Public Case Detail

Cases Count: 8

Case Number : 235233

Data Entry Date : 13/11/2007

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : F

Weight (kg) : 0

Age : 69Y

DOB :

Causality : Causality possible

Information: Dr has performed a prick test with no loss of sensation. BP normal and not diabetic. Giddiness only lasted 6 weeks and has resolved.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Hypoaesthesia			
Musculoskeletal stiffness			
Neuropathy peripheral			
Paraesthesia			

Medicine details :

DOTHEP (Suspected) **Reason :** Depression

100 Milligram 1 time Oral

Batch : **Started :** 15/05/2006 **Stopped :** 15/09/2007 0

COVERSYL (Other drug) **Reason :**

Oral

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

Public Case Detail

Cases Count: 8

Case Number : 235475

Data Entry Date : 21/11/2007

Hospitalisation : Required a visit to the doctor

Onset Date :

Outcome : 10/10/2007
Recovered

Information:

Gender : F

Weight (kg) : 0

Age :

DOB : 25/09/1944

Causality : Causality probable

Reaction :

Preferred Term	Severity	Report Description	Treatment
Oedema		Patient developed significant oedema, leading to symptoms of heart failure on a number of occasions.	Prothiaden ceased.

Medicine details :

PROTHIADEN (Suspected) **Reason :** Depression

Tablet 150 Milligram Daily Oral

Batch : **Started :** L TERM **Stopped :** 01/10/2007

Actonel 35mg Once-a-Week Tablet (Other drug) **Reason :**

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

ANAPROX (Other drug) **Reason :**

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

COLCHICINE (Other drug) **Reason :**

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

METHOTREXATE (Other drug) **Reason :**

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

NEXIUM (Other drug) **Reason :**

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

ZOLOFT (Other drug) **Reason :**

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

Public Case Detail

Cases Count: 8

Case Number : 236818

Data Entry Date : 09/01/2008

Hospitalisation :

Onset Date :

Outcome :

Unknown

Information:

Gender : M

Weight (kg) : 0

Age : 99u

DOB :

Causality : Causality possible

Reaction :

Preferred Term	Severity	Report Description	Treatment
Parkinson's disease		consumer report : developed Parkinsons disease while taking Dothep over 10 years	

Medicine details :

DOTHEP (Suspected) **Reason :**

Tablet 375 Milligram 1 time Oral

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

Public Case Detail

Cases Count: 8

Case Number : 237544

Data Entry Date : 04/02/2008

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : F

Weight (kg) : 0

Age : 99U

DOB :

Causality : Causality possible

Information: Baby was female 2.58kg, 48cm in length. 36/40 weeks gestation, apgar score 7/10.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug exposure during pregnancy		Drug exposure during pregnancy, Alcohol 10grams daily until 5/40 gestation.	

Medicine details :

ALCOHOL (Suspected) **Reason :**

10 Gram Daily Oral

Batch : **Started :** S TERM **Stopped :**

DOTHIEPIN HYDROCHLORIDE (Suspected) **Reason :**

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

KEPPRA (Suspected) **Reason :**

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

Public Case Detail

Cases Count: 8

Case Number : 239036

Data Entry Date : 17/03/2008

Hospitalisation :

Onset Date : 15/03/2007

Outcome :

Unknown

Gender : F

Weight (kg) : 0

Age : 58Y

DOB :

Causality : Causality possible

Information: The patients husband believes the reaction is caused by the red colouring in the Dothep tablet, because the patient has previously taken prothiaden without any problems. He also states that when he removes the red colouring from the outside of the tablet before his wife takes it the wounds get better.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Stasis dermatitis		Stasis dermatitis with weeping ulcers on both legs since Marche 2007.	
Skin ulcer			

Medicine details :

DOTHEP (Suspected) **Reason :** Depression

300 Milligram Daily

Batch : **Started :** 15/09/2006 **Stopped :**

Public Case Detail

Cases Count: 8

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: 8

Case Number : 242324

Data Entry Date : 26/06/2008

Hospitalisation : Required a visit to the doctor

Onset Date : 13/06/2008

Outcome : 13/06/2008
Recovered

Gender : F

Weight (kg) : 0

Age :

DOB : 06/05/1960

Causality : Causality probable

Information: Change of brand due to unavailability.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Swollen tongue		Tongue swelled, shortness of breath	
Dyspnoea			
Therapeutic response unexpected with drug substitution			

Medicine details :

DOTHIEPIN HYDROCHLORIDE (Suspected) **Reason :**
2 Dose Unspec Daily
Batch : **Started :** **Stopped :**

FUNGILIN (Other drug) **Reason :**
As necessary
Batch : **Started :** **Stopped :**

INDERAL (Other drug) **Reason :**
40 Milligram Daily
Batch : **Started :** **Stopped :**

PROTHIADEN (Other drug) **Reason :**
75 Milligram Daily
Batch : **Started :** **Stopped :**

Seretide 250/25 MDI (Other drug) **Reason :**
2 Dose Unspec Daily
Batch : **Started :** **Stopped :**

ZANTAC (Other drug) **Reason :**
150 Milligram Daily
Batch : **Started :** **Stopped :**

Public Case Detail

Cases Count: 8

Case Number : 247167

Data Entry Date : 16/12/2008

Hospitalisation : Admitted to hospital

Onset Date : 12/06/2008

Outcome : 19/06/2008
Recovered

Gender : F

Weight (kg) : 0

Age :

DOB : 26/12/1957

Causality : Causality possible

Information: The cardiologist diagnosis was increased anteroapical infarction diagnosis due to Left Anterior Descending occlusion not due to thrombosis but spasm.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cyanosis	Caused or prolonged inpatient hospitalisation	In 2005, the patient began Prothiaden therapy for agitated depression. On 3 June 2008, the patient began Zeldox for agitated depression. Hours after increasing Zeldox the patient developed nausea, vomiting and heartburn, then tightness in the chest and dizziness. On 10 June patient ceased Zeldox therapy. On 12 June 2008, the patient noticed blue lips and fingernails and was admitted to the Coronary Care Unit with acute myocardial infarction with cardiogenic shock.	Medication ceased.
Acute myocardial infarction	Caused or prolonged inpatient hospitalisation		
Arteriospasm coronary	Caused or prolonged inpatient hospitalisation		
Cardiogenic shock	Caused or prolonged inpatient hospitalisation		
Dizziness	Caused or prolonged inpatient hospitalisation		
Dyspepsia	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		
Transient ischaemic attack	Caused or prolonged inpatient hospitalisation		

Reaction :

Preferred Term	Severity	Report Description	Treatment
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine details :

PROTHIADEN (Suspected) **Reason :** Depression

250 Milligram Daily Oral

Batch : **Started :** **Stopped :** 12/06/2008

Ziprasidone (Suspected) **Reason :** Depression

60 Milligram Daily Oral

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

Selection Parameters : Date Range: 01/08/2007 To 31/01/2009 Unclear causality excluded GM medicines Only Medicine Names: DOTHEP, DOTHIEPIN HYDROCHLORIDE, DOTHIEPIN HYDROCHLORIDE TRIAL, PROTHIADEN