Public Case Detail

Cases Count: 33

Case Number : 231760

Data Entry Date : 09/08/2007

Hospitalisation : Required a visit to the doctor

Onset Date : 26/06/2007

Outcome :

Recovered

Information:

Gender : M

Weight (kg) : 110

Age :

DOB : 15/12/1964

Causality : Causality probable

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pitting oedema		Bilateral marked sitting oedema to below knees.	Cessation of medication

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

Tablet 30 Milligram Daily Oral

Batch : **Started :** 15/06/2007 **Stopped :** 28/06/2007

ACAMPROSATE CALCIUM (Other drug) **Reason :**

Tablet 1.9 Gram Oral

Batch : **Started :** 19/06/2007 **Stopped :**

Public Case Detail

Cases Count: 33

Case Number : 231906

Data Entry Date : 13/08/2007

Hospitalisation : Required a visit to the doctor

Onset Date : 12/07/2007

Outcome : Recovered

Gender : F

Weight (kg) : 53

Age :

DOB : 10/05/1978

Causality : Causality possible

Information: Appears to be tyramine like reaction. Did not have same response to white wine.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Sweating, palpitations, anxiety. Associated with red wine.	
Palpitations			

Medicine details :

ALCOHOL (Interaction) **Reason :**

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

MIRTAZAPINE (Interaction) **Reason :** Depression

Tablet 30 Milligram Daily Oral

Batch : **Started :** 29/05/2007 **Stopped :** 16/07/2007

Public Case Detail

Cases Count: 33

Case Number : 232188

Data Entry Date : 19/08/2007

Hospitalisation :

Onset Date : 23/07/2007

Outcome :

Not yet recovered

Information:

Gender : M

Weight (kg) : 100

Age :

DOB : 30/08/1960

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome	Incapacity/disability		

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

Tablet 30 Milligram 1 time Oral

Batch : **Started :** 01/01/2007 **Stopped :**

Public Case Detail

Cases Count: 33

Case Number : 232193

Data Entry Date : 20/08/2007

Hospitalisation :

Onset Date :

Outcome :

Not yet recovered

Information:

Gender : F

Weight (kg) : 0

Age :

DOB : 12/08/1936

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Rash		Rash. Widespread, branching, non-vesicular, erthyematous, mild itch. Rash on face (urtricarial).	Tramadol Oxynorm ceased. Cetimzine daily started, calamine., Hamiltons. Elocon ointment added. Mirtazepine ceased. Phenergan added.

Medicine details :

MIRTAZAPINE (Suspected) **Reason :**

1 Dose Unspec Daily

Batch : **Started :** 05/06/2007 **Stopped :** 17/06/2007

OXYNORM (Suspected) **Reason :**

Batch : **Started :** 11/06/2007 **Stopped :** 15/06/2007

TRAMADOL HYDROCHLORIDE (Suspected) **Reason :**

Daily

Batch : **Started :** 14/06/2007 **Stopped :** 15/06/2007

Public Case Detail

Cases Count: 33

Case Number : 232274

Data Entry Date : 20/08/2007

Hospitalisation :

Onset Date : 30/04/2007

Outcome :

Recovered

Information:

Gender : M

Weight (kg) : 0

Age :

DOB : 26/11/1985

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal		Patient taking Mirtazepine for 5 days presented with myo-pericarditis (ECG rises and Troponin rise). Angiogram was normal	
Carditis			
Troponin increased			

Medicine details :

MIRTAZAPINE (Suspected) **Reason :**

Tablet 30 Milligram Daily Oral

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

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase	0 - 171	30/04/2007	462	
Creatine phosphokinase	0 - 171	01/05/2007	207	
Troponin	0 - 0.1	30/04/2007	9.0	
Troponin	0 - 0.1	01/05/2007	4.83	

Public Case Detail

Cases Count: 33

Case Number : 232906

Data Entry Date : 03/09/2007

Hospitalisation : Required a visit to the doctor

Onset Date : 07/08/2007

Outcome : 16/08/2007
Recovered

Gender : F

Weight (kg) : 50

Age :

DOB : 22/12/1966

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Patient developed fevers and hypotension on 07/08/07 with subsequent neutropenia on 10/08/07.	Mirtazapine stopped.
Hypotension			
Neutropenia			

