 01/07/2008

Stopped: 04/08/2008

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Cases Count: 172

Case Number: 244902

Gender: M

Data Entry Date: 26/09/2008 **Weight (kg)**: 0

Hospitalisation: Treated in Accident/Emergency Depar Age:

Onset Date: 31/08/2008 **DOB**: 16/06/1970

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Anorexia Seq 1: ON EFEXOR Loss Seq.1 Efexor stopped; seq 2: of appetite worsened since not stated

being on Efexor XR, sleepiness all through the day, did not sleep well, dizziness and headache. Also experienced a seizure whilst driving resulting in a

car accident.

SEq 2 : OFF Efexor :He has also experienced headaches since stopping

Efexor XR.

Convulsion

Dizziness

Headache

Rebound effect

Somnolence

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 75 Milligram Daily Oral

Batch: **Started**: 31/08/2008 **Stopped**: 21/09/2008

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Cases Count: 172

Case Number : 244941

Gender: M

Data Entry Date: 29/09/2008

Weight (kg): 0

Hospitalisation: Admitted to hospital

Age: 50Y

Onset Date :

DOB:

Outcome:

Causality: Causality certain

Treatment

Recovered

Information: CERT

Reaction:

Preferred Term Severity Report Description

Serotonin syndrome

After 100 mg top-up of
Tramadol sudden onset

Venlafaxine and tramadol ceased

confusion, psychomotor

agitation, visual

hallucinations, postural

tremor.

Medicine details:

CLONIDINE HYDROCHLORIDE (Interaction) Reason :

300 Microgram Daily

Batch: Started: Stopped:

FENTANYL (Interaction) Reason :

200 Microgram Daily

Batch: Started: Stopped:

OXYCODONE HYDROCHLORIDE (Interaction) Reason : Pain

20 Milligram Daily

Batch: Started: Stopped:

TRAMADOL HYDROCHLORIDE (Interaction) Reason :

100 Milligram 1 time

Batch: Started: Stopped:

TRAMADOL HYDROCHLORIDE (Interaction) Reason : Pain

200 Milligram Daily

Batch: Started: Stopped:

VENLAFAXINE HYDROCHLORIDE (Interaction) Reason : Depression

75 Milligram Daily

Batch: Started: Stopped: 0

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Cases Count: 172

Age:

Case Number: 245407

Gender: F

Data Entry Date: 14/10/2008 **Weight (kg)**: 60

Onset Date : DOB : 07/10/1977

Outcome: Causality: Causality certain

Recovered

Hospitalisation: Required a visit to the doctor

Information: Cert(rechall)

Reaction:

Preferred Term Severity Report Description Treatment

Withdrawal syndrome Patient startes that if

misses dose by every 1-2 hours-> severe shooting head pains, like electic shock, ceased 20 mins after taking missed tablet.

Headache Paraesthesia

Medicine details:

EFEXOR (Suspected) Reason : Depression

Capsule 150 Milligram Daily Oral

Batch: **Started**: 09/05/2008 **Stopped**: 08/08/2008 0

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Cases Count: 172

Case Number: 245451

Gender: M

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

Age:

Hospitalisation:

Onset Date: 11/10/2008

DOB: 18/08/1953

Outcome: 13/10/2008

Causality: Causality probable

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Paranoia

Incapacity/disability

severe paranoid ideatiation, exacerbation of

cessation of medication led to resolution of symptoms over 24

anxiety symptoms

hours

Anxiety Incapacity/disability

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Capsule

75 Milligram

1 time

Oral

Batch: 69227A

Started: 08/10/2008

Stopped: 12/10/2008

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Cases Count: 172

Case Number: 245545

Gender: F

Data Entry Date: 16/10/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Withdrawal syndrome Incapacity/disability

"Suffering terribly trying to get off Efexor XR" and was "unable to wean off Efexor

XR", "debilitating headaches", vertigo, nausea and "effects the most simple of her daily tasks let alone trying to do a day's work". The patient also "feels that Efexor XR

is addictive".

Headache Incapacity/disability
Nausea Incapacity/disability
Vertigo Incapacity/disability

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 37.5 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 172

Gender: F

Case Number: 245648

Data Entry Date: 20/10/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: 18/11/2006 DOB: 01/09/1976

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Urticaria Started Efexor gradually 75mg up to 300mg.

