

Public Case Detail

Cases Count: 172

Case Number : 231421

Data Entry Date : 01/08/2007

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 60

Onset Date : 18/06/2007

Age :

DOB : 26/07/1949

Outcome : 19/06/2007

Causality : Causality possible

Recovered

Information: History of diabetes, alcoholic. Full improvement with fluids, glucose and recommencement of medication.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation	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	Ambulance called for drowsiness. Fluid and glucose given.

Medicine details :

EFEXOR-XR (Suspected)

Reason : Depression

Capsule

150 Milligram Daily

Oral

Batch :

Started :

L TERM

Stopped : 14/06/2007

0

Case Number : 231460

Data Entry Date : 02/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation	Pneumonia, drug withdrawal syndrome, dysphagia, muscle twitching, staring, infection, nervousness. See attachment.	
Dysphagia	Caused or prolonged inpatient 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 hospitalisation		

Medicine details :

EFEXOR-XR (Suspected)

Reason :

Capsule

75 Milligram

Oral

Batch :

Started :

Stopped : 15/07/2007

0

Public Case Detail

Cases Count: 172

Case Number : 231519

Data Entry Date : 05/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 63

Onset Date : 01/10/2002

Age :

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 :	

Public Case Detail

Cases Count: 172

Case Number : 231523

Data Entry Date : 06/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Drug exposure during pregnancy		had been taking Efexor for approximately 2.5 weeks	cease Efexor
Abortion spontaneous		the patient could not confirm whether the miscarriage occurred after stopping or during Efexor treatment	

Medicine details :			
EFEXOR-XR (Suspected)		Reason : Depression	
Capsule	75 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Case Number : 231897

Data Entry Date : 13/08/2007

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 51

Onset Date : 20/06/2007

Age : 80Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Mania	Caused or prolonged inpatient hospitalisation	Increased energy and activity, increased amount of speech, insomnia, irritability and disinhibition.	Venlafaxine ceased. Lithium commenced.
Disinhibition	Caused or prolonged inpatient 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 :

VENLAFAXINE HYDROCHLORIDE (Suspected)	Reason : Depression
75 Milligram Daily	
Batch :	Started : 04/06/2007 Stopped : 04/07/2007 0
ATORVASTATIN (Other drug)	Reason : Othr&unspec metabolic diseases
Batch :	Started : Stopped :
GLICLAZIDE (Other drug)	Reason : Diabetes mellitus
Batch :	Started : Stopped :
METFORMIN HYDROCHLORIDE (Other drug)	Reason : Diabetes mellitus
Batch :	Started : Stopped :

Medicine details :

PROPRANOLOL HYDROCHLORIDE (Other drug)

Reason : Essential benign hypertension

Batch :

Started :

Stopped :

Public Case Detail

Cases Count: 172

Case Number : 231946

Data Entry Date : 14/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

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		

Medicine details :

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 :

Public Case Detail

Cases Count: 172

Case Number : 231986

Data Entry Date : 15/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 117

Onset Date : 10/07/2007

Age :

DOB : 04/11/1969

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		drug withdrawal symptoms like severe nausea, sweating, dizziness, insomnia	

Medicine details :

EFEXOR-XR (Suspected)		Reason : Depression	
Capsule	450 Milligram	Daily	Oral
Batch :	Started : 08/01/2005	Stopped : 07/10/2007	

Public Case Detail

Cases Count: 172

Case Number : 232096

Data Entry Date : 16/08/2007

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 67

Onset Date : 18/07/2007

Age :

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

Data Entry Date : 16/08/2007

Hospitalisation :

Onset Date : 25/06/2007

Outcome :
Recovered

Gender : F

Weight (kg) : 0

Age : 42Y

DOB :

Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Patient experienced twitching and tingling in arms and legs, serotonin syndrome.	Efexor ceased.
Hepatitis chronic active			
Liver function test abnormal			

Medicine details :			
EFEXOR (Suspected)		Reason : Depression	
	150 Milligram	Daily	
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
GGT = SGGT = GGTP		09/02/2007	512	
GGT = SGGT = GGTP		25/06/2007	3407	
GGT = SGGT = GGTP		26/07/2007	1632	
AST = SGOT		25/06/2007	465	
AST = SGOT		26/07/2007	253	
ALT = SGPT		25/06/2007	248	
ALT = SGPT		26/07/2007	126	
SAP = ALP		25/06/2007	275	
SAP = ALP		26/07/2007	234	
Bilirubin		25/06/2007	28	
Bilirubin		26/07/2007	5	

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Case Number : 232153

Data Entry Date : 17/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 83

Onset Date : 20/01/2006

Age :

DOB : 26/03/1939

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Micturition disorder		Delayed start to urinate and very slow urination, dry mouth, emotional lability, nightmares, libido decreased and erection failure.	Efexor-XR ceased.
Affect lability			
Dry mouth			
Erectile dysfunction			
Libido decreased			
Nightmare			

Medicine details :

EFEXOR-XR (Suspected)		Reason : Depression	
Capsule	75 Milligram	Daily	Oral
Batch :	Started : 10/01/2006	Stopped : 29/01/2006	
ZYLOPRIM (Other drug)		Reason : Gout	
Tablet	150 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Case Number : 232167

Data Entry Date : 17/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 19/12/1956

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal			
Malaise			

Medicine details :

EFEXOR-XR (Suspected)		Reason : Depression	
Capsule	300 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
DIAZEPAM (Other drug)		Reason :	
	5 Milligram		
Batch :	Started :	Stopped :	
GLUCOSAMINE HYDROCHLORIDE (Other drug)		Reason :	
	1 Gram		
Batch :	Started :	Stopped :	0
LOSEC (Other drug)		Reason :	
	40 Milligram		
Batch :	Started :	Stopped :	0
TEMAZEPAM (Other drug)		Reason :	
	10 Milligram		
Batch :	Started :	Stopped :	

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Cases Count: 172

Case Number : 232170

Data Entry Date : 17/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/05/2007

Age :

Outcome : 04/06/2007

DOB : 30/08/1959

Recovered

Causality : Causality possible

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	

Public Case Detail

Cases Count: 172

Case Number : 232330

Data Entry Date : 21/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 67

Onset Date : 20/07/2007

Age :

DOB : 01/05/1960

Outcome :

Causality : Causality probable

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced probable tonic-clonic seizure.	Ceased Efexor.

Medicine details :			
EFEXOR (Suspected)		Reason : Depression	
Tablet	75 Milligram	Daily	Oral
Batch :	Started : 10/06/2007	Stopped : 20/07/2007	

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Case Number : 232454

Data Entry Date : 24/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Rash	Caused or prolonged inpatient hospitalisation	Gradual onset of rash on both lower limbs over 4 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 :	

Case Number : 232466

Data Entry Date : 24/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 62

Onset Date :

Age :

Outcome : 21/08/2007

DOB : 27/03/1942

Recovered

Causality : Causality possible

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 :	Started :
	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 :

Public Case Detail

Cases Count: 172

Case Number : 232515

Data Entry Date : 27/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Blood pressure increased		pre-treatment: 110/70 and since treatment 200/120	

Medicine details :			
EFEXOR-XR (Suspected)		Reason : Depression	
Capsule	300 Milligram	Daily	Oral
Batch :	Started : 01/06/2001	Stopped :	ongoing

Public Case Detail

Cases Count: 172

Case Number : 232520

Data Entry Date : 27/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 24/07/2007

Age :

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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Case Number : 232644

Data Entry Date : 28/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 25Y

Outcome :

DOB :

Unknown

Causality : Causality possible

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

Reaction :

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

Case Number : 232662

Data Entry Date : 29/08/2007
Hospitalisation : Admitted to hospital
Onset Date : 06/08/2007
Outcome :
 Not yet recovered

Gender : F
Weight (kg) : 0
Age :
DOB : 09/05/1924
Causality : Causality possible

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 :			
RISPERIDONE (Suspected)	Reason :		
Batch :	Started :	Stopped :	
VENLAFAXINE HYDROCHLORIDE (Suspected)	Reason :		
Batch :	Started :	Stopped :	
AMIODARONE HYDROCHLORIDE (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 :	