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

Tablet 15 Milligram Daily Oral

Batch : **Started :** 15/06/2007 **Stopped :** 10/08/2007

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		10/08/2007	1.26	
Neutrophils		11/08/2007	0.61	
Neutrophils		12/08/2007	0.32	
Neutrophils		13/08/2007	0.52	

Public Case Detail

Cases Count: 33

Case Number : 232911

Data Entry Date : 03/09/2007

Hospitalisation :

Onset Date :

Outcome : Not yet recovered

Information:

Gender : F

Weight (kg) : 0

Age :

DOB : 02/04/1946

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation	New onset of tremor and myoclonic jerks. Blood electrolytes abnormal.	
Blood electrolytes abnormal	Caused or prolonged inpatient hospitalisation		
Myoclonus	Caused or prolonged inpatient hospitalisation		

Medicine details :

MIRTAZAPINE (Suspected) **Reason :**

Tablet 30 Milligram Daily Oral

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

FENTANYL (Other drug) **Reason :**

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

Lyrica (Other drug) **Reason :**

Capsule 150 Milligram Daily Oral

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

Public Case Detail

Cases Count: 33

Case Number : 233797

Data Entry Date : 26/09/2007

Hospitalisation :

Onset Date :

Outcome :

Recovered

Gender : M

Weight (kg) : 0

Age :

DOB : 09/04/1937

Causality : Causality possible

Information: Discharge summar from psychiatric hospital-final diagnoses-chronic delirium secondary to drug and medical causes. No indication of depression.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Agitation	Caused or prolonged inpatient hospitalisation	Attended Murdoch emergency on 20 October 2006 due to sleeplessness and agitation. Disorientation/paranoia. Diagnosed ? Agitated Depression and Psychotic Paranoi/Vascular Dementia. Considerable fluid build up. Weighed 71 kilos on March 1 and on March 29 he weighed 83 kilos.	Ceased Cipramil - replaced with Mirtazapine.
Disorientation	Caused or prolonged inpatient hospitalisation		
Oedema	Caused or prolonged inpatient hospitalisation		
Paranoia	Caused or prolonged inpatient hospitalisation		

Medicine details :

MIRTAZAPINE (Suspected) **Reason :**

15 Milligram Daily

Batch : **Started :** **Stopped :** 29/03/2007

Stilnox CR (Suspected) **Reason :**

Tablet 1 Dose Unspec Daily Oral

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

ALLOPURINOL (Other drug) **Reason :**

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

ATIVAN (Other drug) **Reason :**

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

Medicine details :

CIPRAMIL (Other drug) **Reason :**

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

Public Case Detail

Cases Count: 33

Case Number : 233902

Data Entry Date : 02/10/2007

Hospitalisation : Admitted to hospital

Onset Date : 28/11/2006

Outcome : Recovered

Gender : M

Weight (kg) : 0

Age :

DOB : 18/12/1946

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Patient developed fever, sweats, rigors, worsening anxiety and urinary retention.	Aropax ceased.
Anxiety	Caused or prolonged inpatient hospitalisation		
Chills	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		
Urinary retention	Caused or prolonged inpatient hospitalisation		

Medicine details :

AROPAX (Suspected) **Reason :**

Tablet 20 Milligram Daily Oral

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

MIRTAZAPINE (Suspected) **Reason :**

Tablet 60 Milligram Daily Oral

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

LEVODOPA (Other drug) **Reason :**

Tablet 5 Dose Unspec Oral

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

Public Case Detail

Cases Count: 33

Case Number : 233972

Data Entry Date : 03/10/2007

Hospitalisation :

Onset Date : 15/06/2007

Outcome :

Recovered

Information:

Gender : M

Weight (kg) : 0

Age : 54Y

DOB :

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion	Life threatening	Patient experienced a seizure and went into respiratory failure.	ICU admission, intubated and ventilated.
Respiratory failure	Life threatening		

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

Tablet 30 Milligram Daily Oral

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

IMMUNOGLOBULIN - NORMAL (Other drug) **Reason :**

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

INTRAGAM P (Other drug) **Reason :**

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

Public Case Detail

Cases Count: 33

Case Number : 235263

Data Entry Date : 14/11/2007

Hospitalisation : Required a visit to the doctor

Onset Date :

Outcome :

Not yet recovered

Information:

Gender : M

Weight (kg) : 0

Age :

DOB : 17/05/1956

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hypogammaglobulinaemia		Panhypogammaglobulinaer Suspected but not definite.	