Urticaria, fever, bruising, weight gain, constipation.

Constipation

Contusion Pyrexia

Weight increased

Medicine details:

Acidophilus (Suspected) Reason :

Tablet 1 Dose Unspec Daily Oral

Batch: Started: Stopped:

EFEXOR (Suspected) Reason: Depression

300 Milligram Daily

Batch: Started: 30/10/2006 **Stopped:** 21/11/2006

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Cases Count: 172

Case Number: 245727

Gender: F

Data Entry Date: 22/10/2008

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Drug effect decreased

Incapacity/disability

Patient experienced "not able to achieve remission", "still not able to return to work", restlessness and flushing on increased

Reluctant to change to another agent as the patient has had some response with Efexor XR.

dose.

Flushing

Restlessness

Incapacity/disability

Impaired work ability

Incapacity/disability Incapacity/disability

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Oral

Batch:

Started:

Stopped:

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Cases Count: 172

Case Number: 245843

Gender: M

Data Entry Date: 27/10/2008

Weight (kg): 0

Hospitalisation:

Age: 49Y

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

Therapy continued.

Withdrawal syndrome

Experienced suicidal thought when stopped

thought when stopped Efexor-XR abruptly for 4

days.

Suicidal ideation

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 75 Milligram Daily Oral

Batch: Started: Stopped:

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Cases Count: 172

Gender: F

Case Number : 245846

Data Entry Date: 27/10/2008 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date: 15/09/2008 DOB: 06/11/1921

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Gastroenteritis Caused or prolonged

inpatient hospitalisation Experienced diarrhoea, gastroenteritis, vomiting, lost 1 stone in weight, gagging on false teeth, drug withdrawal syndrome. Now feels weak, cant eat, nausea, feeling very sick and mild abdominal pain/stomach pains.

Abdominal pain Caused or prolonged

inpatient

hospitalisation

Anorexia Caused or prolonged

inpatient

hospitalisation

Asthenia Caused or prolonged

inpatient

hospitalisation

Drug withdrawal syndrome Caused or prolonged

inpatient

hospitalisation

Malaise Caused or prolonged

inpatient

hospitalisation

Nausea Caused or prolonged

inpatient

hospitalisation

Retching Caused or prolonged

inpatient

hospitalisation

Vomiting Caused or prolonged

inpatient

hospitalisation

Weight decreased Caused or prolonged

inpatient

hospitalisation

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 150 Milligram Daily Oral

Batch : Started : Stopped :

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Cases Count: 172

Case Number : 246015

Gender: F

Data Entry Date: 06/11/2008

Weight (kg): 0

Hospitalisation: Required a specialist consultation

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

CT of neck did not find anything

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Paraesthesia Pins and needles in her

toes, which progressed to the soles of her feet, and then to her fingers, "feet felt like blocks of wood", "motor ability slowed down", "muscle strength lost in legs, knees caved in", "can now not walk up stairs or climb the bus", "sense of balance is compromised", "cannot walk in a straight line and movement is like someone with cerebral palsy", "feet felt ice cold" and sense of

taste was affected.

Paraesthesia

Medicine details:

EFEXOR-XR (Suspected) Reason:

300 Milligram Oral

Batch: Started: Stopped:

EFEXOR-XR (Suspected) Reason: Behavior disorders of childhod

Capsule 75 Milligram Daily Oral

Batch: Started: 15/09/2007 Stopped: Contin

RITALIN (Other drug) Reason :

Tablet, modified release 30 Milligram

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Computerised axial

tomography

Nerve Conduction Nothing found

Studies

Other data spinal x-ray did not find anything wrong.

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Cases Count: 172

Case Number : 246112

Gender: M

Data Entry Date: 10/11/2008

Weight (kg): 0

Hospitalisation:

Age:

Onset Date :

DOB: 28/09/1950

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Ventricular hypokinesia

Preferred Term Severity

Report Description

Treatment

The patient with a history of hypertension and smoking, had an echocardiogram which revealed left atrial

enlargement, a normal left ventricular size and function but a sigmoid shaped septum and a marked difference in the left ventricular shortening in comparison to the last year's echocardiogram which was not commented upon previously. Prior to

this another

echocardiogram performed on 10/08/08 noted sinus tachycardia and a patrial right bundle branch block. No such events were reported in echocardiograms

performed on 02/08/08 and 21/06/08.