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 :

Public Case Detail

Cases Count: 172

Case Number : 232918

Data Entry Date : 03/09/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 20/07/2007

Age : 47Y

Outcome :

DOB :

Recovered

Causality : Causality possible

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 :	
Batch :	Started :	Oral	Stopped : 0

Case Number : 232974

Data Entry Date : 04/09/2007

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 01/06/2006

Age :

Outcome : 02/03/2007

DOB : 28/11/1966

Recovered with sequelae

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug exposure during pregnancy	Congenital anomaly / birth defect	Drug exposure during 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	Oral
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
Batch :	Started : 01/06/2006	Stopped : 31/03/2007	

Case Number : 232986

Data Entry Date : 04/09/2007
Hospitalisation : Admitted to hospital
Onset Date : 09/07/2007
Outcome : 10/07/2007
 Recovered

Gender : F
Weight (kg) : 0
Age :
DOB : 02/03/2007
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Hernia congenital	Congenital anomaly / birth defect	Congenital diaphragmatic hernia. See attachment. Related to case 232974 involving the mother.	surgical correction

Medicine details :			
EFEXOR-XR (Suspected)		Reason :	
	150 Milligram	Daily	Intrauterine
Batch :	Started :	Stopped :	
Seretide 125/25 MDI (Suspected)		Reason :	
Batch :	Started :	Stopped :	
FOLIC ACID (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 232988

Data Entry Date : 04/09/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

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 :	L TERM	Stopped : 0
Seretide MDI Nos (Other drug)		Reason :	
			Inhalation
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 233347

Data Entry Date : 13/09/2007

Hospitalisation : Admitted to hospital

Onset Date :

Outcome :

Unknown

Gender : F

Weight (kg) : 0

Age : 42Y

DOB :

Causality : Causality possible

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
<hr/>			
VALIUM (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 233349

Data Entry Date : 13/09/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

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 :	

Public Case Detail

Cases Count: 172

Case Number : 233757

Data Entry Date : 25/09/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Drug exposure during pregnancy	Congenital anomaly / birth defect	Congenital "lung problems" and drug exposure during pregnancy. See attachment.	
Pulmonary malformation	Congenital anomaly / birth defect		

Medicine details :	
EFEXOR-XR (Suspected)	Reason :
Batch :	Started :
	Stopped :



Public Case Detail

Cases Count: 172

Case Number : 233877

Data Entry Date : 28/09/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident		Stroke. See attachment.	

Medicine details :

EFEXOR-XR (Suspected)	Reason :	
Batch :	Started :	Stopped :

Case Number : 233916

Data Entry Date : 02/10/2007
Hospitalisation : Admitted to hospital
Onset Date : 26/06/2007
Outcome :
 Not yet recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 15/03/1957
Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hallucination	Caused or prolonged inpatient hospitalisation	Patient experienced hallucinations, hyperreflexia, tremors, agitation and sweating, likely serotonin syndrome.	Ceased tramadol and venlafaxine, started risperidone.
Agitation	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)		Reason :	
Injection	100 Milligram	1 time	Intravenous
Batch :	Started : 25/06/2007	Stopped : 25/06/2007	0
TRAMAL (Suspected)		Reason : Pain	
	200 Milligram	Daily	
Batch :	Started : 17/06/2007	Stopped : 26/06/2007	0
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason : Depression	
	150 Milligram	Daily	
Batch :	Started : L TERM	Stopped : 26/06/2007	0

Medicine details :

ATENOLOL (Other drug)

Reason :

Batch : Started : L TERM Stopped : 0

CLONIDINE HYDROCHLORIDE (Other drug)

Reason : Pain

Batch : Started : Stopped : 0

DILTIAZEM HYDROCHLORIDE (Other drug)

Reason :

Batch : Started : L TERM Stopped : 0

ENDONE (Other drug)

Reason : Pain

Tablet 10 Milligram Daily Oral

Batch : Started : 12/06/2007 Stopped : 20/06/2007

SPIRONOLACTONE (Other drug)

Reason :

Batch : Started : L TERM Stopped :

Case Number : 234221

Data Entry Date : 10/10/2007

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 25/07/2007

Age : 33Y

Outcome : 10/08/2007

DOB :

Recovered

Causality : Causality probable

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

Reaction :

Preferred Term	Severity	Report Description	Treatment
Bruxism	Caused or prolonged inpatient hospitalisation	Patient experienced nocturnal teeth grinding (bruxism) also some teeth grinding during the day.	Venlafaxine ceased.

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 :

Case Number : 234228

Data Entry Date : 10/10/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 04/12/1985

Outcome :

Causality : Causality possible

Unknown

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

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hypoglycaemia		Patient developed postprandial hypoglycaemia.	

Medicine details :

AZATHIOPRINE (Suspected)	Reason :		
Batch :	Started :	Stopped :	
DEXAMPHEMINE SULPHATE (Suspected)	Reason :		
Batch :	Started :	Stopped :	
Humira (Suspected)	Reason :		
Injection	1 Dose Unspec		
Batch :	Started :	Stopped :	0
VENLAFAXINE HYDROCHLORIDE (Suspected)	Reason :		
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 234351

Data Entry Date : 15/10/2007

Hospitalisation : Admitted to hospital

Onset Date :

Outcome :
Unknown

Gender : M

Weight (kg) : 0

Age : 99u

DOB :

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Agitation	Caused or prolonged inpatient hospitalisation	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

Case Number : 234466

Data Entry Date : 17/10/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

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
Batch :	Started : Milligram Daily Oral
	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

Public Case Detail

Cases Count: 172

Case Number : 234569

Data Entry Date : 18/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 3.2

Onset Date : 25/09/2007

Age :

DOB : 25/09/2007

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion neonatal	Caused or prolonged inpatient hospitalisation	? seizure activity at 4.5 hours of age associated with back arching, cycling and jitteriness.	Intravenous fluids commenced. Infant retrieved to Flinders Medical Centre Level Three NICU. 1 x dose of Intravenous Phenobarb given.
Drug exposure during pregnancy	Caused or prolonged inpatient hospitalisation		
Feeling jittery	Caused or prolonged inpatient hospitalisation		
Opisthotonus	Caused or prolonged inpatient hospitalisation		

Medicine details :

EFEXOR (Suspected)		Reason :	
Tablet		1 time	Oral
Batch :	Started : 01/01/2004	Stopped :	
OLANZAPINE (Suspected)		Reason :	
Tablet		1 time	Oral
Batch :	Started : 01/01/2004	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Albumin				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.



Public Case Detail

Cases Count: 172

Case Number : 234856

Data Entry Date : 29/10/2007

Hospitalisation :

Onset Date :

Outcome :

Recovered

Gender : F

Weight (kg) : 0

Age : 50Y

DOB :

Causality : Causality possible

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

Public Case Detail

Cases Count: 172

Case Number : 235174

Data Entry Date : 12/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 30/10/2007

Age : 56Y

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 :	

Public Case Detail

Cases Count: 172

Case Number : 235196

Data Entry Date : 12/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 30/10/2007

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

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 :

Case Number : 235206

Data Entry Date : 13/11/2007
Hospitalisation : Admitted to hospital
Onset Date :
Outcome : 15/09/2007
 Recovered

Gender : F
Weight (kg) : 51.5
Age :
DOB : 11/01/1967
Causality : Causality possible

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
Batch :	Started :	L TERM	Stopped : 15/09/2007
SPORANOX (Suspected)		Reason : Moniliasis	
Capsule	100 Milligram	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 :	
Batch :	Started :	Stopped :	0

Case Number : 235329

Data Entry Date : 15/11/2007

Hospitalisation :

Onset Date :

Outcome :

Not yet recovered

Gender : M

Weight (kg) : 0

Age : 44Y

DOB :

Causality : Causality possible

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 :	

Public Case Detail

Cases Count: 172

Case Number : 235439

Data Entry Date : 20/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
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	Oral
Batch :	Started :	Stopped :	