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

Tablet 45 Milligram Daily Oral

Batch : **Started :** 01/04/2007 **Stopped :**

Public Case Detail

Cases Count: 33

Case Number : 235303

Data Entry Date : 14/11/2007

Hospitalisation : Required a visit to the doctor

Onset Date : 15/10/2007

Outcome :

Recovered

Information:

Gender : F

Weight (kg) : 60

Age :

DOB : 14/05/1932

Causality : Causality probable

Reaction :

Preferred Term	Severity	Report Description	Treatment
Dermatitis bullous		Patient experienced a blistering, erythematous rash on the soles of both feet,	Stopped mirtazapine.

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

Tablet 15 Milligram Daily Oral

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

Public Case Detail

Cases Count: 33

Case Number : 235338

Data Entry Date : 15/11/2007

Hospitalisation : Admitted to hospital

Onset Date :

Outcome :

Unknown

Information:

Gender : F

Weight (kg) : 0

Age : 62Y

DOB :

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	described as severe, requiring admission to ICU	

Medicine details :

MIRTAZAPINE (Suspected) **Reason :**

Oral

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

SEROQUEL (Suspected) **Reason :** Depression

Oral

Batch : **Started :** L TERM **Stopped :**

Public Case Detail

Cases Count: 33

Case Number : 235637

Data Entry Date : 26/11/2007

Hospitalisation : Required a visit to the doctor

Onset Date : 01/09/2007

Outcome : Not yet recovered

Information: Cert: Rechall

Gender : F

Weight (kg) : 86

Age :

DOB : 10/11/1929

Causality : Causality certain

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pruritus Rash		Patient experienced an itch and rash.	Ceased Mirtazapine.

Medicine details :

MIRTAZAPINE (Suspected) **Reason :**

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

ATACAND (Other drug) **Reason :**

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

FOSAMAX (Other drug) **Reason :**

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

LAMOTRIGINE (Other drug) **Reason :**

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

LASIX (Other drug) **Reason :**

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

NORVASC (Other drug) **Reason :**

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

PARIET (Other drug) **Reason :**

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

Public Case Detail

Cases Count: 33

Case Number : 236485

Data Entry Date : 21/12/2007

Hospitalisation : Required a visit to the doctor

Onset Date : 22/11/2007

Outcome : 26/11/2007
Recovered

Gender : F

Weight (kg) : 42

Age :

DOB : 13/05/1924

Causality : Causality certain

Information: Other drug taken: Crapeze. Suspected drug is cert/rechallenge.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Nightmare		Patient experienced horrible nightmares for 4 consecutive nights while taking mirtazepine. Patient ceased the medication on her own accord.	Ceased mirtazapine.

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Anxiety neurosis

Tablet 15 Milligram Daily Oral

Batch : **Started :** 22/11/2007 **Stopped :** 26/11/2007 0

ALENDRONATE SODIUM (Other drug) **Reason :** Osteoporosis

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

ASPIRIN (Other drug) **Reason :** Other coagulation defects

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

CALTRATE PLUS (Other drug) **Reason :** Osteoporosis

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

FRUSEMIDE (Other drug) **Reason :** Congestive heart failure

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

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

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

TEMAZEPAM (Other drug) **Reason :** Specific disorders of sleep

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

Public Case Detail

Cases Count: 33

Case Number : 236874

Data Entry Date : 10/01/2008

Hospitalisation :

Onset Date : 15/11/2007

Outcome :

Recovered

Information:

Gender : F

Weight (kg) : 0

Age :

DOB : 13/06/1918

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Agitation		Agitation and restlessness.	Ceased Linezolid
Restlessness			

Medicine details :