Bundle branch block right

Sinus tachycardia

Tachycardia

3

Medicine details:

CLOZARIL (Suspected) Reason: Unspecified schizophrenia

Tablet 600 Milligram Daily Oral

Batch: Started: Stopped:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason :

225 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Type Range Date Tested Result Details

Echocardiogram 21/06/2006 Normal size and

function

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Laboratory Inves	stigations :			
Туре	Range	Date Tested	Result	Details
Echocardiogram		02/08/2007	Normal left ventricular systolic function, normal valve function	
Echocardiogram		10/08/2008	Sinus tachycardia and partial RBBB	
Echocardiogram		08/10/2008	Marked difference in the left ventricular shortening in com[parison to last year echocardiogram. Right ventricular systolic pressure 35mmHg.	

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Cases Count: 172

Case Number: 246134

Gender: M

Data Entry Date: 11/11/2008

Weight (kg): 0

Hospitalisation:

Age: 18Y

Onset Date: 26/09/2008

DOB:

Outcome:

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term

Report Description

Treatment

Severity Dystonia

? Dystonic reaction to

2 mg Benztropine.

acuphase.

Medicine details:

VENLAFAXINE HYDROCHLORIDE (Interaction)

Reason: Depression

300 Milligram

50 Milligram

Daily

Batch:

Started:

Stopped:

ZUCLOPENTHIXOL ACETATE (Interaction)

Reason:

2 times

Cyclical

Batch:

Started: 23/09/2008

Stopped: 25/09/2008

0

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RISPERIDONE (Other drug)

Reason:

37.5 Milligram

Stopped:

Batch:

Started:

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Cases Count: 172

Gender: M

Case Number: 246428

Data Entry Date: 20/11/2008 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date: **DOB**: 03/08/1970

Outcome : Causality : Causality possible

Not yet recovered

Information:

Information.			
Reaction:			
Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Incapacity/disability	Suicidal tendencies/suicidal thoughts/"death would be better than this", brain zaps which feel like "electric shock treatment", "not feeling calm" and "over 50 side effects". The patient also experienced insomnia since stopping Efexor XR. At the time of follow-up, the patient had also experienced convulsions, heat stroke, loss of memory and headaches. The reporter advised that the patient "can only work part-time since being on medication" and was "not motivated" when taking Efexor XR. The reporter also clarified that the patient experienced "39 side effects during and when coming off" Efexor XR. Additional drug withdrawal symptoms included panic attack and grumpy.	Valium
Amnesia	Incapacity/disability		
Anxiety	Incapacity/disability		
Apathy	Incapacity/disability		
Convulsion	Incapacity/disability		
Headache	Incapacity/disability		
Heat stroke	Incapacity/disability		
Insomnia	Incapacity/disability		
Panic attack	Incapacity/disability		
Paraesthesia	Incapacity/disability		
Withdrawal syndrome	Incapacity/disability		

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Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

Capsule 37.5 Milligram Daily Oral

Batch: Started: Stopped: 0

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Cases Count: 172

Case Number: 246493

Data Entry Date: 24/11/2008

Weight (kg): 60

Gender: F

Hospitalisation:

Age: 27Y

Onset Date : 30/06/2008

DOB:

Outcome :

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

Report Description

Treatment

low blood sugar in insulin

eating more frequently

dependent diabetic

Medicine details:

Blood glucose decreased

VENLAFAXINE HYDROCHLORIDE (Suspected)

Reason:

Daily

Batch:

Started:

Stopped:

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Cases Count: 172

Case Number: 246661

Gender: M

Data Entry Date: 27/11/2008

Weight (kg): 117

Hospitalisation:

Age:

Onset Date:

DOB: 06/04/1972

Outcome: 08/10/2008

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description**

Treatment

Anxiety

1st week after, onset of Efexor, anxiety, unusual reaction, with increase paranoia, suicidal thought, violent behaviour, had to hold himself back to stop. Settled after 1 week. Poor memory and strong

cravings for alcohol.