Case Number : 235493

Data Entry Date : 21/11/2007

Gender : F

Hospitalisation :

Weight (kg) : 70

Onset Date :

Age : 47Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged	Caused or prolonged inpatient hospitalisation	Patient experienced an increased QT interval, was anxious, tense, somewhat flat.	Ceased venlafaxine and started on Ziprazidone.
Anxiety	Caused or prolonged 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
Batch :	Started : Stopped :
SIMVASTATIN (Other drug)	Reason :
	40 Milligram
Batch :	Started : Stopped :

Public Case Detail

Cases Count: 172

Case Number : 235569

Data Entry Date : 22/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 78

Onset Date : 18/11/2007

Age :

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	

Public Case Detail

Cases Count: 172

Case Number : 235589

Data Entry Date : 23/11/2007

Gender : U

Hospitalisation : Required a visit to the doctor

Weight (kg) : 70

Onset Date : 14/11/2007

Age :

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	

Public Case Detail

Cases Count: 172

Case Number : 235658

Data Entry Date : 26/11/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/10/2007

Age : 46Y

DOB :

Outcome :

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 inpatient hospitalisation	cluster migraines	

Medicine details :

EFEXOR-XR (Suspected)		Reason : Depression	
Capsule	75 Milligram	Daily	Oral
Batch :	Started : 10/09/2007	Stopped : 27/10/2007	0
PERINDOPRIL (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				CT and lumbar puncture results normal

Public Case Detail

Cases Count: 172

Case Number : 235799

Data Entry Date : 30/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 85

Onset Date :

Age : 37Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Yawning		Excessive yawning . 6 hours after taking Efexor.	
Libido decreased		Reduction in libido.	

Medicine details :			
EFEXOR (Suspected)		Reason :	
Capsule	150 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 235807

Data Entry Date : 03/12/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 29/03/2007

Age : 51Y

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	

Public Case Detail

Cases Count: 172

Case Number : 235827

Data Entry Date : 03/12/2007

Gender : F

Hospitalisation :

Weight (kg) : 62

Onset Date :

Age :

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

Public Case Detail

Cases Count: 172

Case Number : 235873

Data Entry Date : 04/12/2007

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Recovered

Causality : Causality probable

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 :	

Public Case Detail

Cases Count: 172

Case Number : 235995

Data Entry Date : 06/12/2007

Hospitalisation :

Onset Date : 25/10/2007

Outcome :

Not yet recovered

Gender : F

Weight (kg) : 0

Age : 67Y

DOB :

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Palpitations		Patient developed sleep disturbances, dizzy, 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 :	
Capsule	150 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 236057

Data Entry Date : 07/12/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/09/2007

Age :

DOB : 13/08/1984

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous		The patient was applying Zorac cream for approximately 12 days.	

Medicine details :

EFEXOR (Suspected)	Reason : Depression		
Batch :	Started :	Stopped :	
Zorac (Suspected)	Reason : Other acne of sebaceous glands		
Cream	1 Dose Unspec Daily	Topical	
Batch :	Started : 15/07/2007	Stopped : 15/08/2007	

Public Case Detail

Cases Count: 172

Case Number : 236196

Data Entry Date : 12/12/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 24/10/2007

Age : 48Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Menorrhagia		<p>Patient has found her periods have recently gone from every 28/7 to every 31/7 in past 2 months. .</p> <p>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.</p> <p>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.</p>	

Medicine details :

EFEXOR-XR (Suspected)

Reason : Depression

1 Dose Unspec Daily

Batch :

Started : 22/10/2007

Stopped :

0

Case Number : 236334

Data Entry Date : 17/12/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 27Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		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.	
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.	

Reaction :**Preferred Term**

Drug effect decreased

Severity**Report Description**

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.

Treatment

Drug exposure during pregnancy

Medicine details :

EFEXOR-XR (Suspected)

Reason :

150 Milligram

Oral

Batch :**Started :****Stopped :**

0

Case Number : 236357

Data Entry Date : 17/12/2007

Gender : F

Hospitalisation :

Weight (kg) : 55

Onset Date : 02/11/2007

Age :

DOB : 29/04/1967

Outcome :

Causality : Causality probable

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	Severe dystonic reaction - 4 weeks after starting Efexor-XR. Swallowing, speech, breathing difficulties.	
Dysarthria	Caused or prolonged inpatient hospitalisation		
Dysphagia	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 :

Public Case Detail

Cases Count: 172

Case Number : 236411

Data Entry Date : 19/12/2007

Hospitalisation :

Onset Date :

Outcome :
Unknown

Gender : F

Weight (kg) : 0

Age : 32Y

DOB :

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Abnormal labour		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 pregnancy 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	
Uterine injury			
Drug exposure during pregnancy			

Medicine details :

EFEXOR-XR (Suspected)	Reason : Depression
Batch :	150 Milligram Daily Oral
Started :	Stopped :

Public Case Detail

Cases Count: 172

Case Number : 236533

Data Entry Date : 27/12/2007

Gender : U

Hospitalisation : Admitted to hospital

Weight (kg) : 0

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 :	



Public Case Detail

Cases Count: 172

Case Number : 236570

Data Entry Date : 31/12/2007

Hospitalisation :

Onset Date :

Outcome :

Not yet recovered

Gender : F

Weight (kg) : 0

Age :

DOB : 12/06/1949

Causality : Causality possible

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 though the efexor was not treating her depression	

Medicine details :			
EFEXOR-XR (Suspected)		Reason : Depression	
	150 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 236672

Data Entry Date : 07/01/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 28/12/2007

Age : 99u

DOB :

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Pancreatitis	Caused or prolonged inpatient hospitalisation	Patient who had commenced taking Efexor XR approximately 6 weeks prior, developed pancreatitis	

Medicine details :			
EFEXOR-XR (Suspected)		Reason :	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 236765

Data Entry Date : 08/01/2008

Hospitalisation :

Onset Date :

Outcome :

Recovered

Gender : F

Weight (kg) : 0

Age : 99u

DOB :

Causality : Causality probable

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 treatment. 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

Public Case Detail

Cases Count: 172

Case Number : 236871

Data Entry Date : 10/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 23/11/2007

Age :

DOB : 04/02/1961

Outcome :

Causality : Causality possible

Recovered

Information:

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 :
Tablet 25 Milligram Daily	Oral
Batch :	Started :
	Stopped : 24/11/0207
VENLAFAXINE HYDROCHLORIDE (Suspected)	Reason :
75 Milligram Daily	
Batch :	Started :
	Stopped : 23/11/2007
ASCORBIC ACID (Other drug)	Reason :
Batch :	Started :
	Stopped :
CIPROFLOXACIN (Other drug)	Reason :
Batch :	Started :
	Stopped :
CLINDAMYCIN HYDROCHLORIDE (Other drug)	Reason :
Batch :	Started :
	Stopped :
ENOXAPARIN (Other drug)	Reason :
Batch :	Started :
	Stopped :
OXYCONTIN (Other drug)	Reason :
Batch :	Started :
	Stopped :

Medicine details :

PANTOPRAZOLE (Other drug)

Reason :

Batch :

Started :

Stopped :

Laboratory Investigations :

Type	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	

Public Case Detail

Cases Count: 172

Case Number : 236875

Data Entry Date : 10/01/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

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 :	

Public Case Detail

Cases Count: 172

Case Number : 236900

Data Entry Date : 11/01/2008

Hospitalisation : Admitted to hospital

Onset Date :

Outcome :
Unknown

Gender : M

Weight (kg) : 0

Age : 99u

DOB :

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Hyperthermia, muscle rigidity, CK rise. Suspected neuroleptic malignant syndrome. See attachment.	
Blood creatine phosphokinase increased	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 :

Public Case Detail

Cases Count: 172

Case Number : 236932

Data Entry Date : 14/01/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

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 :

Public Case Detail

Cases Count: 172

Case Number : 237055

Data Entry Date : 17/01/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 20Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	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 :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 237056

Data Entry Date : 17/01/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 08/01/2008

Age : 66Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Chest discomfort			
Dyspnoea			

