

Public Case Detail

Cases Count: 8

Case Number : 235233

Data Entry Date : 13/11/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 69Y

Outcome :

DOB :

Unknown

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

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date :

Age :

DOB : 25/09/1944

Outcome : 10/10/2007

Causality : Causality probable

Recovered

Information:

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

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

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

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Unknown

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

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/03/2007

Age : 58Y

DOB :

Outcome :

Causality : Causality possible

Unknown

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

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 35Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

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 :

Case Number : 242324

Data Entry Date : 26/06/2008

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date : 13/06/2008

Age :

Outcome : 13/06/2008

DOB : 06/05/1960

Recovered

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 :

Case Number : 247167

Data Entry Date : 16/12/2008

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 12/06/2008

Age :

Outcome : 19/06/2008

DOB : 26/12/1957

Recovered

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