LINEZOLID (Suspected) **Reason :**

Tablet 600 Milligram Daily Oral

Batch : **Started :** 09/11/2007 **Stopped :** 16/11/2007

MIRTAZAPINE (Suspected) **Reason :**

Tablet 30 Milligram Daily Oral

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

ENOXAPARIN (Other drug) **Reason :**

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

FRUSEMIDE (Other drug) **Reason :**

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

LITHIUM CARBONATE (Other drug) **Reason :**

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

NICOTINE (Other drug) **Reason :**

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

PARACETAMOL (Other drug) **Reason :**

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

SIMVASTATIN (Other drug) **Reason :**

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

Public Case Detail

Cases Count: 33

Case Number : 237171

Gender : F

Data Entry Date : 22/01/2008

Weight (kg) : 0

Hospitalisation :

Age : 91Y

Onset Date : 07/01/2008

DOB :

Outcome :

Causality : Causality possible

Unknown

Information: History of hypertension, hyperlipidaemia, panic attacks, pulmonary fibrosis

Reaction :

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Patient was treated with 30 mg mirtazapine intially for a period of 12 months. The dose was raised to 45 mg 6 weeks prior to hospitalization on 7 January with onset of chest pain, shortness of breath and peripheral oedema. THe ECG showed QTC prolongation and ST elevation.	
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Electrocardiogram QT prolonged	Caused or prolonged inpatient hospitalisation		
Electrocardiogram ST segment elevation	Caused or prolonged inpatient hospitalisation		
Oedema peripheral	Caused or prolonged inpatient hospitalisation		

Medicine details :

MIRTAZAPINE (Suspected) **Reason :**

Tablet 45 Milligram 1 time Oral

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

ASPIRIN (Other drug) **Reason :**

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

DIAZEPAM (Other drug) **Reason :**

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

PANADEINE (Other drug) **Reason :**

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

Public Case Detail

Cases Count: 33

Case Number : 237303

Data Entry Date : 25/01/2008

Hospitalisation : Required a visit to the doctor

Onset Date : 08/11/2007

Outcome : Not yet recovered

Gender : F

Weight (kg) : 75

Age :

DOB : 20/02/1947

Causality : Causality possible

Information: Previous similar reaction to Sandomigran

Reaction :

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Patient had a skin rash on her face, head, arms and trunk. She had oedema of both feet.	Ceased Mirtazapine
Rash			

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Migraine

Tablet 30 Milligram Daily Oral

Batch : **Started :** 23/10/2007 **Stopped :** 08/11/2007 0

CARTIA (Other drug) **Reason :** Acute,ill-def cerebrovascular disease w/o hyperte

Tablet 100 Milligram Daily Oral

Batch : **Started :** L TERM **Stopped :**

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

Tablet 20 Milligram Daily Oral

Batch : **Started :** L TERM **Stopped :**

LOSEC (Other drug) **Reason :** Other diseases of esophagus

20 Milligram Daily Oral

Batch : **Started :** L TERM **Stopped :** 0

TOPAMAX (Other drug) **Reason :** Migraine

100 Milligram Daily Oral

Batch : **Started :** 15/01/2007 L TERM **Stopped :** 0

Public Case Detail

Cases Count: 33

Case Number : 237889

Data Entry Date : 14/02/2008

Hospitalisation :

Onset Date :

Outcome :

Unknown

Information:

Gender : F

Weight (kg) : 0

Age : 83Y

DOB :

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormone secretion		Patient initiated mirtazapine therapy and 3 days later presented to the doctor with inappropriate antidiuretic hormone sectretion.	

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

Tablet 15 Milligram 1 time Oral

Batch : **Started :** **Stopped :** 0

Public Case Detail

Cases Count: 33

Case Number : 238051

Data Entry Date : 19/02/2008

Hospitalisation :

Onset Date : 07/01/2008

Outcome :

Not yet recovered

Information:

Gender : M

Weight (kg) : 57.2

Age : 40Y

DOB :

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Tachycadia.	Mirtazapine ceased.