Medicine details :			
EFEXOR-XR (Suspected)		Reason :	
	75 Milligram	Daily	Oral
Batch :	Started :	Stopped :	0
AVAPRO (Other drug)		Reason :	
Batch :	Started :	Stopped :	
CELEBREX (Other drug)		Reason :	
Batch :	Started :	Stopped :	
NORVASC (Other drug)		Reason :	
Batch :	Started :	Stopped :	
VITAMIN NOS (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Case Number : 237110

Data Entry Date : 21/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 69Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

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 experienced triglycerides increased and cholesterol increased, pancreatitis.	
Blood triglycerides increased	Caused or prolonged inpatient hospitalisation		
Pancreatitis	Caused or prolonged inpatient hospitalisation		

Medicine details :

CARBAMAZEPINE (Suspected)	Reason :		
	400 Milligram		
Batch :	Started :	Stopped :	
EFEXOR-XR (Suspected)	Reason :		
	450 Milligram Daily		Oral
Batch :	Started :	Stopped :	
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
Biochemistry	0.5-1.5 mmol/L	06/01/2008	86.2	Triglycerides

Public Case Detail

Cases Count: 172

Case Number : 237245

Data Entry Date : 23/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 37Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Patient had severe, intolerable sweating on all doses of Efexor.	Dosage reduced

Medicine details :			
EFEXOR-XR (Suspected)		Reason :	
Capsule	150 Milligram	Daily	Oral
Batch :	Started : 15/05/2007	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 237541

Data Entry Date : 04/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 73Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

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 :	

Public Case Detail

Cases Count: 172

Case Number : 237863

Data Entry Date : 13/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 39

Onset Date : 10/01/2008

Age : 99u

Outcome : 30/01/2008

DOB :

Recovered

Causality : Causality possible

Information: poor temporal relationship

Reaction :

Preferred Term	Severity	Report Description	Treatment
Feeling abnormal		"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". See attachment.	
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

Public Case Detail

Cases Count: 172

Case Number : 237864

Data Entry Date : 13/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

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 decreased		Patient experienced a 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

Case Number : 237930

Data Entry Date : 15/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 14/10/2007

Age :

DOB : 02/08/1923

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Nausea, vomiting, hyponatremia, 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	
Batch :	Started : Stopped :
Fosamax Plus Once Weekly (Other drug)	Reason :
Batch :	Started : Stopped :
OXAZEPAM (Other drug)	Reason :
Batch :	Started : Stopped :
Rosuvastatin (Other drug)	Reason :
10 Milligram	
Batch :	Started : Stopped :
TELMISARTAN (Other drug)	Reason :
Batch :	Started : Stopped :

Medicine details :
VENTOLIN ROTACAPS (Other drug) Reason :
Batch : Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Sodium		13/10/2007	118	
Serum osmolality		13/10/2007	264	

Case Number : 238259

Data Entry Date : 25/02/2008

Hospitalisation :

Onset Date : 14/02/2008

Outcome :
Recovered

Gender : F

Weight (kg) : 0

Age :

DOB : 01/11/1933

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hallucination	Caused or prolonged inpatient hospitalisation	Hallucinations, dizziness, nausea, tinnitus, blurred vision, hyponatraemia.	Both medicines suspected of contributing were ceased. IV fluids and electrolytes were given.
Dizziness	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 :		
		75 Milligram	Daily	Oral
Batch :	Started : 14/02/2008	Stopped : 15/02/2008		0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Sodium				Upon admission sodium level was 121 mmol/L,
Chloride				chloride was 80 mmol/L,
Potassium				potassium was 3.3 mmol/L

Public Case Detail

Cases Count: 172

Case Number : 238260

Data Entry Date : 25/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion		Convulsions	

Medicine details :

EFEXOR-XR (Suspected)

Reason :

Batch :

Started :

Stopped :

Public Case Detail

Cases Count: 172

Case Number : 238274

Data Entry Date : 25/02/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date :

Age : 50Y

Outcome :

DOB :

Not yet recovered

Causality : Causality probable

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 :	

Public Case Detail

Cases Count: 172

Case Number : 238283

Data Entry Date : 26/02/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date :

Age : 30Y

Outcome :

DOB :

Not yet recovered

Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		When patient withdraws from Efexor she develops agitation, palpitations, butterfly feeling in head.	Cannot stop Efexor or reduce dose.
Agitation			
Feeling abnormal			
Palpitations			

Medicine details :			
EFEXOR (Suspected)		Reason : Anxiety neurosis	
	75 Milligram	Daily	
Batch :	Started : 30/01/2005	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 238329

Data Entry Date : 27/02/2008
Hospitalisation : Admitted to hospital
Onset Date : 02/01/2008
Outcome :
 Unknown

Gender : M
Weight (kg) : 0
Age :
DOB : 29/01/1952
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased	Life threatening	Delirium, narcoleptic malignant syndrome.	Aciclovir, ceftriaxone and vancomycin. Transferred to Royal Adelaide Hospital.
Coma	Life threatening		
Delirium	Life threatening		
Neuroleptic malignant syndrome	Life threatening		

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 :	

Public Case Detail

Cases Count: 172

Case Number : 238350

Data Entry Date : 27/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/02/2008

Age :

DOB : 21/04/1983

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Incapacity/disability	Likely Serotonin Syndrome -Agitation, dilated pupils, sweats	Withdrawal of medication; Low dose benzodiazapine
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

Public Case Detail

Cases Count: 172

Case Number : 238352

Data Entry Date : 27/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Intentional self-injury	Caused or prolonged inpatient hospitalisation	Self harm (hitting his head against walls), agitation, aggression.	
Aggression	Caused or prolonged inpatient hospitalisation		
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine details :

EFEXOR-XR (Suspected)		Reason :	
	150 Milligram	Daily	Oral
Batch :	Started :	Stopped :	0

Public Case Detail

Cases Count: 172

Case Number : 238370

Data Entry Date : 28/02/2008

Hospitalisation :

Onset Date : 15/01/2008

Outcome :
Recovered

Gender : F

Weight (kg) : 0

Age : 39Y

DOB :

Causality : Causality possible

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

Public Case Detail

Cases Count: 172

Case Number : 238429

Data Entry Date : 29/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 32Y

Outcome :

DOB :

Recovered

Causality : Causality possible

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

Reaction :

Preferred Term	Severity	Report Description	Treatment
Depression		Worsening of depression symptoms when Stilnox was introduced.	Stilnox ceased.
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 :**

Public Case Detail

Cases Count: 172

Case Number : 238527

Data Entry Date : 03/03/2008

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 75

Onset Date : 02/11/2007

Age :

DOB : 13/11/1945

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Bruxism		Developed 24 hour bruxism following the increase of Venlafaxine from 75 to 150mg nocte.	Off all medication

Medicine details :	
VENLAFAXINE HYDROCHLORIDE (Suspected)	Reason : Depression
	150 Megabecquer Daily
Batch :	Started : 26/10/2007 Stopped : 02/11/2007

Public Case Detail

Cases Count: 172

Case Number : 238746

Data Entry Date : 10/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 84Y

Outcome :

DOB :

Recovered

Causality : Causality possible

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 Term	Severity	Report Description	Treatment
Cardiac arrest	Life threatening	Cardiac Arrest during ECT for severe depression, while on Efexor	Previous ECT courses on Efexor without event. spontaneous reversion to normal rhythm
Cardiac arrest	Life threatening	Two episodes of Cardiac Arrest during ECT for severe depression, while on Efexor	spontaneous reversion to normal rhythm
Bradycardia	Life threatening		1. bradycardia requiring atropine and ephedrine; 2. spontaneous reversion to normal rhythm

Medicine details :

EFEXOR (Suspected)

Reason : Depression

75 Milligram

Daily

Oral

Batch :

Started :

Stopped :

0

Public Case Detail

Cases Count: 172

Case Number : 238766

Data Entry Date : 11/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Agitation	Caused or prolonged inpatient hospitalisation	Agitation, hyperactivity and "other symptoms".	
Psychomotor hyperactivity	Caused or prolonged inpatient hospitalisation		