Aggression Alcoholism

Memory impairment

Paranoia

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Capsule

37.5 Milligram

Daily

Oral

Batch:

Started: 01/08/2008

Stopped:

0

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Cases Count: 172

Gender: F

Case Number: 246732

Data Entry Date: 02/12/2008 **Weight (kg)**: 0

Hospitalisation: Required a visit to the doctor **Age**: 46Y

Onset Date: 01/11/2008 **DOB**:

Outcome: Causality: Causality possible

Not yet recovered

Information:

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т.				
	vч	vu	•	

Preferred Term Severity Report Description Treatment

Miosis With discontinuation of

venlafaxine-marked miosis,

minimally reactive, dizziness, nausea, fatigue.

Dizziness

Fatigue

Nausea

Withdrawal syndrome

Medicine details :

EFEXOR-XR (Suspected)Reason: Menopausal symptoms

Capsule 150 Milligram Daily Oral

Batch: **Started**: 15/01/2008 **Stopped**: 15/10/2008

ENDONE (Other drug) Reason :

Tablet Oral

Batch: Started: Stopped:

PETHIDINE HYDROCHLORIDE (Other drug) Reason :

Batch: Started: Stopped:

TAMOXIFEN CITRATE (Other drug) Reason :

Tablet 20 Milligram Oral

Batch: Started: Stopped:

TEMAZE (Other drug) Reason : Specific disorders of sleep

Tablet 10 Milligram Daily Oral

Batch: Started: Stopped:

VENLAFAXINE HYDROCHLORIDE (Other drug) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 246881

Gender: F

Data Entry Date: 08/12/2008 **Weight (kg)**: 0

Hospitalisation: Age: 99u

Onset Date: 06/10/2008 **DOB**:

Outcome: Causality: Causality possible

Death, maybe drug

Information: Baby girl born 06/10/2008. Mother taking 225mg daily. Mother has past history of

amphetamine use. Not confirmed whether she used any substances during the the

pregnancy (however, tox screen was negative). tal

Reaction:

Preferred Term Severity Report Description Treatment

Respiration abnormal Congenital anomaly / At birth: irregular

birth defect respirations (CPAP), foetal distress. Following: poor perfusion, decreased tone,

grunting and jittery.

Maternal drugs affecting

fetus.

Foetal distress syndrome Congenital anomaly /

birth defect

Hypoperfusion Congenital anomaly /

birth defect

Maternal drugs affecting foetus Congenital anomaly /

birth defect

Medicine details:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason :

225 Milligram Daily

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 246963

Data Entry Date: 09/12/2008 Weight (kg): 0

Hospitalisation : Age :

Onset Date: 11/11/2007 DOB: 27/08/1944

Outcome : Causality : Causality possible

Recovered

Information:

Reaction:

Preferred Term	Severity		Report Desc	ription	Treatment
Hyponatraemia			Hyponatraem	nia.	Ceased venlafaxine.
Medicine details :					
Olmesartan-hydrochlorothiazide (Su	uspected)	F	Reason :		
Batch :	Started :			Stopped :	
VENLAFAXINE HYDROCHLORIDE (Suspected)	F	Reason :		
Capsule		150 Milligram	Daily		Oral
Batch :	Started :			Stopped :	13/11/2007
DIAZEPAM (Other drug)		F	Reason :		
Batch :	Started :			Stopped :	
MORPHINE SULPHATE (Other drug))	F	Reason :		
Batch :	Started :			Stopped :	
MS CONTIN (Other drug)		F	Reason :		
Batch :	Started :			Stopped :	
SIMVASTATIN (Other drug)		F	Reason :		-
Batch :	Started :			Stopped :	
Symbicort Turbuhaler (Other drug)		F	Reason :		
Batch :	Started :			Stopped :	

Laboratory Investigations:

Type Range Date Tested Result Details
Sodium 129
Urine Sodium 28

Urine osmolality Normal 351

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Cases Count: 172

Case Number: 247016

Data Entry Date: 09/12/2008

Weight (kg): 105

Gender: M

Hospitalisation:

Age:

Onset Date: 28/11/2008

DOB: 08/01/1951

Outcome: 08/12/2008

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Suicidal ideation Incapacity/disability Was well controlled on

Venlafaxine, changed to Desvenlafaxine and rapidly developed suicidal

ideation, bad dreams, early morning wakening, memory loss, angry

outbursts.

