



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 69282 **Seq:** 1 **Gender:** F
Reported: 15/01/1991 **Weight:**
Hospitalisation: **Age:** 41Y
Onset Date: 06/01/1991 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			
Dizziness			
Fatigue			
Migraine			

Medicine Details:

TRIFLUOPERAZINE HYDROCHLORIDE (Other drug)	Reason:
Oral application 10.0 Milligram Daily Oral	
Batch:	Started: 01/01/1991 Stopped: CONTIN
PROTHIADEN (Suspected)	Reason:
Oral application 225.0 Milligram Daily Oral	
Batch:	Started: 04/01/1991 Stopped: 06/01/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 69497 **Seq:** 1 **Gender:** U
Reported: 10/01/1991 **Weight:** 72.00
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 01/02/1987 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 69582 **Seq:** 1 **Gender:** M
Reported: 18/02/1991 **Weight:** 70.00
Hospitalisation: **Age:** 38Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache			
Stomatitis			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 07/01/1991 Stopped: 31/01/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 69642 **Seq:** 1 **Gender:** F
Reported: 22/02/1991 **Weight:**
Hospitalisation: **Age:** 26Y
Onset Date: 06/02/1991 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Hepatic function abnormal Nausea Vomiting			

Medicine Details:

PANADEINE FORTE (Suspected) Oral application Batch:	2.0 Dose Unspecified	Reason: Pain As necessary	Oral Stopped: 06/02/1991
RIVOTRIL (Suspected) Tablet Batch:	6.0 Dose Unspecified	Daily Reason: Pain	Oral Stopped: 06/02/1991
PROTHIADEN (Suspected) Oral application Batch:	75.0 Milligram	Daily Reason: Pain	Oral Stopped: 06/02/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 69694	Seq: 1	Gender: F
Reported: 01/03/1991		Weight: 65.00
Hospitalisation:		Age: 71Y
Onset Date: 07/10/1990		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arteritis			
Pain			
Rash erythematous			

Medicine Details:

KEFLEX (Other drug)	Reason: Pain refer to urinary system
Oral application	0.0
Batch:	Started: 21/08/1990
	Stopped:
KEFLEX (Other drug)	Reason: Influenza,unqualified
Oral application	0.0
Batch:	Started: 08/09/1990
	Stopped:
BETALOC (Other drug)	Reason: Essential benign hypertension
	100.0 Milligram
Batch:	Started: 01/01/1980
	Daily
	Stopped:
LANOXIN (Other drug)	Reason:
	250.0 Microgram
Batch:	Started: 13/09/1990
	Daily
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Histology				Biopsy with occlusive change and thrombosis of small deep dermal arteries (s & n 12/12/90). with endarteritis obliterans.

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 69694

Seq: 1

Gender: F

Reported: 01/03/1991

Weight: 65.00

Hospitalisation:

Age: 71Y

Onset Date: 07/10/1990

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

ALDOMET (Suspected)	Reason: Essential benign hypertension
500.0 Milligram	Daily
Batch:	Started: 13/09/1990
	Stopped: 01/11/1990
PROTHIADEN (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 13/09/1990
	Stopped: 01/11/1990

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 69791 **Seq:** 1 **Gender:** M
Reported: 05/03/1991 **Weight:**
Hospitalisation: **Age:** 44Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)		Reason:
Batch:	0.0	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 69911 **Seq:** 1 **Gender:** M
Reported: 11/03/1991 **Weight:**
Hospitalisation: **Age:** 68Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			Prednisone & intragam

Medicine Details:

CARBAMAZEPINE (Suspected)	Reason: Pain
0.0	
Batch:	Started: Stopped:
CLONAZEPAM (Suspected)	Reason: Pain
0.0	
Batch:	Started: Stopped:
PROTHIADEN (Suspected)	Reason: Pain
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology			1	platelet count 3.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 69938 **Seq:** 1 **Gender:** M
Reported: 14/03/1991 **Weight:** 88.00
Hospitalisation: **Age:** 66Y
Onset Date: 08/03/1991 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Insomnia			
Migraine			
Palpitations			
Paraesthesia			

Medicine Details:

DESERIL (Other drug)	Reason: Migraine
Tablet 3.0 Dose Unspecified Daily Oral	
Batch:	Started: 08/03/1991 Stopped: CONTIN
CAPOTEN (Other drug)	Reason: Essential benign hypertension
Tablet 2.0 Dose Unspecified Daily Oral	
Batch:	Started: 01/03/1991 Stopped: CONTIN
PROTHIADEN (Suspected)	Reason:
Tablet 1.0 Dose Unspecified Daily Oral	
Batch:	Started: 08/03/1991 Stopped: 10/03/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 69993	Seq: 1	Gender: F
Reported: 13/03/1991		Weight: 69.00
Hospitalisation:		Age: 59Y
Onset Date: 22/02/1991		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Encephalopathy			
Hepatic function abnormal			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
0.0	
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Bili 122 198 alkphos 343 70 ggt 726 87 ast 67 alt prt 35 04/03/91 alb 10 132 24 70

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 70036	Seq: 1	Gender: F
Reported: 18/03/1991		Weight: 58.00
Hospitalisation:		Age: 24Y
Onset Date: 09/11/1990		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination			
Nightmare			

Medicine Details:

MIGRAL (Other drug)	Reason: Migraine
0.0	
Batch:	Started:
Batch:	Stopped:
VALIUM (Other drug)	Reason: Essential benign hypertension
Oral application	0.0
	Oral
Batch:	Started:
Batch:	Stopped:
EPHEDRINE HYDROCHLORIDE (Other drug)	Reason:
Tablet	60.0 Milligram
	Daily
	Oral
Batch:	Started:
Batch:	Stopped:
AUGMENTIN FORTE (Other drug)	Reason:
Oral application	3.0 Dose Unspecified
	Daily
	Oral
Batch:	Started:
Batch:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 70036

Seq: 1

Gender: F

Reported: 18/03/1991

Weight: 58.00

Hospitalisation:

Age: 24Y

Onset Date: 09/11/1990

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

ROACCUTANE (Other drug)	Reason: Other acne of sebaceous glands	
3.0 Dose Unspecified Daily		
Batch:	Started: 01/04/1990	Stopped: 28/12/1990
PROTHIADEN (Suspected)	Reason:	
150.0 Milligram Total		
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 70205	Seq: 1	Gender: F
Reported: 13/03/1991		Weight:
Hospitalisation:		Age: 69Y
Onset Date: 22/08/1990		DOB:
Outcome: Death, maybe drug		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension			
Oliguria			
Peptic ulcer perforation			
Renal failure acute			
Tachycardia			

Medicine Details:

PANADEINE (Suspected)	Reason: Pain
2.0 Dose Unspecified As necessary	
Batch:	Started:
	Stopped: 30/08/1990
ORUDIS SR (Suspected)	Reason: Other rheumatoid arthritis
Capsule 200.0 Milligram Daily Oral	
Batch:	Started: 24/07/1990
	Stopped: 21/08/1990
PROTHIADEN (Suspected)	Reason: Depression
Oral application 50.0 Milligram Daily Oral	
Batch:	Started:
	Stopped: 21/08/1990
LACTULOSE (Suspected)	Reason: Constipation
Oral Liquid 200.0 Millilitre Daily Oral	
Batch:	Started:
	Stopped: 21/08/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 70205

Seq: 1

Gender: F

Reported: 13/03/1991

Weight:

Hospitalisation:

Age: 69Y

Onset Date: 22/08/1990

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Detail

Medicine Details:

IMIPRAMINE HYDROCHLORIDE (Suspected)	10.0 Milligram	Daily	reason: Incontinence of urine
Batch:	started: 02/08/1990	stopped: 21/08/1990	
PREDNISOLONE (Suspected)	10.0 Milligram	Alternate days	reason: Other rheumatoid arthritis
Batch:	started: 10/08/1990	stopped: 22/08/1990	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 70222	Seq: 1	Gender: F
Reported: 11/03/1991		Weight: 71.00
Hospitalisation:		Age: 70Y
Onset Date: 14/08/1990		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bruxism Coordination abnormal Cough Hyperventilation Thinking abnormal			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
0.0	
Batch:	Started: 01/06/1990 Stopped: 14/08/1990
RANITIDINE (Suspected)	Reason: Abdominal pain
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 01/06/1990 Stopped: 15/08/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 70318	Seq: 1	Gender: F
Reported: 02/04/1991		Weight: 65.00
Hospitalisation:		Age: 44Y
Onset Date: 09/12/1990		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	25.0 Milligram Daily Oral
Batch:	Started: 10/07/1990 Stopped: 20/03/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 70701	Seq: 1	Gender: F
Reported: 09/05/1991		Weight: 82.00
Hospitalisation:		Age: 44Y
Onset Date: 01/04/1991		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Salivary gland enlargement			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)		Reason: Anxiety neurosis
Oral application	225.0 Milligram	Daily Oral
Batch:	Started: 01/03/1991	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 71308 **Seq:** 1 **Gender:** M
Reported: 12/06/1991 **Weight:** 76.00
Hospitalisation: **Age:**
Onset Date: 30/05/1991 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paranoia			

Medicine Details:

THYROXINE SODIUM (Other drug) 75.0 Milligram Daily Batch: Started: 01/01/1985 Stopped:	Reason: Myxedema
TAGAMET (Other drug) 400.0 Milligram Daily Batch: Started: 01/01/1985 Stopped:	Reason: Ulcer of duodenum w/o ment perf
PROTHIADEN (Suspected) 25.0 Milligram Daily Batch: Started: 28/05/1991 Stopped: 11/06/1991	Reason: Depression

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 71375 **Seq:** 1 **Gender:** M
Reported: 18/06/1991 **Weight:** 89.00
Hospitalisation: **Age:** 62Y
Onset Date: 31/05/1991 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Tablet	75.0 Milligram Daily Oral
Batch:	Started: 01/01/1990 Stopped: 28/05/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 71433 **Seq:** 1 **Gender:** F
Reported: 19/06/1991 **Weight:** 53.00
Hospitalisation: **Age:** 54Y
Onset Date: 31/10/1990 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cough			Patient started prothiaden 50mg daily again on 8/5/91 for 5days with no cough, & then increased to 75mg on 13/5/91 & cough re-appeared.
Cough			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application 50.0 Milligram Daily Oral	
Batch:	Started: 01/02/1989 Stopped: 28/04/1990
PROTHIADEN (Suspected)	Reason: Depression
Oral application 75.0 Milligram Daily Oral	
Batch:	Started: 01/04/1990 Stopped: 03/12/1990

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 71625 **Seq:** 1 **Gender:** F
Reported: 03/06/1991 **Weight:** 48.00
Hospitalisation: **Age:** 61Y
Onset Date: 09/04/1991 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysuria		Difficulty voiding	
Abdominal pain		Stomach cramps	

Medicine Details:

DIAZEPAM (Other drug)	Reason: Depression	
Tablet 7.5 Milligram Daily Oral		
Batch:	Started:	Stopped:
AUGMENTIN (Other drug)	Reason: Chronic sinusitis	
Tablet 3.0 Dose Unspecified Daily Oral		
Batch:	Started: 01/02/1991	Stopped:
FOLIC ACID (Other drug)	Reason:	
Tablet 5.0 Milligram Daily Oral		
Batch:	Started:	Stopped:
BRUFEN (Other drug)	Reason: Unspecified arthritis	
Tablet 400.0 Milligram Daily Oral		
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 71625

Seq: 1

Gender: F

Reported: 03/06/1991

Weight: 48.00

Hospitalisation:

Age: 61Y

Onset Date: 09/04/1991

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

PREDNISOLONE (Other drug)	Reason:		
Tablet	12.5 Milligram	Alternate days	Oral
Batch:	Started: 30/01/1991	Stopped:	
PROTHIADEN (Suspected)	Reason: Depression		
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 05/04/1991	Stopped: 15/04/1991	

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 71641	Seq: 1	Gender: F
Reported: 16/07/1991		Weight:
Hospitalisation:		Age: 30Y
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Severe		Mersyndol prn

Medicine Details:

PARNATE (Suspected)	Reason: Depression
10.0 Milligram	Daily
Batch:	Started:
	Stopped:
PROTHIADEN (Suspected)	Reason: Depression
150.0 Milligram	Daily
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 71823 **Seq:** 1 **Gender:** M
Reported: 25/07/1991 **Weight:** 63.00
Hospitalisation: **Age:** 79Y
Onset Date: 12/06/1991 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Urticaria rash on arms/legs/upper trunk	

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 17/01/1991 Stopped: 28/06/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Rash disappeared 48 hrs after ceasing drug. off it for 3 days, restarted it, rash reappeared, went 2 days after ceasing. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 72049	Seq: 1	Gender: F
Reported: 30/06/1991		Weight: 57.00
Hospitalisation:		Age: 39Y
Onset Date: 11/05/1991		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Face oedema Right ventricular failure Tachycardia		Shortness of breath	

Medicine Details:

PROTHIADEN (Suspected)	Reason:
0.0	
Batch:	Started: 09/05/1991 Stopped: 15/05/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 72051	Seq: 1	Gender: M
Reported: 16/07/1991		Weight:
Hospitalisation:		Age: 60Y
Onset Date: 02/07/1991		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			

Medicine Details:

SALBUTAMOL (Other drug)	Reason:
Inhalation	2.0 Dose Unspecified As necessary Inhalation
Batch:	Started: Stopped:
UREX (Other drug)	Reason:
	40.0 Milligram Daily
Batch:	Started: Stopped:
CAPOTEN (Other drug)	Reason:
	75.0 Milligram Daily
Batch:	Started: Stopped:
PROTHIADEN (Suspected)	Reason: Anxiety neurosis
Tablet	75.0 Milligram Daily Oral
Batch:	Started: Stopped: 04/07/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Borderline cerebral circulation 100% stenosis (r) ica, 70% stenosis (l) ica.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 72198	Seq: 1	Gender: M
Reported: 01/08/1991		Weight: 71.00
Hospitalisation: Admitted to hospital		Age: 66Y
Onset Date: 25/07/1991		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angina pectoris		Angina	

Medicine Details:

RESPOLIN (Suspected)	Reason:
Inhalation	8.0 Dose Unspecified Daily Inhalation
Batch:	Started: 11/07/1991 Stopped: 25/07/1991
BECLOFORTE (Suspected)	Reason:
Inhalation	8.0 Dose Unspecified Daily Inhalation
Batch:	Started: L TERM Stopped:
PROTHIADEN (Suspected)	Reason: Depression
Tablet	75.0 Milligram Daily Oral
Batch:	Started: S TERM Stopped:
TEMAZEPAM (Suspected)	Reason: Anxiety neurosis
Capsule	20.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous allergies.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 72198 **Seq:** 1 **Gender:** M
Reported: 01/08/1991 **Weight:** 71.00
Hospitalisation: Admitted to hospital **Age:** 66Y
Onset Date: 25/07/1991 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

ATROVENT (Suspected)	Reason:
Inhalation	16.0 Dose Unspecified Daily Inhalation
Batch:	Started: 11/07/1991 Stopped: 25/07/1991

Laboratory Investigations:

Additional Information:

No previous allergies.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 72257	Seq: 1	Gender: M
Reported: 09/08/1991		Weight: 75.00
Hospitalisation:		Age: 59
Onset Date: 25/07/1991		DOB: 25/10/1931
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Jaundice		Cholestatic jaundice	

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
150.0 Milligram	Daily
Batch:	Started: 25/05/1991 Stopped: 17/06/1991
PROTHIADEN (Suspected)	Reason: Depression
300.0 Milligram	Daily
Batch:	Started: 17/06/1991 Stopped: 23/07/1991
PROTHIADEN (Suspected)	Reason: Depression
225.0 Milligram	Daily
Batch:	Started: 23/07/1991 Stopped: 25/07/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Bili - 18, alk - 463, ggt - 486, ast - 70.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 72292 **Seq:** 1 **Gender:** F
Reported: 13/08/1991 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: 10/03/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Grand mal seizures x 6	

Medicine Details:

DILANTIN (Other drug)	Reason:
Tablet 400.0 Milligram Daily Oral	
Batch: Started: Stopped:	
MYSOLINE (Other drug)	Reason:
Tablet 500.0 Milligram Daily Oral	
Batch: Started: Stopped:	
ZOCOR (Suspected)	Reason: Othr&unspec metabolic diseases
Tablet 10.0 Milligram Daily Oral	
Batch: Started: 17/01/1991 Stopped: CONTIN	
OGEN (Suspected)	Reason:
0.6 Milligram Daily	
Batch: Started: 17/01/1991 Stopped: CONTIN	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 72292

Seq: 1

Gender: F

Reported: 13/08/1991

Weight:

Hospitalisation:

Age: 49Y

Onset Date: 10/03/1991

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ISOPTIN SR (Suspected)	240.0 Milligram	Daily	Reason: Essential benign hypertension
Batch:	Started: 17/01/1991	Stopped:	CONTIN
PROTHIADEN (Suspected)	25.0 Milligram	Daily	Reason: Depression
Batch:	Started: 17/01/1991	Stopped:	CONTIN

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 72387 **Seq:** 1 **Gender:** M
Reported: 16/08/1991 **Weight:** 80.00
Hospitalisation: **Age:** 79Y
Onset Date: 06/07/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Daytime somnolence	

Medicine Details:

MODURETIC (Other drug)	Reason: Essential benign hypertension
1.0 Dose Unspecified Daily	
Batch:	Started: 01/01/1985 Stopped:
MINIPRESS (Other drug)	Reason: Essential benign hypertension
2.0 Dose Unspecified Daily	
Batch:	Started: 01/01/1987 Stopped:
PROTHIADEN (Suspected)	Reason: Depression
Capsule	1.0 Dose Unspecified Daily Oral
Batch:	Started: 05/07/1991 Stopped: 20/07/1991
MINOMYCIN (Suspected)	Reason: Prostatitis
Powder	1.0 Dose Unspecified Daily Oral
Batch:	Started: Stopped: 26/07/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 72462 **Seq:** 1 **Gender:** F
Reported: 09/08/1991 **Weight:**
Hospitalisation: **Age:** 61Y
Onset Date: 31/12/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Glaucoma			
Visual disturbance			

Medicine Details:

MOGADON (Other drug)	Reason:
5.0 Milligram Daily	
Batch:	Started: L TERM Stopped: 20/01/1991
FLUPHENAZINE HYDROCHLORIDE (Other drug)	Reason:
1.0 Milligram Daily	
Batch:	Started: 08/10/1990 Stopped: 21/05/1991
PROTHIADEN (Suspected)	Reason: Depression
175.0 Milligram Daily	
Batch:	Started: 22/09/1990 Stopped: 08/01/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 73677	Seq: 1	Gender: M
Reported: 22/10/1991		Weight: 64.00
Hospitalisation:		Age: 54
Onset Date: 06/08/1991		DOB: 01/01/1937
Outcome: Death, maybe drug		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatosplenomegaly Pancytopenia Pseudolymphoma Pyrexia			

Medicine Details:

PANADOL (Suspected)	Reason:
Tablet	6.0 Gram As necessary Oral
Batch:	Started: Stopped:
COLOXYL WITH SENNA (Suspected)	Reason:
	1.0 Dose Unspecified As necessary
Batch:	Started: Stopped:
DILANTIN (Suspected)	Reason: Convulsions
Capsule	300.0 Milligram Daily Oral
Batch:	Started: 01/06/1991 Stopped: 10/09/1991
PROTHIADEN (Suspected)	Reason: Depression
Tablet	125.0 Milligram Daily Oral
Batch:	Started: 01/06/1991 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				12/08/91 immunophenotyping (flow cytometry) - an abnormal nk cell-like population has been detected, the findings suggest a lymphoproliferative disorder.
	Haemoglobin Histology	13.0-18.0G/DL	16/08/1991	11.2	13/09/1991 - patient has a population of very abnormal cells in the blood and marrow. these are associated with cytopenia and an enlarged spleen. the abnormal cells have markers of nk-cells. they may represent a malignant cell population conversely the marrow trephine shows granulomata

Additional Information:

Patient died 28/9/91 the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 73677	Seq: 1	Gender: M
Reported: 22/10/1991		Weight: 64.00
Hospitalisation:		Age: 54
Onset Date: 06/08/1991		DOB: 01/01/1937
Outcome: Death, maybe drug		Causality: Causality possible

Reaction Detail

Medicine Details:

PANADOL (Suspected)		Reason:	
Tablet	6.0 Gram	As necessary	Oral
Batch:	Started:	Stopped:	
COLOXYL WITH SENNA (Suspected)		Reason:	
	1.0 Dose Unspecified	As necessary	
Batch:	Started:	Stopped:	
DILANTIN (Suspected)		Reason: Convulsions	
Capsule	300.0 Milligram	Daily	Oral
Batch:	Started: 01/06/1991	Stopped: 10/09/1991	
PROTHIADEN (Suspected)		Reason: Depression	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 01/06/1991	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Histology				23/08/91 bone marrow aspiration report- comment- marrow granuloma of undetermined aetiology.
	Other data				Com.01 = there are two populations of lymphocytes differentiated on the basis of size. the larger cells appear to represent a clone with a peculiar -ation of surface markers, i.e. positive for hla-dr, nk cell markers cd16/56 and kappa light chains but negative for the pan b cell marker cd19.
	Red blood cells	4.60-6.20X10 ¹²	16/08/1991	3.89	
	White blood cells	4.0-11.0X10 ⁹ /L	16/08/1991	2.8	

Additional Information:

Patient died 28/9/91 the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 73804	Seq: 1	Gender: F
Reported: 11/10/1991		Weight: 65.00
Hospitalisation:		Age: 73Y
Onset Date: 25/09/1991		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention			

Medicine Details:

PANADOL (Other drug)	Reason: Thyrotoxicosis w/o ment goiter
Tablet	2.0 Gram
Batch:	Started: L TERM Stopped:
EUHYPNOS (Other drug)	Reason:
Capsule	10.0 Milligram
Batch:	Started: 26/07/1991 Stopped:
OROXINE (Other drug)	Reason: Thyrotoxicosis w/o ment goiter
Tablet	100.0 Microgram
Batch:	Started: L TERM Stopped:
MELLERIL (Other drug)	Reason: Hallucinations
Tablet	50.0 Milligram
Batch:	Started: 20/08/1991 Stopped: 28/08/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 73804

Seq: 1

Gender: F

Reported: 11/10/1991

Weight: 65.00

Hospitalisation:

Age: 73Y

Onset Date: 25/09/1991

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression		
Capsule	25.0 Milligram	Daily	Oral
Batch:	Started: 28/08/1991	Stopped: 04/09/1991	
PROTHIADEN (Suspected)	Reason: Depression		
Capsule	50.0 Milligram	Daily	Oral
Batch:	Started: 05/09/1991	Stopped: 22/09/1991	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 73805	Seq: 1	Gender: F
Reported: 11/10/1991		Weight: 65.00
Hospitalisation:		Age: 73Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Constipation			Given soap and water enema and 2 litres of go-lytely orally.

Medicine Details:

PROTHIADEN (Suspected)		Reason: Depression
Tablet	75.0 Milligram	Daily Oral
Batch:	Started: 23/09/1991	Stopped: 24/09/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 74038 **Seq:** 1 **Gender:** M
Reported: 05/11/1991 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: 01/11/1991 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

PROTHIADEN (Suspected)		Reason: Depression
Oral application	75.0 Milligram	Daily Oral
Batch:	Started: 25/10/1991	Stopped: 01/11/1991
THIAMINE (Suspected)		Reason:
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: L TERM	Stopped:
ATIVAN (Suspected)		Reason: Anxiety neurosis
Tablet	1.5 Milligram	Daily Oral
Batch:	Started: 25/10/1991	Stopped:
SALBUTAMOL (Suspected)		Reason:
Inhalation	6.0 Dose Unspecified	Daily Inhalation
Batch:	Started: L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrolytes				Osmolality of urine and serum results suggested siadh.
	Sodium	135-145	01/11/1991	123	Osmolality of serum - 257mmol/kg
	Sodium	135-145	04/11/1991	129	Osmolality of serum - 257mmol/kg
	Sodium	135-145	06/11/1991	133	Osmolality of serum - 257mmol/kg
	Urine Potassium		01/11/1991	52	Osmolality of urine-485mmol/kg
	Urine Sodium		01/11/1991	53	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 74038 **Seq:** 1 **Gender:** M
Reported: 05/11/1991 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: 01/11/1991 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

MYLANTA (Suspected)	Reason:
Solution	80.0 Millilitre Daily Oral
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 74130 **Seq:** 1 **Gender:** M
Reported: 09/11/1991 **Weight:** 70.00
Hospitalisation: **Age:** 27Y
Onset Date: 20/07/1991 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Glossitis		Dry tongue/lips.	
Dry mouth		Sore tongue.	

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	37.0 Milligram Daily Oral
Batch:	Started: 01/07/1991 Stopped: 20/09/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 74340 **Seq:** 1 **Gender:** F
Reported: 25/11/1991 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: 24/11/1991 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			

Medicine Details:

INDERAL (Suspected)	Reason: Migraine
Tablet	10.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:
PROTHIADEN (Suspected)	Reason: Depression
	25.0 Milligram Daily
Batch:	Started: 21/11/1991 Stopped: 25/11/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 74451 **Seq:** 1 **Gender:** F
Reported: 02/12/1991 **Weight:** 57.00
Hospitalisation: **Age:** 36Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disturbance in attention			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Anxiety neurosis
75.0 Milligram	Daily
Batch:	Started: 01/09/1991 Stopped: 20/11/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 74695 **Seq:** 1 **Gender:** F
Reported: 13/12/1991 **Weight:** 57.00
Hospitalisation: **Age:** 46Y
Onset Date: 04/06/1991 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperaesthesia		Abnormal sensitivity of skin.	
Dysgeusia		Foul taste in mouth.	
Nausea			
Parosmia			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
375.0 Milligram	Daily
Batch:	Started: 26/04/1991 Stopped: 04/06/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 74706	Seq: 1	Gender: M
Reported: 09/12/1991		Weight: 56.00
Hospitalisation:		Age: 82Y
Onset Date: 29/10/1991		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Inappropriate antidiuretic hormone		Acute confusional state.	Cessation of prothiaden, fluid restriction.