Medicine details :			
EFEXOR-XR (Suspected)		Reason :	
Capsule			Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 238880

Data Entry Date : 13/03/2008

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 100

Onset Date : 15/02/2008

Age :

Outcome : 20/02/2008

DOB : 01/08/1969

Recovered

Causality : Causality probable

Information:

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 :	

Public Case Detail

Cases Count: 172

Case Number : 238952

Data Entry Date : 14/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 29/02/2008

Age : 26Y

Outcome :

DOB :

Recovered

Causality : Causality possible

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

Public Case Detail

Cases Count: 172

Case Number : 238964

Data Entry Date : 14/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :			
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 :	

Case Number : 239110

Data Entry Date : 19/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 65

Onset Date : 12/02/2008

Age :

Outcome : 18/03/2008

DOB : 30/07/1929

Recovered with sequelae

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation	Doctor doubled dose of venlafaxine on 12th Feb 2008 to 150mg daily. Patient became increasingly confused during the ensuing days. Admitted to St Vincents Hospital in Darlinghurst with hyponatraemia and acute delirium 1st March 2008.	Hospitalise. Cease venlafaxine 2nd March 2008, commence Olanzapine, restrict fluids
Delirium	Caused or prolonged inpatient hospitalisation		
Hyponatraemia	Caused or prolonged inpatient hospitalisation		

Medicine details :

Medicine Name	Reason :
VENLAFAXINE HYDROCHLORIDE (Suspected)	
Tablet 150 Milligram Daily	Oral
Batch : unknown	Started : 12/02/2008
	Stopped : 01/03/2008 0
LIPITOR (Other drug)	
40 Milligram	Oral
Batch :	Started :
	Stopped : 0
MICARDIS (Other drug)	
80 Milligram	Oral
Batch :	Started :
	Stopped : 0
OMEPRAZOLE (Other drug)	
20 Milligram	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.

Public Case Detail

Cases Count: 172

Case Number : 239111

Data Entry Date : 19/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 60

Onset Date : 20/02/2008

Age : 61Y

Outcome :

DOB :

Recovered

Causality : Causality possible

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

Public Case Detail

Cases Count: 172

Case Number : 239161

Data Entry Date : 20/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	Severe dystonic reaction.	

Medicine details :			
EFEXOR-XR (Suspected)		Reason :	
Capsule	225 Milligram	Oral	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 239163

Data Entry Date : 20/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

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 :

Case Number : 239352

Data Entry Date : 31/03/2008
Hospitalisation : Admitted to hospital
Onset Date : 04/03/2008
Outcome :
 Not yet recovered

Gender : F
Weight (kg) : 95
Age :
DOB : 01/11/1952
Causality : Causality possible

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 :	

Public Case Detail

Cases Count: 172

Case Number : 239424

Data Entry Date : 31/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

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

Public Case Detail

Cases Count: 172

Case Number : 239626

Data Entry Date : 07/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 31/12/1948

Outcome :

Causality : Causality probable

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Withdrawal syndrome	Incapacity/disability	Discontinuation symptoms, physical shaking, anxiety, hysteria, very fearful, "out of sorts", unable to focus mentally, "melting down". The events started 2 days after missing the capsules.	Restarted Efexor XR.
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 :



Public Case Detail

Cases Count: 172

Case Number : 239767

Data Entry Date : 10/04/2008

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : U

Weight (kg) : 0

Age : 99u

DOB :

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Reporter had a patient who became psychotic when using combinations of 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 :	

Public Case Detail

Cases Count: 172

Case Number : 239831

Data Entry Date : 11/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/03/2008

Age :

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 legs	Wet dressings, betamethazone bd, 10% WSP in aqueous cream, hydrocortisone to face.
Eczema			

Medicine details :

METFORMIN HYDROCHLORIDE (Suspected)	Reason : Diabetes mellitus
Tablet	1 Gram Daily Oral
Batch :	Started : 07/02/2008 Stopped :
VENLAFAXINE HYDROCHLORIDE (Suspected)	Reason :
	150 Milligram Daily
Batch :	Started : 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 : 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 :

Public Case Detail

Cases Count: 172

Case Number : 239945

Data Entry Date : 14/04/2008

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 105

Onset Date : 25/02/2008

Age :

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	

Public Case Detail

Cases Count: 172

Case Number : 239974

Data Entry Date : 15/04/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 33Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Drug exposure before pregnancy		Drug exposure during pregnancy	

Medicine details :			
EFEXOR-XR (Suspected)		Reason : Depression	
Capsule	37.5 Milligram	Daily	Oral
Batch :	Started : 15/08/2007	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 239975

Data Entry Date : 15/04/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 12/12/2007

Age :

DOB : 12/12/2007

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Body temperature decreased	Caused or prolonged inpatient hospitalisation	Temperature did not stabilise for 48 hours following birth - kept dropping. Had in-utero exposure to Efexor XR.	
Drug exposure during pregnancy	Caused or prolonged inpatient hospitalisation		

Medicine details :			
EFEXOR-XR (Suspected)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 240354

Data Entry Date : 24/04/2008
Hospitalisation : Admitted to hospital
Onset Date : 28/01/2008
Outcome :
 Unknown

Gender : M
Weight (kg) : 0
Age : 75Y
DOB :
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormone secretion	Caused or prolonged inpatient hospitalisation	SIADH and confusion.	Venlafaxine and ramipril ceased. Fluid restriction.
Confusional state	Caused or prolonged inpatient 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	Daily	Oral
Batch :	Started :	Stopped :	
CARVEDILOL HYDROCHLORIDE (Other drug)		Reason :	
	6.3 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Sodium				Se Na = 120 urine Na 71 and Se OSM = 251 urine OSM 424.



Public Case Detail

Cases Count: 172

Case Number : 240428

Data Entry Date : 29/04/2008

Hospitalisation :

Onset Date : 01/10/2004

Outcome :

Not yet recovered

Information:

Gender : F

Weight (kg) : 0

Age : 40Y

DOB :

Causality : Causality possible

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 inflamed and infected.

2. Increased skin oiliness and acne (face, forehead, back, shoulders) - patient never had skin problems before commencing venlafaxine even during 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.

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

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)

Public Case Detail

Cases Count: 172

Case Number : 240434

Data Entry Date : 29/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

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

Batch :

Started : 15/04/2008

Stopped :

EFEXOR-XR (Suspected)

Reason :

150 Milligram Daily

Batch :

Started :

Stopped : 15/04/2008

Public Case Detail

Cases Count: 172

Case Number : 240535

Data Entry Date : 02/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Alcohol abuse		Started binge drinking and acting irrationally - threatens to leave partner and breaks windows.	Dose increased to 150mg once daily.
Aggression			
Thinking abnormal			

Medicine details :			
EFEXOR-XR (Suspected)		Reason :	
Capsule	150 Milligram	Daily	Oral
Batch :	Started : 01/04/2008	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 240791

Data Entry Date : 10/05/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

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 :

Public Case Detail

Cases Count: 172

Case Number : 240807

Data Entry Date : 12/05/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 19Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information: Patient had a past illness of bacteraemia 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 inpatient hospitalisation	Experienced lock jaw, difficulty breathing due to 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

Public Case Detail

Cases Count: 172

Case Number : 240810

Data Entry Date : 12/05/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/01/2008

Age : 48Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		"Funny head", dizziness, 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 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	Daily	Oral
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 :	

Public Case Detail

Cases Count: 172

Case Number : 240920

Data Entry Date : 15/05/2008

Gender : F

Hospitalisation : Treated in outpatient department only.