Medicine details :

MAXOLON (Suspected) **Reason :**

60 Milligram Daily

Batch : **Started :** 28/12/2007 **Stopped :**

MIRTAZAPINE (Suspected) **Reason :**

15 Milligram Daily

Batch : **Started :** 27/12/2007 **Stopped :** 17/01/2008

HEPARIN CALCIUM (Other drug) **Reason :**

10 Thousand Inte Subcutaneous

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

MAGMIN (Other drug) **Reason :**

2 Gram Oral

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

METRONIDAZOLE (Other drug) **Reason :**

1.5 Gram Intravenous

Batch : **Started :** 30/12/2007 **Stopped :** 11/01/2008

Ostevit D (Other drug) **Reason :**

2 Thousand Inte

Batch : **Started :** 08/12/2007 **Stopped :**

OXYCONTIN (Other drug) **Reason :**

40 Milligram

Batch : **Started :** 30/12/2007 **Stopped :** 02/12/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Heart Rate		07/01/2008	103 (1340)	
Heart Rate		08/01/2008	- 12/1/08, 100-110	
Heart Rate		13/01/2008	- 17/1/08 >120	

Public Case Detail

Cases Count: 33

Case Number : 238465

Data Entry Date : 29/02/2008

Hospitalisation :

Onset Date :

Outcome :

Unknown

Information:

Gender : F

Weight (kg) : 55

Age : 40Y

DOB :

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug ineffective		Switched over to generic form of Avenza recently. Has been emotional since. The tablets do not seem to be working (feeling down).	
Therapeutic response unexpected with drug substitution			

Medicine details :

MIRTAZAPINE (Suspected) **Reason :**

Tablet 30 Milligram Daily Oral

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

Public Case Detail

Cases Count: 33

Case Number : 238525

Data Entry Date : 03/03/2008

Hospitalisation :

Onset Date : 22/01/2008

Outcome : 28/01/2008
Recovered

Information:

Gender : F

Weight (kg) : 45

Age :

DOB : 18/10/1958

Causality : Causality probable

Reaction :

Preferred Term	Severity	Report Description	Treatment
Somnolence	Life threatening	Severe drowsiness (almost comatose) after one dose of murtazapine 15mg. Doctors believed patient had given up and was willing herselft to go i.e. given up. Alert after 6 days (i.e. woke up).	

Medicine details :

MIRTAZAPINE (Suspected) **Reason :**

15 Milligram 1 time

Batch : **Started :** 22/01/2008 **Stopped :**

ASPIRIN (Other drug) **Reason :**

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

COUMADIN (Other drug) **Reason :**

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

LIPITOR (Other drug) **Reason :**

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

Meprazol (Other drug) **Reason :**

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

SLOW-K (Other drug) **Reason :**

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

THIAMINE (Other drug) **Reason :**

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

UREMIDE (Other drug) **Reason :**

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

Public Case Detail

Cases Count: 33

Case Number : 239120

Data Entry Date : 19/03/2008

Hospitalisation :

Onset Date :

Outcome :

Unknown

Information:

Gender : M

Weight (kg) : 0

Age : 35Y

DOB :

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Paranoia		Paranoia; nightmare; loss of libido; emotional disorder; fatigue; drug interaction	
Drug ineffective			
Emotional disorder			
Fatigue			
Loss of libido			
Nightmare			

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

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

PROTHIADEN (Suspected) **Reason :** Depression

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

STILNOX (Suspected) **Reason :** Specific disorders of sleep

Oral

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

ATACAND (Other drug) **Reason :**

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

Public Case Detail

Cases Count: 33

Case Number : 239176

Data Entry Date : 25/03/2008

Hospitalisation :

Onset Date : 16/03/2008

Outcome :

Not yet recovered

Information:

Gender : F

Weight (kg) : 0

Age :

DOB : 19/08/1959

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Dry eye	Incapacity/disability	This patient received a generic brand of mirtazepine (Douglas Pharmaceuticals) and after taking this for about 10 days complained of symptoms indicative of anticholinergic adverse effects (dry eyes, dry mouth, constipation) as well as an observed decrease in therapuetic effect.	Brand or mirtazepine changed
Constipation	Incapacity/disability		
Dry mouth	Incapacity/disability		
Therapeutic response decreased	Incapacity/disability		
Therapeutic response unexpected with drug substitution	Incapacity/disability		

Medicine details :

MIRTAZAPINE (Suspected)

Reason :

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

Public Case Detail

Cases Count: 33

Case Number : 240578

Data Entry Date : 05/05/2008

Hospitalisation :