Medicine Details:

PROTHIADEN (Suspected)	Reason: Specific disorders of sleep
25.0 Milligram	Daily
Batch:	Started: 04/10/1991 Stopped: 07/11/1991
ZANTAC (Suspected)	Reason: Otr intestine&peritoneum disease
300.0 Milligram	Daily
Batch:	Started: 11/10/1991 Stopped: 11/11/1991
NILSTAT (Suspected)	Reason: Moniliasis
Solution 8.0 Millilitre	Daily Oral
Batch:	Started: 22/10/1991 Stopped: 03/11/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details												
	Electrolytes				<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;"></td> <td style="width: 33%;">9/11/91 11/11/91 21/11/91</td> <td style="width: 33%;"></td> </tr> <tr> <td></td> <td>serum urine serum sodium</td> <td style="text-align: right;">27</td> </tr> <tr> <td>125 136</td> <td>mmol/l osmolality 414 259</td> <td>---</td> </tr> <tr> <td></td> <td>mmol/kg</td> <td></td> </tr> </table>		9/11/91 11/11/91 21/11/91			serum urine serum sodium	27	125 136	mmol/l osmolality 414 259	---		mmol/kg	
	9/11/91 11/11/91 21/11/91																
	serum urine serum sodium	27															
125 136	mmol/l osmolality 414 259	---															
	mmol/kg																

Additional Information:

See original report for other continuing medication.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 74719	Seq: 1	Gender: F
Reported: 13/12/1991		Weight: 86.00
Hospitalisation:		Age: 69Y
Onset Date: 03/12/1991		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Back pain			
Fatigue			
Leukopenia			
Pyrexia			
Thrombocytopenia			

Medicine Details:

LASIX (Other drug)	Reason: Chron isch heart dis no hyper
1.0 Dose Unspecified Daily	
Batch:	Started: L TERM Stopped: CONTIN
SPAN-K (Other drug)	Reason: Essential benign hypertension
2.0 Dose Unspecified Daily	
Batch:	Started: L TERM Stopped: CONTIN
TENORMIN (Other drug)	Reason: Essential benign hypertension
50.0 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN
DUCENE (Other drug)	Reason: Depression
5.0 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haemoglobin		03/12/1991	15.8	
	Haemoglobin		04/12/1991	14.8	
	Haemoglobin		09/12/1991	13.0	
	Neutrophils		03/12/1991	56%	
	Neutrophils		04/12/1991	80%	
	Neutrophils		09/12/1991	58%	
	Platelets		03/12/1991	117	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 74719	Seq: 1	Gender: F
Reported: 13/12/1991		Weight: 86.00
Hospitalisation:		Age: 69Y
Onset Date: 03/12/1991		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Medicine Details:

LOSEC (Other drug)	Reason: Ulcer of stomach w/o ment perf
40.0 Milligram	Daily
Batch:	Started: 01/07/1991 Stopped: CONTIN
PROTHIADEN (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 01/09/1991 Stopped: 03/12/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets		04/12/1991	86	
	Platelets		09/12/1991	145	
	White blood cells		03/12/1991	0.67 0.58	
	White blood cells		04/12/1991	6.31	
	White blood cells		09/12/1991	4.05	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 74772 **Seq:** 1 **Gender:** F
Reported: 12/12/1991 **Weight:**
Hospitalisation: **Age:** 62Y
Onset Date: **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			
Hyponatraemia			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	75.0 Milligram Daily Oral
Batch:	Started: 12/10/1991 Stopped: 22/11/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 74793 **Seq:** 1 **Gender:** F
Reported: 09/12/1991 **Weight:**
Hospitalisation: **Age:** 73Y
Onset Date: 27/10/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypokalaemia			
Hyponatraemia			Fluid restriction, iv hydration.

Medicine Details:

TRIAZOLAM (Suspected)	Reason:
0.0	
Batch:	Started: Stopped: 27/10/1991
LIBRIUM (Suspected)	Reason:
20.0 Milligram Daily	
Batch:	Started: Stopped: 29/10/1991
PROTHIADEN (Suspected)	Reason:
50.0 Milligram Daily	
Batch:	Started: 20/10/1991 Stopped: 27/10/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium	3.4-5.0 MMOL/L	27/10/1991	3.3	
	Potassium	3.4-5.0 MMOL/L	28/10/1991	2.8	
	Potassium	3.4-5.0 MMOL/L	30/10/1991	3.5	
	Potassium	3.4-5.0 MMOL/L	29/10/1991	3.3	
	Sodium	134-146	27/10/1991	122	
	Sodium	134-146	28/10/1991	126	
	Sodium	134-146	29/10/1991	137	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 74793 **Seq:** 1 **Gender:** F
Reported: 09/12/1991 **Weight:**
Hospitalisation: **Age:** 73Y
Onset Date: 27/10/1991 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

TRIAZOLAM (Suspected)	Reason:
0.0	
Batch:	Started: Stopped: 27/10/1991
LIBRIUM (Suspected)	Reason:
20.0 Milligram Daily	
Batch:	Started: Stopped: 29/10/1991
PROTHIADEN (Suspected)	Reason:
50.0 Milligram Daily	
Batch:	Started: 20/10/1991 Stopped: 27/10/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	134-146	30/10/1991	137	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 74905	Seq: 1	Gender: F
Reported: 20/12/1991		Weight: 60.00
Hospitalisation:		Age: 71Y
Onset Date: 07/12/1991		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Torsade de pointes			

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected)	Reason: Unspecified schizophrenia
Oral application	200.0 Milligram Daily Oral
Batch:	Started: 01/01/1986 Stopped: 18/12/1991
DOTHIPIIN HYDROCHLORIDE (Suspected)	Reason: Depression
	150.0 Milligram Daily
Batch:	Started: 01/01/1986 Stopped: 18/12/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Qt grossly prolonged

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 75452	Seq: 1	Gender: F
Reported: 07/02/1992		Weight: 80.00
Hospitalisation:		Age: 71Y
Onset Date: 01/02/1992		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia Hyperhidrosis Rash		Aches.	

Medicine Details:

ZYLOPRIM (Suspected)	Reason:
300.0 Milligram Daily	
Batch:	Started: 18/01/1992 Stopped: 03/02/1992
DYAZIDE (Suspected)	Reason: Essential benign hypertension
1.0 Dose Unspecified Daily	
Batch:	Started: 01/01/1986 Stopped: 03/02/1992
AUGMENTIN FORTE (Suspected)	Reason: Acute pharyngitis
3.0 Dose Unspecified Daily	
Batch:	Started: 30/01/1992 Stopped: 03/02/1992
BETALOC (Suspected)	Reason: Essential benign hypertension
150.0 Milligram Daily	
Batch:	Started: 01/06/1991 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 75452 Seq: 1

Gender: F

Reported: 07/02/1992

Weight: 80.00

Hospitalisation:

Age: 71Y

Onset Date: 01/02/1992

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

CARTIA (Suspected)	Reason:		
	1.0 Dose Unspecified Daily		
Batch:	Started: 01/06/1991	Stopped:	CONTIN
PROTHIADEN (Suspected)	Reason: Depression		
	50.0 Milligram Daily		
Batch:	Started: 01/06/1991	Stopped:	CONTIN

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 75789 **Seq:** 1 **Gender:** M
Reported: 28/02/1992 **Weight:**
Hospitalisation: **Age:** 64Y
Onset Date: 14/11/1990 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paranoia			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application 150.0 Milligram Daily Oral	
Batch:	Started: 13/09/1990 Stopped:
CAPOTEN (Suspected)	Reason: Essential benign hypertension
Tablet 12.5 Milligram Daily Oral	
Batch:	Started: 09/11/1990 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died on the 15/11/90.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 75898	Seq: 1	Gender: M
Reported: 10/03/1992		Weight:
Hospitalisation:		Age: 39Y
Onset Date: 26/02/1992		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aplastic anaemia			
Retinal haemorrhage			

Medicine Details:

PROTHIADEN (Suspected) Oral application Batch:	0.0	Reason: Depression Daily	Oral Started: 01/07/1991 Stopped: 21/02/1992
PROZAC (Suspected) Tablet Batch:	0.0	Reason: Depression Daily	Oral Started: 01/10/1991 Stopped: 4D
PROZAC (Suspected) Tablet Batch:	0.0	Reason: Depression Daily	Oral Started: 24/02/1992 Stopped: 26/02/1992
ANATENSOL (Suspected) Tablet Batch:	0.0	Reason: Paranoid states Daily	Oral Started: 01/11/1991 Stopped: 28/12/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 75982 **Seq:** 1 **Gender:** F
Reported: 23/09/1991 **Weight:** 57.00
Hospitalisation: **Age:** 28Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Acne		Acne over back and chest	

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 26/06/1991 Stopped: 28/08/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 76194	Seq: 1	Gender: F
Reported: 27/03/1992		Weight: 70.00
Hospitalisation:		Age: 42Y
Onset Date: 01/03/1992		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia		Jaw clenched.	
Muscle twitching		Twitching tongue	
Agitation			

Medicine Details:

PREMARIN (Other drug)	Reason:
Tablet	625.0 Microgram Daily Oral
Batch:	Started: 03/02/1992 Stopped:
EPILIM (Other drug)	Reason: Other&unspecified epilepsy
Oral application	1.8 Gram Daily Oral
Batch:	Started: 01/01/1990 Stopped:
SEREPAX (Other drug)	Reason: Anxiety neurosis
Tablet	60.0 Milligram Daily Oral
Batch:	Started: 01/01/1979 Stopped:
INDERAL (Other drug)	Reason: Essential benign hypertension
Tablet	80.0 Milligram Daily Oral
Batch:	Started: 01/01/1990 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 76194

Seq: 1

Gender: F

Reported: 27/03/1992

Weight: 70.00

Hospitalisation:

Age: 42Y

Onset Date: 01/03/1992

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

PEPCIDINE (Other drug)	Reason: Ulcer of stomach w/o ment perf		
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1990	Stopped:	
PROTHIADEN (Suspected)	Reason: Depression		
	150.0 Milligram	Daily	
Batch:	Started: 21/02/1992	Stopped: 28/02/1992	

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 76200 **Seq:** 1 **Gender:** F
Reported: 25/03/1992 **Weight:** 32.00
Hospitalisation: **Age:** 69Y
Onset Date: 20/03/1992 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination		Seeing people and ants.	