Weight (kg) : 0

Age : 99u

Onset Date :

DOB :

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Palpitations		Palpitations and ventricular fibrillation.	Efexor XR stopped and digoxin commenced.
Ventricular fibrillation			

Medicine details :			
EFEXOR-XR (Suspected)		Reason : Depression	
Capsule	150 Milligram	Daily	Oral
Batch :	Started :	Stopped :	0

Public Case Detail

Cases Count: 172

Case Number : 241027

Data Entry Date : 19/05/2008

Hospitalisation :

Onset Date : 15/05/2008

Outcome :

Unknown

Gender : M

Weight (kg) : 0

Age : 99u

DOB :

Causality : Causality possible

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 :	
Capsule	150 Milligram Daily	Oral
Batch :	Started : 15/01/2008	Stopped : 07/05/2008

Public Case Detail

Cases Count: 172

Case Number : 241030

Data Entry Date : 20/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Recovered

Causality : Causality certain

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 Efexor XR and experienced headaches and hypertension of 220/110 mmHg.	No treatment, events resolved when missed dose of Efexor XR was taken.
Headache			
Hypertension			

Medicine details :

EFEXOR-XR (Suspected) Reason : Depression

Capsule 300 Milligram Daily Oral

Batch : **Started :** **Stopped :** Contin

Public Case Detail

Cases Count: 172

Case Number : 241486

Data Entry Date : 03/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Neuroleptic malignant syndrome.	

Medicine details :			
EFEXOR-XR (Suspected)		Reason :	
Capsule			Oral
Batch :	Started :	Stopped :	

Case Number : 241863

Data Entry Date : 13/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 04/09/1949

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		No libido since on Efexor XR and drug withdrawal syndrome including mind not with body, vivid dreams, nausea, can not sleep, lack of balance, response time decreased and vertigo.	Reduced Efexor XR and then increased again
Abnormal dreams			
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 :	

Case Number : 241899

Data Entry Date : 16/06/2008

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 50

Onset Date : 13/04/2008

Age :

DOB : 02/05/1988

Outcome :

Causality : Causality possible

Recovered

Information: Possible overdose denied by patient.

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 :

VENLAFAXINE HYDROCHLORIDE (Suspected)

Reason :

Batch :

Started :

Stopped :

Public Case Detail

Cases Count: 172

Case Number : 241900

Data Entry Date : 16/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

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 :	

Public Case Detail

Cases Count: 172

Case Number : 241902

Data Entry Date : 16/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 04/06/2008

Age : 99u

DOB :

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Self-injurious ideation		Thoughts of "harming himself".	

Medicine details :			
EFEXOR-XR (Suspected)		Reason :	
Capsule	37.5 Milligram	Daily	Oral
Batch :	Started : 04/06/2008	Stopped :	05/06/2008

Case Number : 241903

Data Entry Date : 16/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 21/05/1980

Unknown

Causality : Causality possible

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 Hormone	0.40 - 4.00	03/07/2004	0.7	
Thyroid Stimulating Hormone	0.40 - 4.00	10/08/2006	0.5	
Other data		10/08/2006	130	Oestradoil level

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Ultrasound				<p>Pelvis 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 kidneys are normal in size and appearance.</p>

Public Case Detail

Cases Count: 172

Case Number : 241982

Data Entry Date : 17/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 85

Onset Date : 10/06/2008

Age :

DOB : 25/07/1955

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Tongue discolouration		tongue went yellow, dizzy, light headed marked rise in liver function test	cessation of medication
Dizziness			
Hepatic function abnormal			

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 = GGTP				GTT 2844

Public Case Detail

Cases Count: 172

Case Number : 242026

Data Entry Date : 18/06/2008
Hospitalisation : Admitted to hospital
Onset Date :
Outcome :
 Unknown

Gender : F
Weight (kg) : 0
Age : 25Y
DOB :
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Epilepsy	Caused or prolonged inpatient hospitalisation	Epilepsy continuing, eyes rolling, consciousness, muscle spasms of hand and feet and hallucinations.	Treated with Xanax and lamotrigine.
Consciousness fluctuating	Caused or prolonged inpatient hospitalisation		
Convulsion	Caused or prolonged inpatient hospitalisation		
Eye rolling	Caused or prolonged inpatient hospitalisation		
Hallucination	Caused or prolonged inpatient hospitalisation		
Muscle spasms	Caused or prolonged inpatient hospitalisation		

Medicine details :			
EFEXOR (Suspected)		Reason : Debility&undue fatigue	
Tablet	150 Milligram	Daily	Oral
Batch :	Started : 15/02/2008	Stopped :	Continued.
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
Batch :	Started :	Stopped :	0

Case Number : 242058

Data Entry Date : 19/06/2008

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 04/05/2008

Age :

DOB : 09/07/1934

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome: febrile, tachycardic, sweating, dystonic, rigidity	stopped: efexor, clopine, benztropine; treated with bromocriptine.

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 phosphokinase		04/08/2008	2810	

Public Case Detail

Cases Count: 172

Case Number : 242189

Data Entry Date : 24/06/2008
Hospitalisation : Admitted to hospital
Onset Date : 11/05/2008
Outcome :
 Not yet recovered

Gender : M
Weight (kg) : 0
Age : 71Y
DOB :
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Epistaxis	Caused or prolonged inpatient hospitalisation	Epistaxis x 2 episodes, brought in by ambulance. Lasting approx 20 minutes.	Pressure and nasal packing.

Medicine details :			
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason : Depression	
	150 Milligram	Daily	Oral
Batch :	Started : 06/05/2008	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 242249

Data Entry Date : 25/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

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	
Insomnia			

Medicine details :

EFEXOR-XR (Suspected)

Reason :

150 Milligram

Daily

Oral

Batch :

Started : 15/03/2008

Stopped : 15/05/2008

0

Case Number : 242250

Data Entry Date : 25/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 03/06/2008

Age :

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, 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

Public Case Detail

Cases Count: 172

Case Number : 242409

Data Entry Date : 30/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 10/06/2008

Age : 30Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Choreoathetosis		single dopse of phenergan (within 12 hrs) followed by seretonin syndrome, next day stiffness, choreoathetosis, confusion, sweaty, paranoid psychosis/mania.	valium
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 :

Public Case Detail

Cases Count: 172

Case Number : 242413

Data Entry Date : 30/06/2008

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : M

Weight (kg) : 0

Age : 99u

DOB :

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged			

Medicine details :			
EFEXOR-XR (Suspected)	Reason :		
	150 Milligram	Oral	
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Other data				QT interval raised to 0.42 ,before it was 0.36

Case Number : 242645

Data Entry Date : 07/07/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date : 22/06/2008

Age :

DOB : 01/07/1972

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Nausea		Nausea, vomiting, small flecks of fresh blood in some vomit, also in early morning sputum.	Slowly discontinued Efexor.
Haematemesis		Pounding/throbbing frontal headache. BP 130/100.	
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 :

Public Case Detail

Cases Count: 172

Case Number : 242735

Data Entry Date : 09/07/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date :

Age : 46Y

Outcome :

DOB :

Unknown

Causality : Causality possible

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

Reaction :

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

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 :	

Public Case Detail

Cases Count: 172

Case Number : 242836

Data Entry Date : 11/07/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/03/2008

Age : 37Y

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 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	

Public Case Detail

Cases Count: 172

Case Number : 242969

Data Entry Date : 16/07/2008

Gender : U

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

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 :	
RISPERIDONE (Suspected)		Reason :	
Batch :	Started :	Stopped :	
SYNTOCINON (Suspected)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 243017

Data Entry Date : 18/07/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

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 :

Public Case Detail

Cases Count: 172

Case Number : 243042

Data Entry Date : 21/07/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

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 antidepressants. 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, hallucinations, 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		

Medicine details :

EFEXOR-XR (Suspected)

Reason : Depression

Capsule

Oral

Batch :

Started :

Stopped : 15/02/2008

0

Public Case Detail

Cases Count: 172

Case Number : 243104

Data Entry Date : 22/07/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Drug effect decreased	Caused or prolonged inpatient hospitalisation	Felt depressed again and dose was increased.	
Depression	Caused or prolonged inpatient hospitalisation		

Medicine details :			
EFEXOR-XR (Suspected)		Reason : Depression	
Capsule	300 Milligram	Daily	Oral
Batch :	Started :	Stopped :	Contin
AVANZA (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 243198

Data Entry Date : 24/07/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Not yet recovered

Causality : Causality certain

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

Medicine details :

EFEXOR-XR (Suspected)

Reason : Depression

Capsule

375 Milligram

Daily

Oral

Batch :

Started :

Stopped : 15/02/2008

Public Case Detail

Cases Count: 172

Case Number : 243229

Data Entry Date : 25/07/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Recovered

Causality : Causality possible

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 :	

Public Case Detail

Cases Count: 172

Case Number : 243239

Data Entry Date : 28/07/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 70Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Hypertension		Experienced a sudden increase in blood pressure	Therapy discontinued.