Onset Date : 27/10/2007

Outcome :

Not yet recovered

Information:

Gender : F

Weight (kg) : 0

Age :

DOB : 21/09/1927

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Rash macuclopapular, itchy rash over trunk and head.	Mirtazapam ceased.
Pruritus			

Medicine details :

MIRTAZAPINE (Suspected) **Reason :**

Tablet 15 Milligram Daily Oral

Batch : **Started :** 21/10/2007 **Stopped :** 29/10/2007

ASPIRIN (Other drug) **Reason :**

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

CALCIUM CARBONATE (Other drug) **Reason :**

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

DIGOXIN (Other drug) **Reason :**

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

DILTIAZEM HYDROCHLORIDE (Other drug) **Reason :**

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

NEXIUM (Other drug) **Reason :**

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

OSTELIN 1000 (Other drug) **Reason :**

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

PERINDOPRIL (Other drug) **Reason :**

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

RISEDRONATE SODIUM (Other drug) **Reason :**

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

Medicine details :

SALBUTAMOL (Other drug) **Reason :**

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

SERETIDE ACCUHALER NOS (Other drug) **Reason :**

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

SPIRIVA (Other drug) **Reason :**

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

Public Case Detail

Cases Count: 33

Case Number : 241560

Data Entry Date : 04/06/2008

Hospitalisation :

Onset Date : 02/06/2008

Outcome :

Unknown

Information:

Gender : F

Weight (kg) : 0

Age : 99u

DOB :

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Swelling face		Her face was slightly swollen, allergic reaction.	

Medicine details :

MIRTAZAPINE (Suspected) **Reason :**

Tablet 15 Milligram 1 time Oral

Batch : **Started :** 01/06/2008 **Stopped :**

PONSTAN (Suspected) **Reason :**

Capsule 6 Dose Unspec Total Oral

Batch : **Started :** 01/06/2008 **Stopped :**

Public Case Detail

Cases Count: 33

Case Number : 243782

Data Entry Date : 13/08/2008

Hospitalisation :

Onset Date : 02/07/2008

Outcome :

Recovered

Information:

Gender : F

Weight (kg) : 66

Age :

DOB : 13/05/1917

Causality : Causality probable

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hallucination		Patient started having hallucinations, 24 to 48 hours post commencement of mirtazapine.	

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

Tablet 15 Milligram Daily Oral

Batch : **Started :** 30/06/2008 **Stopped :** 03/07/2008

ASPIRIN (Other drug) **Reason :**

100 Milligram Oral

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

CHOLECALCIFEROL (Other drug) **Reason :**

1 Gram Oral

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

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug) **Reason :**

40 Milligram

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

NOVERIL (Other drug) **Reason :**

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

TRIMETHOPRIM (Other drug) **Reason :**

150 Milligram Oral

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

Public Case Detail

Cases Count: 33

Case Number : 243811

Data Entry Date : 13/08/2008

Hospitalisation :

Onset Date :

Outcome :

Recovered

Information:

Gender : F

Weight (kg) : 0

Age : 79Y

DOB :

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Profound hyponatraemia shortly after starting mirtazapine. Admitted for confusion.	Both mirtazapine and frusemide were stopped and fluid intake restricted. Once sodium level had improved, frusemide was restarted without adverse effect.
Blood osmolarity decreased	Caused or prolonged inpatient hospitalisation		
Blood sodium decreased	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

30 Milligram Daily Oral

Batch : **Started :** **Stopped :** 0

FRUSEMIDE (Other drug) **Reason :**

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

METOPROLOL TARTRATE (Other drug) **Reason :**

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

RAMIPRIL (Other drug) **Reason :**

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

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Sodium				Investigations showed a sodium level of 113. By day 10 her sodium level had improved to 132.
Serum osmolality				Blood osmolarity decreased to 243 (275-295).