Amnesia Incapacity/disability Anger Incapacity/disability Early morning awakening Incapacity/disability

Nightmare Incapacity/disability

Medicine details:

Pristiq (Suspected) Reason:

Capsule 75 Milligram Daily Oral

Started: 28/11/2008 Stopped: 01/12/2008 0 Batch:

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Cases Count: 172

Case Number: 247156

Weight (kg): 66

Data Entry Date: 15/12/2008

Age:

Gender: M

Hospitalisation:

Ago .

Onset Date: 02/12/2008

Outcome: 15/12/2008

Causality: Causality possible

DOB: 15/09/1958

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Anxiety Incapacity/disability Fatigue, very anxious, not Medication ceased and Efexor sleeping, incoherent restarted.

sleeping, incoherent speech with slurring of words, profuse sweating,

poor appetite.

Anorexia Incapacity/disability
Dysarthria Incapacity/disability
Fatigue Incapacity/disability
Hyperhidrosis Incapacity/disability

Incoherent Incapacity/disability

Insomnia Incapacity/disability

Medicine details:

Pristiq (Suspected) Reason : Depression

Tablet 50 Milligram 1 time Oral

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Hospitalisation:

Outcome:

Public Case Detail

Cases Count: 172

Case Number: 247158

Gender: F

Data Entry Date: 16/12/2008 **Weight (kg)**: 51

Age: 34Y

Onset Date: 13/11/2008

DOB:

50: 54:5: 10/11/2000

Causality: Causality possible

Recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Drug withdrawal syndrome Experienced suspected patient was started on Pristiq

withdrawal from Efexor XR, with vomiting, dizziness

and nausea

Medicine details:

EFEXOR-XR (Suspected) Reason : Depression

150 Milligram Oral

Batch: Started: Stopped:

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Cases Count: 172

Gender: M

Case Number: 247265

Data Entry Date: 19/12/2008 **Weight (kg)**: 0

Hospitalisation: Hospitalisation prolonged Age:

Onset Date : DOB : 01/12/2008

Outcome: Causality: Causality possible

Unknown

Information:

Reaction:

Preferred TermSeverityReport DescriptionTreatmentDrug exposure duringCaused or prolongedMother switched fromas above

Drug exposure during pregnancy Caused or prolonged inpatient Mother switched from Venlafaxine to Sertraline

hospitalisation during 3rd trimester of pregnancy. Baby born with persistant pulmonary hypertension (currently

recovering in neonatal

ICU)

Pulmonary hypertension Caused or prolonged

inpatient hospitalisation

Medicine details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason:

Batch: Started: Stopped:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason :

Batch: Started: Stopped:

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Cases Count: 172

Gender: F

Case Number: 247267

Data Entry Date: 19/12/2008 **Weight (kg)**: 0

Hospitalisation : Age :

Onset Date: DOB: 12/11/1951

Outcome: Causality: Causality possible

Not yet recovered

Information: CT scan could not confirm seizure. Tremor is ongoing but other symptoms have

resolved. Efexor is ongoing. EEG was done and results are pending.

Reaction: **Preferred Term Report Description Treatment** Severity Caused or prolonged Experienced occasional Syncope tremors at night, lost inpatient control of her bladder, hospitalisation heavy sweating and passed out. The patient's treating doctor suspected a seizure. Also reported withdrawal symptoms such as dizziness. Dizziness Caused or prolonged inpatient hospitalisation Caused or prolonged Hyperhidrosis inpatient hospitalisation Tremor Caused or prolonged inpatient hospitalisation Caused or prolonged Urinary incontinence inpatient hospitalisation Withdrawal syndrome Caused or prolonged inpatient hospitalisation

Medicine details	• •					
EFEXOR-XR (Suspected)		Re	ason : Depre	ession		
Capsule		75 Milligram	Daily	Oral		
Batch :	Started :			Stopped :	0	
ATACAND (Other drug)		Re	ason :			
Batch :	Started :			Stopped :		
CARTIA (Other drug)		Re	ason :			
Batch :	Started :			Stopped :		
HYDROCHLOROTHIAZIDE (O	ther drug)	Re	ason :			
Batch :	Started :			Stopped :		

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Medicine details	:			
PARIET (Other drug)		Reason:		
Batch :	Started :	Stopped :		
TRAMAL (Other drug)		Reason:		
Batch :	Started :	Stopped :		

Laboratory Investigations:

Type Range Date Tested Result Details

Electroencephalograph EEG on 5 December 2008: normal,

confirmed that the patient did not have epilepsy.