Medicine details :			
EFEXOR-XR (Suspected)		Reason :	
Capsule	225 Milligram	Daily	Oral
Batch :	Started :	Stopped :	0

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Blood pressure				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.

Public Case Detail

Cases Count: 172

Case Number : 243274

Data Entry Date : 29/07/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion		Convulsion after increasing Efexor-XR from 75mg daily to 150mg daily in June 2008.	Efexor-XR ceased

Medicine details :

EFEXOR-XR (Suspected)		Reason : Depression	
Capsule	150 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 243279

Data Entry Date : 29/07/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date :

Age :

DOB : 10/04/1956

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Hearing impaired	Incapacity/disability	Experienced 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		
Vomiting	Incapacity/disability		

Medicine details :			
EFEXOR-XR (Suspected)		Reason : Depression	
Capsule	75 Milligram	Daily	Oral
Batch :	Started :	Stopped :	05/07/2008 0
ASPIRIN (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Case Number : 243314

Data Entry Date : 30/07/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/12/2007

Age :

DOB : 15/01/1961

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

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

Medicine details :

EFEXOR-XR (Suspected)	Reason : Depression
Capsule	375 Milligram Daily Oral
Batch :	Started : 15/06/2007 Stopped : 15/07/2008 0
ATENOLOL (Other drug)	Reason :
Batch :	Started : Stopped :
DUPHASTON (Other drug)	Reason :
Batch :	Started : Stopped :

Medicine details :

LAMOTRIGINE (Other drug)

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 :

Public Case Detail

Cases Count: 172

Case Number : 243513

Data Entry Date : 05/08/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 22Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

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	Life threatening		

Medicine details :

EFEXOR (Suspected)

Reason : Anxiety neurosis

75 Milligram Daily

Batch :

Started : 15/04/2008

Stopped :

STILNOX (Suspected)

Reason :

Tablet Milligram Daily Oral

Batch :

Started : L TERM

Stopped :

Public Case Detail

Cases Count: 172

Case Number : 243877

Data Entry Date : 18/08/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Headache		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.	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 :	

Public Case Detail

Cases Count: 172

Case Number : 243907

Data Entry Date : 19/08/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/03/2006

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

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	Stopped :	Contin
TAMSULOSIN HYDROCHLORIDE (Other drug)		Reason :	
	400 Microgram		
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 243921

Data Entry Date : 19/08/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 18Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

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 mentally slow to keep up. Could not cope without Efexor	Efexor permanently discontinued.
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 :

Case Number : 244452

Data Entry Date : 08/09/2008

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 68

Onset Date : 28/07/2008

Age :

DOB : 04/10/1924

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	
Capsule	300 Milligram	Daily	Oral
Batch :	Started : 01/07/2008	Stopped :	07/08/2008
ASPIRIN (Other drug)		Reason : Acute heart failure,undefined	
	100 Milligram	Daily	Oral
Batch :	Started :	L TERM	Stopped :
Combigan (Other drug)		Reason : Unspecified glaucoma	
Batch :	Started :		Stopped :
Lyrice (Other drug)		Reason : Pain	
Capsule	150 Milligram	Daily	Oral
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

Public Case Detail

Cases Count: 172

Case Number : 244605

Data Entry Date : 15/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 28Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Psychotic episode and paranoia.	Efexor XR reduced
Paranoia			

Medicine details :			
EFEXOR-XR (Suspected)		Reason :	
		225 Milligram	Daily
			Oral
Batch :	Started :	Stopped :	Contin

Case Number : 244696

Data Entry Date : 18/09/2008

Gender : F

Hospitalisation :

Weight (kg) : 75

Onset Date : 29/07/2008

Age :

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	

Public Case Detail

Cases Count: 172

Case Number : 244775

Data Entry Date : 22/09/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 08/09/2008

Age :

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 :	

Case Number : 244812

Data Entry Date : 23/09/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date : 15/04/2008

Age : 34Y

Outcome :

DOB :

Not yet recovered

Causality : Causality certain

Information: Cert (rechall)

Reaction :

Preferred Term	Severity	Report Description	Treatment
Malaise		Has not felt well, feels detached and numb. When she forgets to take it feelings disappear and she feels more "alive" for about 6 hours.	Cease Efexor, change to Duloxetine
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 :

Case Number : 244813

Data Entry Date : 23/09/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date : 15/04/2008

Age : 34Y

Outcome :

DOB :

Not yet recovered

Causality : Causality certain

Information: Cert (Rechall)

Reaction :

Preferred Term	Severity	Report Description	Treatment
Withdrawal syndrome		Withdrawal symptoms, like pins and needles, dizzy head, muscle ache and pains.	Efexor ceased, changed to duloxetine
Dizziness			
Myalgia			
Paraesthesia			

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 :
	4 Milligram Daily
Batch :	Started : Stopped :
SELENIUM SULPHIDE (Other drug)	Reason :
Batch :	Started : Stopped :

Public Case Detail

Cases Count: 172

Case Number : 244832

Data Entry Date : 24/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/07/2008

Age :

DOB : 30/12/1983

Outcome :

Causality : Causality probable

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Insomnia		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	

Public Case Detail

Cases Count: 172

Case Number : 244902

Data Entry Date : 26/09/2008

Gender : M

Hospitalisation : Treated in Accident/Emergency Depar

Weight (kg) : 0

Onset Date : 31/08/2008

Age :

DOB : 16/06/1970

Outcome :
Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Anorexia		Seq 1: ON EFEXOR Loss of appetite worsened since 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.	Seq.1 Efexor stopped; seq 2: not stated
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

Case Number : 244941

Data Entry Date : 29/09/2008
Hospitalisation : Admitted to hospital
Onset Date :
Outcome :
 Recovered
Information: CERT

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

Reaction :

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		After 100 mg top-up of Tramadol sudden onset confusion, psychomotor agitation, visual hallucinations, postural tremor.	Venlafaxine and tramadol ceased

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

Public Case Detail

Cases Count: 172

Case Number : 245407

Data Entry Date : 14/10/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 60

Onset Date :

Age :

DOB : 07/10/1977

Outcome :

Causality : Causality certain

Recovered

Information: Cert(rechall)

Reaction :

Preferred Term	Severity	Report Description	Treatment
Withdrawal syndrome		Patient states that if misses dose by every 1-2 hours-> severe shooting head pains, like electric 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

Public Case Detail

Cases Count: 172

Case Number : 245451

Data Entry Date : 15/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 11/10/2008

Age :

Outcome : 13/10/2008

DOB : 18/08/1953

Recovered

Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Paranoia	Incapacity/disability	severe paranoid ideation, exacerbation of anxiety symptoms	cessation of medication led to resolution of symptoms over 24 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	

Public Case Detail

Cases Count: 172

Case Number : 245545

Data Entry Date : 16/10/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

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 :	

Public Case Detail

Cases Count: 172

Case Number : 245648

Data Entry Date : 20/10/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/11/2006

Age :

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	

Public Case Detail

Cases Count: 172

Case Number : 245727

Data Entry Date : 22/10/2008

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : F

Weight (kg) : 0

Age : 99u

DOB :

Causality : Causality possible

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 dose.	Reluctant to change to another agent as the patient has had some response with Eflexor XR.
Flushing	Incapacity/disability		
Impaired work ability	Incapacity/disability		
Restlessness	Incapacity/disability		

Medicine details :			
EFEXOR-XR (Suspected)		Reason : Depression	
		Oral	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 245843

Data Entry Date : 27/10/2008

Hospitalisation :

Onset Date :

Outcome :

Recovered

Gender : M

Weight (kg) : 0

Age : 49Y

DOB :

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Withdrawal syndrome		Experienced suicidal thought when stopped Efexor-XR abruptly for 4 days.	Therapy continued.
Suicidal ideation			

Medicine details :			
EFEXOR-XR (Suspected)		Reason : Depression	
Capsule	75 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Case Number : 245846

Data Entry Date : 27/10/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/09/2008

Age :

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 :

Case Number : 246015

Data Entry Date : 06/11/2008

Gender : F

Hospitalisation : Required a specialist consultation

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

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 childhood	
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				CT of neck did not find anything
Nerve Conduction Studies				Nothing found
Other data				spinal x-ray did not find anything wrong.