Public Case Detail

Cases Count: 33

Case Number : 243812

Data Entry Date : 13/08/2008

Hospitalisation :

Onset Date :

Outcome :

Recovered

Information:

Gender : M

Weight (kg) : 0

Age : 61Y

DOB :

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Profound hyponatraemmia. Experienced drowsiness. His blood osmolarity decreased	Mirtazapine was ceased and sodium returned to normal at day 19 following treatment with hypertonic slaine and then fluid restriction.
Blood osmolarity decreased	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine details :

MIRTAZAPINE (Suspected) **Reason :**

15 Milligram Daily

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

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Sodium				Sodium levels declined by 1-2 mEq/L daily with a precipitous drop from 126 to 112. Level was normal on day 19.
Serum osmolality	275-295			Blood osmolarity decreased to 239.

Public Case Detail

Cases Count: 33

Case Number : 245337

Data Entry Date : 10/10/2008

Hospitalisation :

Onset Date : 01/09/2008

Outcome : 02/09/2008
Recovered

Gender : M

Weight (kg) : 0

Age :

DOB : 14/08/1936

Causality : Causality possible

Information: Patient on 10mg Chlorpromazine daily- ceased befroe commencement of Mirtazepine.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		30/08/08 - Tonic-clonic seizure Babinski both feet; sluggish eyes; weakness left arm and leg. No history of past seizure disorde.	5mg diazepam IM, transferred to PAH, midazolam 5mg sc given prior.

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

Tablet 30 Milligram Daily Oral

Batch : **Started :** 27/08/2008 **Stopped :** 01/09/2008

ASPIRIN (Other drug) **Reason :**

100 Milligram Daily

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

OMEPRAZOLE (Other drug) **Reason :**

40 Milligram Daily

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

THIAMINE (Other drug) **Reason :**

100 Milligram Daily

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

Public Case Detail

Cases Count: 33

Case Number : 246271

Data Entry Date : 14/11/2008

Hospitalisation :

Onset Date : 25/08/2008

Outcome :

Unknown

Gender : M

Weight (kg) : 0

Age : 61Y

DOB :

Causality : Causality probable

Information: Pelvis may have tipped him over from asymptomatic hyponatraemia to symptomatic decreased Na.
In hospital-> incidental finding of pelvis.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia, seizures, SIADH.	Ceased Mirtazepine, required ICU.
Convulsion			
Inappropriate antidiuretic hormone secretion			

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

15 Milligram Daily

Batch : **Started :** 15/02/2008 **Stopped :** 25/08/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Sodium				116

Public Case Detail

Cases Count: 33

Case Number : 246296

Data Entry Date : 17/11/2008

Hospitalisation :

Onset Date : 26/08/2008

Outcome :

Recovered

Information:

Gender : F

Weight (kg) : 0

Age : 88Y

DOB :

Causality : Causality probable

Reaction :

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation	Shaking, Mouth constantly moving-agitated, 2 episodes of hallucinations visual.	Ceased mirtazepine
Agitation	Caused or prolonged inpatient hospitalisation		
Dyskinesia	Caused or prolonged inpatient hospitalisation		
Hallucination, visual	Caused or prolonged inpatient hospitalisation		

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

Tablet 15 Milligram Daily Oral

Batch : **Started :** 22/08/2006 **Stopped :** 26/08/2008

ARICEPT (Other drug) **Reason :**

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

CORDILOX SR (Other drug) **Reason :**

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

Glucosamine Nos (Other drug) **Reason :**

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

MODURETIC (Other drug) **Reason :**

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

RISPERDAL (Other drug) **Reason :**

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

Medicine details :

TEMAZEPAM (Other drug) **Reason :**

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

Public Case Detail

Cases Count: 33

Case Number : 246375

Data Entry Date : 18/11/2008

Hospitalisation :

Onset Date :

Outcome : 25/09/2008
Recovered

Information:

Gender : F

Weight (kg) : 0

Age :

DOB : 12/06/1971

Causality : Causality probable

Reaction :

Preferred Term	Severity	Report Description	Treatment
Arthralgia		Gradual onset arthralgia, myalgia and bone pain with dependent oedema.	Ceased mirtazapine and commence Duloxetine60mg.
Bone pain			
Gravitational oedema			
Myalgia			

Medicine details :

MIRTAZAPINE (Suspected) **Reason :** Depression

Tablet 30 Milligram Daily Oral

Batch : **Started :** 06/08/2008 **Stopped :** 28/08/2008

Selection Parameters : Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: MIRTAZAPINE