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Cases Count: 172

Case Number: 247714

Gender: M

Data Entry Date: 15/01/2009

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Suicidal ideation

Suicidal thoughts, not recovered from depression, sexual dysfunction and thoughts

of harming his family.

Depression

Drug ineffective

Homicidal ideation

Sexual dysfunction

Medicine details:

EFEXOR-XR (Suspected)

Reason: Depression

Capsule

Oral

Batch:

Started:

Stopped:

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Cases Count: 172

Case Number: 247831

Gender: M

Weight (kg): 0

Data Entry Date: 20/01/2009

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome:

Causality: Causality probable

Unknown

Information:

Reaction:

Preferred Term Severity **Report Description Treatment**

Drug withdrawal syndrome

Has been on venlafaxine for more than ten years. Tried to stop (tapering) 5 years ago. After 2-3 weeks developed akathisia and was forced to go back on it

(300mg)

This year tried again, tapering for 4 months. The same thing has happened, is now back on 300mg.

Akathisia

Medicine details:

VENLAFAXINE HYDROCHLORIDE (Suspected) Reason:

300 Milligram Oral Capsule Daily

Batch: Started: Stopped:

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Cases Count: 172

Case Number: 247931

Gender: M

Data Entry Date: 22/01/2009

Weight (kg): 0

Hospitalisation:

Age:

Onset Date: 15/11/2008

DOB: 13/02/1950

Outcome:

Not yet recovered

Causality: Causality possible

Information:

Reaction:

Preferred Term

Severity

Report Description

Treatment

Suicidal ideation

Suicidal thoughts, never gets any sleep - only 3 hours, headaches. Only put on 10kg in weight.

Drug ineffective

Headache

Insomnia

Weight increased

Medicine details:

Pristiq (Suspected)

Reason: Depression

Tablet

250 Milligram

Daily

Oral

Batch:

Started :

Stopped:

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Cases Count: 172

Case Number: 247937

Gender: F

Data Entry Date: 23/01/2009

Weight (kg): 0

Hospitalisation:

Age: 99u

Onset Date :

DOB:

Outcome:

Causality: Causality possible

Unknown

Information:

Reaction:

Preferred Term Severity

Report Description Treatment

Inappropriate schedule of drug

patient would miss once

administration

daily doses

Abortion spontaneous

Dizziness

Drug exposure during

pregnancy

Medicine details:

EFEXOR-XR (Suspected) Reason :

Capsule 75 Milligram Oral

Batch: Started: 01/08/2007 Stopped:

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Cases Count: 172

Case Number : 247943

Gender: F

Data Entry Date: 23/01/2009 **Weight (kg)**: 0

Hospitalisation: Age:

Onset Date: 23/05/2008 **DOB**: 24/12/1930

Outcome: Causality: Causality possible

Not yet recovered

Information:

Reaction:

Preferred Term Severity Report Description Treatment

Hepatic failure

Medicine details:

EFEXOR (Suspected) Reason:

Capsule 150 Milligram Daily Oral

Batch: Started: L TERM Stopped: 0

LIPITOR (Suspected) Reason :

Batch: Started: Stopped: 0

COVERSYL (Other drug) Reason :

Batch: Started: Stopped: 0

Laboratory Investigations:

Type Range Date Tested Result Details

Liver function tests 07/01/2009 Bil 10, AST 41,ALT

49, GGT 76, ALP

155

Selection Parameters: Date Range: 01/08/2007 To 31/01/2009 Unclear causality excluded GM medicines Only Medicine Names: EFEXOR, EFEXOR-XR, VENLAFAXINE HYDROCHLORIDE, Desvenlafaxine, Pristiq

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