Case Number : 246112

Data Entry Date : 10/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 28/09/1950

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Ventricular hypokinesia		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 atrial 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			

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	

Laboratory Investigations :

Type	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 comparison to last year echocardiogram. Right ventricular systolic pressure 35mmHg.	

Public Case Detail

Cases Count: 172

Case Number : 246134

Data Entry Date : 11/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 26/09/2008

Age : 18Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Dystonia		? Dystonic reaction to acuphase.	2 mg Benztropine.

Medicine details :			
VENLAFAXINE HYDROCHLORIDE (Interaction)		Reason : Depression	
	300 Milligram	Daily	
Batch :	Started :	Stopped :	
ZUCLOPENTHIXOL ACETATE (Interaction)		Reason :	
	50 Milligram	2 times	
Batch :	Started : 23/09/2008	Stopped : 25/09/2008	0
RISPERIDONE (Other drug)		Reason :	
	37.5 Milligram	Cyclical	
Batch :	Started :	Stopped :	

Case Number : 246428

Data Entry Date : 20/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 03/08/1970

Outcome :

Causality : Causality possible

Not yet recovered

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		

Medicine details :

EFEXOR-XR (Suspected)

Reason : Depression

Capsule

37.5 Milligram

Daily

Oral

Batch :

Started :

Stopped :

0

Public Case Detail

Cases Count: 172

Case Number : 246493

Data Entry Date : 24/11/2008

Gender : F

Hospitalisation :

Weight (kg) : 60

Onset Date : 30/06/2008

Age : 27Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Blood glucose decreased		low blood sugar in insulin dependent diabetic	eating more frequently

Medicine details :			
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason :	
		Daily	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 246661

Data Entry Date : 27/11/2008

Hospitalisation :

Onset Date :

Outcome : 08/10/2008

Recovered

Gender : M

Weight (kg) : 117

Age :

DOB : 06/04/1972

Causality : Causality possible

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

Public Case Detail

Cases Count: 172

Case Number : 246732

Data Entry Date : 02/12/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date : 01/11/2008

Age : 46Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :			
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 :	

Public Case Detail

Cases Count: 172

Case Number : 246881

Data Entry Date : 08/12/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 06/10/2008

Age : 99u

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 pregnancy (however, tox screen was negative). tal

Reaction :

Preferred Term	Severity	Report Description	Treatment
Respiration abnormal	Congenital anomaly / birth defect	At birth: irregular 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 :

Public Case Detail

Cases Count: 172

Case Number : 246963

Data Entry Date : 09/12/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 11/11/2007

Age :

DOB : 27/08/1944

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatraemia.	Ceased venlafaxine.

Medicine details :			
Olmesartan-hydrochlorothiazide (Suspected)	Reason :		
Batch :	Started :	Stopped :	
VENLAFAXINE HYDROCHLORIDE (Suspected)	Reason :		
Capsule	150 Milligram	Daily	Oral
Batch :	Started :	Stopped : 13/11/2007	
DIAZEPAM (Other drug)	Reason :		
Batch :	Started :	Stopped :	
MORPHINE SULPHATE (Other drug)	Reason :		
Batch :	Started :	Stopped :	
MS CONTIN (Other drug)	Reason :		
Batch :	Started :	Stopped :	
SIMVASTATIN (Other drug)	Reason :		
Batch :	Started :	Stopped :	
Symbicort Turbuhaler (Other drug)	Reason :		
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Sodium				129
Urine Sodium				28
Urine osmolality				Normal 351

Case Number : 247016

Data Entry Date : 09/12/2008

Gender : M

Hospitalisation :

Weight (kg) : 105

Onset Date : 28/11/2008

Age :

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

Batch :

Started : 28/11/2008

Stopped : 01/12/2008

0

Case Number : 247156

Data Entry Date : 15/12/2008

Gender : M

Hospitalisation :

Weight (kg) : 66

Onset Date : 02/12/2008

Age :

DOB : 15/09/1958

Outcome : 15/12/2008

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Anxiety	Incapacity/disability	Fatigue, very anxious, not sleeping, incoherent speech with slurring of words, profuse sweating, poor appetite.	Medication ceased and Efexor restarted.
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

Batch : D15363

Started : 02/12/2008

Stopped : 08/12/2008

Public Case Detail

Cases Count: 172

Case Number : 247158

Data Entry Date : 16/12/2008

Hospitalisation :

Onset Date : 13/11/2008

Outcome :
Recovered

Gender : F

Weight (kg) : 51

Age : 34Y

DOB :

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		Experienced suspected withdrawal from Efexor XR, with vomiting, dizziness and nausea	patient was started on Pristiq

Medicine details :			
EFEXOR-XR (Suspected)		Reason : Depression	
	150 Milligram		Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 172

Case Number : 247265

Data Entry Date : 19/12/2008

Gender : M

Hospitalisation : Hospitalisation prolonged

Weight (kg) : 0

Onset Date :

Age :

DOB : 01/12/2008

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Drug exposure during pregnancy	Caused or prolonged inpatient hospitalisation	Mother switched from Venlafaxine to Sertraline during 3rd trimester of pregnancy. Baby born with persistant pulmonary hypertension (currently recovering in neonatal ICU)	as above
Pulmonary hypertension	Caused or prolonged inpatient hospitalisation		

Medicine details :			
SERTRALINE HYDROCHLORIDE (Suspected)		Reason :	
Batch :	Started :	Stopped :	
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason :	
Batch :	Started :	Stopped :	

Case Number : 247267

Data Entry Date : 19/12/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

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	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation	Experienced occasional tremors at night, lost control of her bladder, 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		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		
Urinary incontinence	Caused or prolonged inpatient hospitalisation		
Withdrawal syndrome	Caused or prolonged inpatient hospitalisation		

Medicine details :

EFEXOR-XR (Suspected)	Reason : Depression
Capsule	75 Milligram Daily Oral
Batch :	Started : Stopped : 0
ATACAND (Other drug)	Reason :
Batch :	Started : Stopped :
CARTIA (Other drug)	Reason :
Batch :	Started : Stopped :
HYDROCHLOROTHIAZIDE (Other drug)	Reason :
Batch :	Started : Stopped :

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.

Public Case Detail

Cases Count: 172

Case Number : 247714

Data Entry Date : 15/01/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

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 :	

Public Case Detail

Cases Count: 172

Case Number : 247831

Data Entry Date : 20/01/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Unknown

Causality : Causality probable

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

Medicine details :

VENLAFAXINE HYDROCHLORIDE (Suspected)	Reason :
Capsule	300 Milligram Daily Oral
Batch :	Started :
	Stopped :

Public Case Detail

Cases Count: 172

Case Number : 247931

Data Entry Date : 22/01/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/11/2008

Age :

DOB : 13/02/1950

Outcome :

Causality : Causality possible

Not yet recovered

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 :	

Public Case Detail

Cases Count: 172

Case Number : 247937

Data Entry Date : 23/01/2009

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Inappropriate schedule of drug administration		patient would miss once 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 :	

Public Case Detail

Cases Count: 172

Case Number : 247943

Data Entry Date : 23/01/2009

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 23/05/2008

Age :

DOB : 24/12/1930

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Hepatic failure			

Medicine details :			
Medicine Name	Reason	Batch	Started / Stopped
EFEXOR (Suspected)			
Capsule	150 Milligram Daily		Oral
Batch :	Started :	L TERM	Stopped : 0
LIPITOR (Suspected)			
Batch :	Started :		Stopped : 0
COVERSYL (Other drug)			
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