Medicine Details:

QUINATE (Other drug)	Reason: Pain in limb
Tablet 300.0 Milligram Daily Oral	
Batch:	Started: Stopped:
PROTHIADEN (Suspected)	Reason: Depression
Tablet 150.0 Milligram Daily Oral	
Batch:	Started: 11/03/1992 Stopped: 20/03/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 76289	Seq: 1	Gender: F
Reported: 30/03/1992		Weight: 55.00
Hospitalisation:		Age: 79Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Tonic-clonic fitting	

Medicine Details:

LITHIUM CARBONATE (Other drug) 500.0 Milligram Daily Batch: Started: Stopped:	Reason:
DOTHIEPIN HYDROCHLORIDE (Suspected) 75.0 Milligram Daily Batch: Started: Stopped:	Reason:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 76306	Seq: 1	Gender: F
Reported: 27/03/1992		Weight: 53.00
Hospitalisation:		Age: 59Y
Onset Date: 25/03/1992		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysgeusia		Peculiar taste sensation	
Rash maculo-papular		Rash on tongue	

Medicine Details:

SEREPAX (Other drug)		Reason:	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
PROTHIADEN (Suspected)		Reason:	
Oral application	75.0 Milligram	Daily	Oral
Batch:	Started: 24/03/1992	Stopped: 27/03/1992	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 76313 **Seq:** 1 **Gender:** M
Reported: 31/03/1992 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anticholinergic syndrome			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)		Reason:	
Batch:	0.0	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 76388 **Seq:** 1 **Gender:** M
Reported: 29/03/1992 **Weight:**
Hospitalisation: **Age:** 70
Onset Date: **DOB:** 19/05/1921
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Accommodation disorder			
Diplopia			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient stoped the dothiepin and noted the diplopia disappeared. he than recommenced the drug after a month and the diplopia returned.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 76486 **Seq:** 1 **Gender:** F
Reported: 09/04/1992 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: 31/03/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased			

Medicine Details:

PROTHIADEN (Suspected)	Reason:	
Batch:	Started:	Stopped:
	0.0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 76836 **Seq:** 1 **Gender:** F
Reported: 10/04/1992 **Weight:** 75.00
Hospitalisation: **Age:** 80Y
Onset Date: 04/04/1992 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		On full body	

Medicine Details:

KEFLEX (Suspected)	Reason: Other diseases of lung
Oral application 2.0 Gram Daily Oral	
Batch:	Started: 30/03/1992 Stopped: 02/04/1992
VIBRAMYCIN (Suspected)	Reason: Other diseases of lung
Tablet 1.0 Dose Unspecified Daily Oral	
Batch:	Started: 03/04/1992 Stopped: 05/04/1992
NOCTEC (Suspected)	Reason:
Capsule 1.0 Dose Unspecified Daily Oral	
Batch:	Started: 27/03/1992 Stopped: 10/04/1992
PROTHIADEN (Suspected)	Reason: Depression
Oral application 75.0 Milligram Daily Oral	
Batch:	Started: 27/03/1992 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 76836 Seq: 1

Gender: F

Reported: 10/04/1992

Weight: 75.00

Hospitalisation:

Age: 80Y

Onset Date: 04/04/1992

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PREDNISOLONE (Suspected)	Reason: Asthma		
Oral application	30.0 Milligram	Daily	Oral
Batch:	Started: 27/03/1992	Stopped:	
PULMICORT TURBUHALER (Suspected)	Reason: Asthma		
	2.4 Milligram	Daily	
Batch:	Started: 04/04/1992	Stopped:	
LASIX (Suspected)	Reason:		
Oral application	0.0	Daily	Oral
Batch:	Started: 04/04/1992	Stopped:	
SLOW-K (Suspected)	Reason:		
Tablet	1.2 Gram	Daily	Oral
Batch:	Started: 04/04/1992	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 76836 Seq: 1

Gender: F

Reported: 10/04/1992

Weight: 75.00

Hospitalisation:

Age: 80Y

Onset Date: 04/04/1992

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

VENTOLIN (Suspected)	Reason: Asthma
Inhalation 20.0 Milligram Daily Inhalation	
Batch:	Started: 21/03/1992 Stopped:
THEO-DUR (Suspected)	Reason: Asthma
Tablet 600.0 Milligram Daily Oral	
Batch:	Started: 27/03/1992 Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 76920 **Seq:** 1 **Gender:** F
Reported: 30/04/1992 **Weight:** 40.00
Hospitalisation: **Age:** 20Y
Onset Date: 01/04/1992 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	50.0 Milligram Daily Oral
Batch:	Started: 24/03/1992 Stopped: 15/04/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets	150-400	01/10/1990	249	
	Platelets	150-400	14/04/1992	86	
	Platelets	150-400	28/04/1992	150	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 77200	Seq: 1	Gender: M
Reported: 22/05/1992		Weight: 75.00
Hospitalisation:		Age: 78Y
Onset Date: 18/05/1992		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Photosensitivity reaction Pyrexia			

Medicine Details:

MOGADON (Other drug)	Reason: Specific disorders of sleep
2.0 Dose Unspecified Daily	
Batch:	Started: 01/01/1987 Stopped: CONTIN
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
75.0 Milligram Daily	
Batch:	Started: 11/05/1992 Stopped: 19/05/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	0-41	18/06/1992	50	
	AST = SGOT	0-37	18/06/1992	36	
	Bilirubin	0-20	18/06/1992	9	
	GGT = SGGT =	0-50	18/06/1992	85	
	LDH	UP TO 500	18/06/1992	872	
	SAP = ALP	0-120	18/06/1992	217	

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 77379	Seq: 1	Gender: F
Reported: 04/06/1992		Weight:
Hospitalisation:		Age: 64Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypochloraemia			
Hyponatraemia			Saline and diuresis.

Medicine Details:

MODURETIC (Suspected)	Reason: Essential benign hypertension
Tablet	1.0 Dose Unspecified Daily Oral
Batch:	Started: L TERM Stopped:
PROTHIADEN (Suspected)	Reason: Depression
	50.0 Milligram Daily
Batch:	Started: 09/11/1990 Stopped:
VALIUM (Suspected)	Reason: Anxiety neurosis
Oral application	10.0 Milligram Daily Oral
Batch:	Started: 03/11/1990 Stopped:
THYROXINE SODIUM (Suspected)	Reason: Simple goiter unspecified
	150.0 Microgram Daily
Batch:	Started: 15/05/1992 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chloride		25/05/1992	69	
	Sodium		25/05/1992	196	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 77392	Seq: 1	Gender: M
Reported: 03/06/1992		Weight: 78.00
Hospitalisation:		Age: 51Y
Onset Date: 28/05/1992		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Severe		Antibiotic cover.

Medicine Details:

DIAZEPAM (Other drug)	Reason:	As necessary
Batch:	5.0 Milligram	Stopped:
Started:		
PROTHIADEN (Suspected)	Reason:	
Batch:	0.0	Stopped:
Started: 01/12/1991		
ANAFRANIL (Suspected)	Reason: Depression	
Batch:	100.0 Milligram	Daily
Started: 06/04/1992		Stopped: 28/05/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	5-44 U/L	28/05/1992	44	
	Bilirubin	0-20 UMOL/L	28/05/1992	30	
	GGT = SGGT = GGT	0-60 U/L	28/05/1992	62	
	Lymphocytes	1.5-4.0	28/05/1992	0.5	
	Lymphocytes	1.5-4.0	29/05/1992	-	
	Lymphocytes	1.5-4.0	31/05/1992	-	
	Lymphocytes	1.5-4.0	01/06/1992	1.4	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 77392	Seq: 1	Gender: M
Reported: 03/06/1992		Weight: 78.00
Hospitalisation:		Age: 51Y
Onset Date: 28/05/1992		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Medicine Details:

DIAZEPAM (Other drug)	Reason:	
5.0 Milligram	As necessary	
Batch:	Started:	Stopped:
PROTHIADEN (Suspected)	Reason:	
0.0		
Batch:	Started: 01/12/1991	Stopped:
ANAFRANIL (Suspected)	Reason: Depression	
100.0 Milligram	Daily	
Batch:	Started: 06/04/1992	Stopped: 28/05/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Lymphocytes	1.5-4.0	30/05/1992	0.7	
	Lymphocytes	1.5-4.0	04/06/1992	3.2	
	Monocytes	0.2-0.8	28/05/1992	0.0	
	Monocytes	0.2-0.8	31/05/1992	-	
	Monocytes	0.2-0.8	04/06/1992	0.4	
	Monocytes	0.2-0.8	01/06/1992	0.1	
	Monocytes	0.2-0.8	30/05/1992	-	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 77392

Seq: 1

Gender: M

Reported: 03/06/1992

Weight: 78.00

Hospitalisation:

Age: 51Y

Onset Date: 28/05/1992

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

DIAZEPAM (Other drug)	Reason:
5.0 Milligram	As necessary
Batch:	Started:
Stopped:	
PROTHIADEN (Suspected)	Reason:
0.0	
Batch:	Started: 01/12/1991
Stopped:	
ANAFRANIL (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 06/04/1992
Stopped:	28/05/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Monocytes	0.2-0.8	29/05/1992	-	
	Neutrophils	2.0-7.5	28/05/1992	0.1	
	Neutrophils	2.0-7.5	29/05/1992	-	
	Neutrophils	2.0-7.5	30/05/1992	0.0	
	Neutrophils	2.0-7.5	04/06/1992	2.0	
	Neutrophils	2.0-7.5	01/06/1992	0.1	
	Neutrophils	2.0-7.5	31/05/1992	-	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 77392

Seq: 1

Gender: M

Reported: 03/06/1992

Weight: 78.00

Hospitalisation:

Age: 51Y

Onset Date: 28/05/1992

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

DIAZEPAM (Other drug)	Reason:
5.0 Milligram	As necessary
Batch:	Started:
Stopped:	
PROTHIADEN (Suspected)	Reason:
0.0	
Batch:	Started: 01/12/1991
Stopped:	
ANAFRANIL (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 06/04/1992
Stopped:	28/05/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	39-117	28/05/1992	101	
	White blood cells	4.0-11.0	28/05/1992	0.8	
	White blood cells	4.0-11.0	29/05/1992	0.8	
	White blood cells	4.0-11.0	30/05/1992	0.8	
	White blood cells	4.0-11.0	31/05/1992	1.0	
	White blood cells	4.0-11.0	01/06/1992	1.8	
	White blood cells	4.0-11.0	04/06/1992	7.6	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 77705	Seq: 1	Gender: F
Reported: 18/06/1992		Weight: 58.00
Hospitalisation:		Age: 57Y
Onset Date: 23/04/1992		DOB:
Outcome: Recovered		Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperacusis			

Medicine Details:

SALAZOPYRIN (Other drug)		Reason:	
Tablet	2.0 Gram	Daily	Oral
Batch:	Started: 01/01/1972	Stopped:	
PROTHIADEN (Suspected)		Reason:	
Oral application	25.0 Milligram	Daily	Oral
Batch:	Started: 09/04/1992	Stopped: 08/05/1992	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient rechallenged on prothiaden with same reaction. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 77965	Seq: 1	Gender: M
Reported: 30/06/1992		Weight: 58.00
Hospitalisation:		Age: 34Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bone marrow failure Headache Leukopenia Malaise Pyrexia Thrombocytopenia			

Medicine Details:

PANADEINE FORTE (Other drug)	Reason:	
0.0		
Batch:	Started:	Stopped:
ENDONE (Other drug)	Reason:	
0.0		
Batch:	Started:	Stopped:
PROTHIADEN (Suspected)	Reason:	
Oral application	3.0 Dose Unspecified Daily	Oral
Batch:	Started: 01/01/1992	Stopped: 11/06/1992
TEGRETOL (Suspected)	Reason:	
Tablet	200.0 Milligram Daily	Oral
Batch:	Started: 01/01/1992	Stopped: 11/06/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets	150-400 X10 ⁹ /L	20/11/1991	267	
	Platelets	150-400 X10 ⁹ /L	11/06/1992	64	
	Platelets	150-400 X10 ⁹ /L	12/06/1992	73	
	Red blood cells	4.5 - 6/3	20/11/1991	4.69	
	Red blood cells	4.5 - 6/3	11/06/1992	4.40	
	Red blood cells	4.5 - 6/3	12/06/1992	4.15	
	White blood cells	4.0 - 11.0	20/11/1991	6.3	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 77965	Seq: 1	Gender: M
Reported: 30/06/1992		Weight: 58.00
Hospitalisation:		Age: 34Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Medicine Details:

PANADEINE FORTE (Other drug)	Reason:
0.0	
Batch:	Started:
Batch:	Stopped:
ENDONE (Other drug)	Reason:
0.0	
Batch:	Started:
Batch:	Stopped:
PROTHIADEN (Suspected)	Reason:
Oral application	3.0 Dose Unspecified Daily Oral
Batch:	Started: 01/01/1992 Stopped: 11/06/1992
TEGRETOL (Suspected)	Reason:
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 01/01/1992 Stopped: 11/06/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells	4.0 - 11.0	11/06/1992	3.3	
	White blood cells	4.0 - 11.0	12/06/1992	2.8	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 78062	Seq: 1	Gender: F
Reported: 06/07/1992		Weight:
Hospitalisation:		Age:
Onset Date: 02/07/1992		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination		Visual and auditory hallucinations	

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
25.0 Milligram Daily	
Batch:	Started: 11/05/1992 Stopped: 03/07/1992
VISKEN (Suspected)	Reason: Essential benign hypertension
20.0 Milligram Daily	
Batch:	Started: 01/01/1987 Stopped: 03/07/1992
MINIPRESS (Suspected)	Reason: Essential benign hypertension
2.0 Milligram Daily	
Batch:	Started: 21/05/1991 Stopped: 03/07/1992
NORMISON (Suspected)	Reason: Specific disorders of sleep
10.0 Milligram Daily	
Batch:	Started: 01/01/1987 Stopped: 03/02/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 78169 **Seq:** 1 **Gender:** M
Reported: 10/07/1992 **Weight:**
Hospitalisation: **Age:** -1
Onset Date: 31/10/1991 **DOB:** 29/05/1992
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Limb reduction defect		Rudimentary lower leg and boneless foot	

Medicine Details:

PROTHIADEN (Suspected)	Reason:
Batch:	50.0 Milligram Daily
Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Right lower leg which showed a tapering with a vestigial rudimentary foot at the end of the shortened leg. the knee seems normal and the leg down 6 cms. below the knee also seems normal. subsequent x-rays have suggested both bones are present in the leg but there are no bones in the foot at all

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 78541	Seq: 1	Gender: F
Reported: 25/07/1992		Weight:
Hospitalisation:		Age: 35Y
Onset Date: 23/04/1992		DOB:
Outcome: Recovered		Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Muscle twitching	
Aggression		Uncontrollable anger	
Paranoia			

Medicine Details:

PROTHIADEN (Suspected)		Reason: Depression
Oral application	25.0 Milligram	Daily Oral
Batch:	Started: 23/04/1992	Stopped: 26/04/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred on 3 occasions consecutively



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 78603	Seq: 1	Gender: F
Reported: 16/07/1992		Weight: 72.00
Hospitalisation:		Age:
Onset Date: 09/04/1992		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Agitation Anxiety Confusional state Coordination abnormal Delusion Hallucination Nightmare		At night Restlessness	

Medicine Details:

PROTHIADEN (Suspected)		Reason: Depression
Capsule	25.0 Milligram	Daily Oral
Batch:	Started: 09/04/1992	Stopped: 14/04/1992
TOFRANIL (Suspected)		Reason:
Tablet	10.0 Milligram	Daily Oral
Batch:	Started: 01/04/1992	Stopped: 15/04/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Tofranil commenced 14/4/92 the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 79270 **Seq:** 1 **Gender:** F
Reported: 08/09/1992 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 26/08/1954
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Life		
Hypokalaemia	Life		

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected)	Reason: Anxiety neurosis
Oral application 0.0 Oral	
Batch: Started: Stopped:	
DOTHIPIIN HYDROCHLORIDE (Suspected)	Reason: Depression
Oral application 225.0 Milligram Daily Oral	
Batch: Started: 01/01/1988 Stopped:	
LASIX (Suspected)	Reason:
120.0 Milligram Daily	
Batch: Started: Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium				Serum potassium level - 2.2 mmol/l.

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 79271	Seq: 1	Gender: F
Reported: 07/09/1992		Weight:
Hospitalisation:		Age: 30Y
Onset Date: 04/09/1992		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash vesicular		Rash on upper trunk and face	Hydrocortisone cream 1% tds
Pruritus			
Rash			

Medicine Details:

RULIDE (Suspected)	Reason: Chronic sinusitis
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 25/08/1992 Stopped: 31/08/1992
PROTHIADEN (Suspected)	Reason: Depression
Oral application	75.0 Milligram Daily Oral
Batch:	Started: 01/09/1991 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 79284	Seq: 1	Gender: F
Reported: 07/09/1992		Weight:
Hospitalisation:		Age: 85Y
Onset Date: 03/09/1992		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haematemesis		Coffee ground vomiting	

Medicine Details:

PROTHIADEN (Suspected)	Reason: Anxiety neurosis
100.0 Milligram	Daily
Batch:	Started:
Stopped:	
SERENACE (Suspected)	Reason: Depression
Tablet	500.0 Microgram
Daily	Oral
Batch:	Started:
Stopped:	
FELDENE (Suspected)	Reason:
Capsule	20.0 Milligram
Daily	Oral
Batch:	Started:
Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 79639 **Seq:** 1 **Gender:** M
Reported: 21/09/1992 **Weight:** 76.00
Hospitalisation: **Age:** 25Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Pins and needles in feet and legs	

Medicine Details:

PROTHIADEN (Suspected)	Reason:
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 10/03/1992 Stopped: 24/03/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 79674	Seq: 1	Gender: M
Reported: 22/09/1992		Weight: 77.00
Hospitalisation:		Age: 55Y
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			

Medicine Details:

PLENDIL ER (Suspected)		Reason: Essential benign hypertension
Tablet	10.0 Milligram	Daily Oral
Batch:	Started: 01/01/1991	Stopped: CONTIN
PROTHIADEN (Suspected)		Reason: Depression
Tablet	75.0 Milligram	Daily Oral
Batch:	Started: 01/01/1988	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 80640	Seq: 1	Gender: F
Reported: 20/10/1992		Weight:
Hospitalisation:		Age: 23Y
Onset Date: 03/05/1992		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Focal tonic clonic seizures	Diazepam and clonazepam for seizure control

Medicine Details:

PROTHIADEN (Interaction)		Reason: Depression
Tablet	100.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 03/05/1992
EPILIM (Interaction)		Reason: Partl,templobe,psychomo epilep
Tablet	2.0 Gram	Daily Oral
Batch:	Started:	Stopped:
TEGRETOL (Interaction)		Reason: Partl,templobe,psychomo epilep
Tablet	1.0 Gram	Daily Oral
Batch:	Started:	Stopped:
PROMINAL (Interaction)		Reason: Partl,templobe,psychomo epilep
Tablet	240.0 Milligram	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				3/5/92 6/5/92 7/5/92 carbamazepine 8 29 23 (25 - 50) sodium valproate 41 278 273 (300 - 700) phenobarbitone 62 59 56 (55 - 110)

Additional Information:

28 weeks pregnant - no problem with fitting in previous 2 pregnancies



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 80816	Seq: 1	Gender: F
Reported: 03/11/1992		Weight: 82.00
Hospitalisation:		Age: 34Y
Onset Date: 20/08/1992		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chloasma		Forehead	

Medicine Details:

PROTHIADEN (Suspected)		Reason: Depression
Capsule	150.0 Milligram	Daily Oral
Batch:	Started: 29/04/1992	Stopped: 09/10/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 80990	Seq: 1	Gender: M
Reported: 20/11/1992		Weight: 64.00
Hospitalisation:		Age: 52Y
Onset Date: 24/10/1992		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Jaundice			

Medicine Details:

PARACETAMOL (Other drug)	500.0 Milligram	Reason: As necessary
Batch:	Started:	Stopped:
PROTHIADEN (Suspected)	75.0 Milligram	Reason: Depression Daily
Batch:	Started: 01/01/1989	Stopped: 24/10/1992
PROPRANOLOL HYDROCHLORIDE (Suspected)	80.0 Milligram	Reason: Essential benign hypertension Daily
Batch:	Started: 01/06/1992	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		24/10/1992	355	Liver biopsy quasi granulomas, normal liver architecture
	AST = SGOT		24/10/1992	258	
	Bilirubin		24/10/1992	65	
	GGT = SGGT =		24/10/1992	660	
	Histology				
	SAP = ALP		24/10/1992	515	

Additional Information:

Past tegretol for pain 89. two months later developed jaundice, ruq mixed cholestatic, transaminitis picture. resolved 2/12 after ceasing tegretol. tegretol reintroduced and within 4 days = jaundiced again. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 80993	Seq: 1	Gender: F
Reported: 17/11/1992		Weight: 55.00
Hospitalisation:		Age: 42Y
Onset Date: 30/10/1992		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			

Medicine Details:

DIAZEPAM (Other drug)	Reason: Nervousness
5.0 Milligram	As necessary
Batch:	Started: 25/09/1992 Stopped:
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 25/09/1992 Stopped: 22/10/1992
PROVERA (Suspected)	Reason:
5.0 Milligram	Daily
Batch:	Started: 25/09/1992 Stopped: 08/11/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 81305 **Seq:** 1 **Gender:** F
Reported: 12/12/1992 **Weight:** 57.00
Hospitalisation: **Age:** 23Y
Onset Date: 26/11/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
250.0 Milligram	Daily
Batch:	Started: 23/07/1992 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 81360	Seq: 1	Gender: F
Reported: 07/12/1992		Weight: 61.00
Hospitalisation:		Age: 69Y
Onset Date: 30/11/1992		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania			

Medicine Details:

ANAFRANIL (Suspected)	Reason: Depression	
100.0 Milligram	Daily	
Batch:	Started: 01/10/1992	Stopped: 05/11/1992
PROTHIADEN (Suspected)	Reason: Depression	
150.0 Milligram	Daily	
Batch:	Started: 08/11/1992	Stopped: CONTIN
OXAZEPAM (Suspected)	Reason: Specific disorders of sleep	
60.0 Milligram	Daily	
Batch:	Started: L TERM	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Acute hypomania secondary to concurrent tca and electroconvulsive treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 81790 **Seq:** 1 **Gender:** F
Reported: 28/12/1992 **Weight:** 55.00
Hospitalisation: **Age:** 37Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia			

Medicine Details:

CAFFEINE (Interaction)	Reason:
0.0	
Batch:	Started: Stopped:
PROTHIADEN (Interaction)	Reason: Depression
25.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Now been on prothiaden 75mg for 2 months with normal sleep.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 81857	Seq: 1	Gender: F
Reported: 13/01/1993		Weight:
Hospitalisation:		Age: 60Y
Onset Date: 31/10/1992		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dry mouth			

Medicine Details:

PREMARIN (Other drug)	Reason:
0.0	
Batch:	Started: L TERM Stopped:
ALLOPURINOL (Other drug)	Reason:
0.0	
Batch:	Started: L TERM Stopped:
LIPEX (Other drug)	Reason:
30.0 Milligram	Daily
Batch:	Started: L TERM Stopped:
PROTHIADEN (Suspected)	Reason: Depression
150.0 Milligram	Daily
Batch:	Started: 01/09/1992 Stopped: 06/01/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 81927	Seq: 1	Gender: F
Reported: 06/01/1993		Weight: 41.00
Hospitalisation:		Age: 32Y
Onset Date: 31/12/1992		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hot flush			
Hyperhidrosis			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Tablet	25.0 Milligram Daily Oral
Batch:	Started: 30/12/1992 Stopped: 06/01/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 81937	Seq: 1	Gender: F
Reported: 04/12/1992		Weight:
Hospitalisation: Admitted to hospital		Age: 35
Onset Date: 29/09/1992		DOB: 02/03/1957
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Pyrexia			

Medicine Details:

PANADEINE FORTE (Other drug)	Reason:
Tablet	2.0 Dose Unspecified As necessary Oral
Batch:	Started: Stopped:
PANADEINE (Other drug)	Reason:
Tablet	2.0 Dose Unspecified As necessary Oral
Batch:	Started: Stopped:
NORGESIC (Other drug)	Reason:
Tablet	3.0 Dose Unspecified Daily Oral
Batch:	Started: Stopped:
PROTHIADEN (Suspected)	Reason:
	0.0
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	(N: 6-42)	30/09/1992	49	
	Erythrocyte	(N: 1-20)	30/09/1992	96	
	GGT = SGGT =	(N: F<40)	30/09/1992	33	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 82329	Seq: 1	Gender: F
Reported: 05/02/1993		Weight:
Hospitalisation:		Age: 31Y
Onset Date: 05/10/1992		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			
Somnolence			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Tablet	150.0 Milligram Daily Oral
Batch: 315MMR	Started: 05/10/1992 Stopped: 29/10/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 82750 **Seq:** 1 **Gender:** F
Reported: 12/02/1993 **Weight:** 55.00
Hospitalisation: **Age:** 75Y
Onset Date: 12/02/1993 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction			

Medicine Details:

PROZAC (Suspected)		Reason:	
Capsule	20.0 Milligram	1 time	Oral
Batch:	Started: 11/02/1993	Stopped:	
PROTHIADEN (Suspected)		Reason: Depression	
Capsule	75.0 Milligram	Daily	Oral
Batch:	Started: 01/12/1992	Stopped: 11/02/1993	
GRISOVIN (Suspected)		Reason: Unspecified systemic mycosis	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 01/12/1992	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 83350 **Seq:** 1 **Gender:** F
Reported: 19/03/1993 **Weight:**
Hospitalisation: **Age:** 37Y
Onset Date: 02/02/1993 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Deafness Drug withdrawal syndrome Tinnitus Vertigo Vomiting			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)		Reason: Depression
Capsule	75.0 Milligram	Daily Oral
Batch:	Started: 01/12/1992	Stopped: 19/02/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient rechallenged on dothiepin with same reaction



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 83883	Seq: 1	Gender: F
Reported: 01/04/1993		Weight: 57.00
Hospitalisation:		Age: 38Y
Onset Date: 18/03/1993		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Eosinophilia			
Hepatocellular damage			
Jaundice			

Medicine Details:

MERSYNDOL (Suspected)	Reason: Migraine
2.0 Dose Unspecified As necessary	
Batch:	Started: 17/02/1993 Stopped: 24/02/1993
PROTHIADEN (Suspected)	Reason: Depression
100.0 Milligram Daily	
Batch:	Started: 17/02/1993 Stopped: 30/03/1993
DIAZEPAM (Suspected)	Reason: Otr spec symp psychopathol nec
5.0 Milligram Daily	
Batch:	Started: 01/06/1992 Stopped: 24/02/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT		30/03/1993	134	
	AST = SGOT		05/04/1993	209	
	AST = SGOT		21/04/1993	70	
	Bilirubin		30/03/1993	59	
	Bilirubin		05/04/1993	76	
	Bilirubin		21/04/1993	16	
	Eosinophils	0 - 0.5	30/03/1993	0.5 9%	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 83883	Seq: 1	Gender: F
Reported: 01/04/1993		Weight: 57.00
Hospitalisation:		Age: 38Y
Onset Date: 18/03/1993		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Medicine Details:

MERSYNDOL (Suspected)	Reason: Migraine
2.0 Dose Unspecified As necessary	
Batch:	Started: 17/02/1993 Stopped: 24/02/1993
PROTHIADEN (Suspected)	Reason: Depression
100.0 Milligram Daily	
Batch:	Started: 17/02/1993 Stopped: 30/03/1993
DIAZEPAM (Suspected)	Reason: Otr spec symp psychopathol nec
5.0 Milligram Daily	
Batch:	Started: 01/06/1992 Stopped: 24/02/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =		30/03/1993	138	
	GGT = SGGT =		05/04/1993	72	
	GGT = SGGT =		21/04/1993	36	
	SAP = ALP		30/03/1993	305	
	SAP = ALP		05/04/1993	240	
	SAP = ALP		21/04/1993	135	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 84161 **Seq:** 1 **Gender:** F
Reported: 14/04/1993 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 18/07/1992 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	350.0 Milligram Daily Oral
Batch:	Started: 01/05/1992 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 84206 **Seq:** 1 **Gender:** F
Reported: 20/04/1993 **Weight:**
Hospitalisation: **Age:** 76Y
Onset Date: 23/03/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium			

Medicine Details:

GLIBENCLAMIDE (Other drug)	Reason:
Tablet 15.0 Milligram Daily Oral	
Batch: Started: Stopped: CONTIN	
METFORMIN HYDROCHLORIDE (Other drug)	Reason:
Tablet 1.5 Gram Daily Oral	
Batch: Started: Stopped: CONTIN	
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason:
Capsule 25.0 Milligram Daily Oral	
Batch: Started: 20/03/1993 Stopped: 23/03/1993	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 84643 **Seq:** 1 **Gender:** M
Reported: 21/05/1993 **Weight:**
Hospitalisation: **Age:** 83
Onset Date: 19/10/1992 **DOB:** 22/12/1908
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal impairment			

Medicine Details:

ROHYPNOL (Suspected)	Reason:
Batch:	0.0 Started: Stopped: 20/10/1992
DI-GESIC (Suspected)	Reason:
Batch:	1.0 Dose Unspecified As necessary Started: Stopped: 17/12/1992
CAPTOPRIL (Suspected)	Reason:
Batch:	12.0 Milligram Daily Started: 13/10/1992 Stopped: 16/11/1992
SLOW-K (Suspected)	Reason:
Tablet	2.0 Dose Unspecified Daily Oral
Batch:	Started: Stopped: 29/10/1992

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine		02/10/1992	102	
	Creatinine		19/10/1992	377	
	Creatinine		20/10/1992	270	
	Creatinine		21/10/1992	183	
	Creatinine		24/10/1992	130	
	Creatinine		03/11/1992	132	
	Creatinine		10/11/1992	142	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 84643 **Seq:** 1 **Gender:** M
Reported: 21/05/1993 **Weight:**
Hospitalisation: **Age:** 83
Onset Date: 19/10/1992 **DOB:** 22/12/1908
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason:
25.0 Milligram Daily	
Batch:	Started: 03/10/1992 Stopped: 08/11/1992
ASPIRIN (Suspected)	Reason:
Tablet, enteric coated 100.0 Milligram Daily Oral	
Batch:	Started: 10/10/1992 Stopped: CONTIN
ISORDIL (Suspected)	Reason:
80.0 Milligram Daily	
Batch:	Started: 09/10/1992 Stopped: CONTIN
FRUSEMIDE (Suspected)	Reason:
160.0 Milligram Daily	
Batch:	Started: 08/10/1992 Stopped: 29/10/1992

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 84782	Seq: 1	Gender: F
Reported: 31/05/1993		Weight:
Hospitalisation:		Age: 54Y
Onset Date: 10/01/1993		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Parosmia			

Medicine Details:

BRICANYL (Suspected)	Reason: Asthma
Inhalation	0.0 Inhalation
Batch:	Started: 01/06/1992 Stopped:
DUCENE (Suspected)	Reason: Nervousness
5.0 Milligram	As necessary
Batch:	Started: L TERM Stopped:
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 22/12/1992 Stopped: 04/02/1993
OGEN (Suspected)	Reason: Menopausal symptoms
1.2 Milligram	Daily
Batch:	Started: 07/08/1991 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 85023	Seq: 1	Gender: F
Reported: 01/06/1993		Weight: 91.00
Hospitalisation:		Age: 43Y
Onset Date: 19/08/1992		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Peripheral ischaemia			

Medicine Details:

MORPHINE HYDROCHLORIDE (Other drug)		Reason: Migraine
Injection	30.0 Milligram	As necessary Intramuscular
Batch:	Started:	Stopped: 28/08/1992
MERSYNDOL FORTE (Other drug)		Reason: Migraine
Tablet	1.0 Dose Unspecified	As necessary Oral
Batch:	Started:	Stopped:
LARGACTIL (Other drug)		Reason: Migraine
Oral application	50.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
DUCENE (Other drug)		Reason: Migraine
Tablet	10.0 Milligram	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Bilateral duplex scan - bilateral ileal occlusive disease.

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 85023 **Seq:** 1 **Gender:** F
Reported: 01/06/1993 **Weight:** 91.00
Hospitalisation: **Age:** 43Y
Onset Date: 19/08/1992 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

CLONIDINE HYDROCHLORIDE (Other drug)	Reason: Migraine
Tablet 100.0 Microgram Daily Oral	
Batch: Started: Stopped:	
SIMVASTATIN (Other drug)	Reason: Othr&unspec metabolic diseases
Tablet 20.0 Milligram Daily Oral	
Batch: Started: Stopped:	
TEMAZEPAM (Other drug)	Reason:
Capsule 30.0 Milligram Daily Oral	
Batch: Started: Stopped:	
DIHYDROERGOTAMINE (Suspected)	Reason: Migraine
Injection 1.0 Milligram As necessary Subcutaneous	
Batch: Started: Stopped: 28/08/1992	

Laboratory Investigations:

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 85023 **Seq:** 1

Gender: F

Reported: 01/06/1993

Weight: 91.00

Hospitalisation:

Age: 43Y

Onset Date: 19/08/1992

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ERGOTAMINE TARTRATE (Suspected)	Reason: Migraine
Oral application 1.0 Milligram As necessary Oral	
Batch: Started: 01/01/1974 Stopped: 28/08/1992	
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Migraine
Oral application 225.0 Milligram Daily Oral	
Batch: Started: Stopped: 28/08/1992	

Laboratory Investigations:

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 85068	Seq: 1	Gender: F
Reported: 01/06/1993		Weight: 50.00
Hospitalisation:		Age: 90Y
Onset Date: 10/05/1993		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			

Medicine Details:

LANOXIN PG (Other drug)	Reason:
Batch:	1.0 Dose Unspecified Daily
Started:	Stopped:
PROTHIADEN (Suspected)	Reason: Depression
Batch:	75.0 Milligram Daily
Started: 01/04/1993	Stopped: 25/05/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 85193 **Seq:** 1 **Gender:** F
Reported: 09/06/1993 **Weight:** 103.00
Hospitalisation: **Age:** 40Y
Onset Date: 15/03/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Extrasystoles		Multiple ve.	

Medicine Details:

ALDECIN (Other drug)	Reason: Otr ecz&der due otr&unsp cause
Spray	6.0 Dose Unspecified Daily Nasal
Batch:	Started: 01/01/1993 Stopped:
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
Oral application	150.0 Milligram Daily Oral
Batch:	Started: 15/02/1993 Stopped: 15/03/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient allergy to penicillin and moclobemide. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 85391 **Seq:** 1 **Gender:** F
Reported: 21/06/1993 **Weight:** 68.00
Hospitalisation: **Age:** 68Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Both legs and arms starting jumping.	
Muscle twitching			

Medicine Details:

RENITEC (Other drug)	Reason: Essential benign hypertension
10.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
XANAX (Other drug)	Reason: Anxiety neurosis
500.0 Microgram Daily	
Batch:	Started: L TERM Stopped:
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
150.0 Milligram Daily	
Batch:	Started: 09/02/1993 Stopped: 15/03/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 86010 **Seq:** 1 **Gender:** M
Reported: 12/07/1993 **Weight:** 80.00
Hospitalisation: **Age:** 80Y
Onset Date: 02/07/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state			

Medicine Details:

PROTHIADEN (Suspected) Oral application Batch:	25.0 Milligram Started: 11/06/1993	Reason: Specific disorders of sleep Daily Stopped: 03/07/1993	Oral
TAGAMET (Suspected) Batch:	800.0 Milligram Started: 29/06/1993	Reason: Other diseases of esophagus Daily Stopped: 03/07/1993	
ACTIFED (Suspected) Tablet Batch:	5.0 Dose Unspecified Started:	Reason: Ac upr resp inf,mult,unsp stes Daily Stopped: 03/07/1993	Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 86089	Seq: 1	Gender: F
Reported: 16/07/1993		Weight:
Hospitalisation: Admitted to hospital		Age: 72Y
Onset Date: 03/07/1993		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain			
Hepatitis			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
75.0 Milligram Daily	
Batch:	Started: 10/05/1993 Stopped: 03/07/1993
OROXINE (Suspected)	Reason: Myxedema
100.0 Microgram Daily	
Batch:	Started: L TERM Stopped:
NITRADISC (Suspected)	Reason: Chron isch heart dis no hyper
5.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
CARDIZEM (Suspected)	Reason: Chron isch heart dis no hyper
120.0 Milligram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	0-40 U/L	03/07/1993	396	
	ALT = SGPT	0-40 U/L	04/07/1993	976	
	ALT = SGPT	0-40 U/L	06/07/1993	493	
	ALT = SGPT	0-40 U/L	07/07/1993	365	
	ALT = SGPT	0-40 U/L	05/07/1993	754	
	ALT = SGPT	0-40 U/L	08/07/1993	260	
	AST = SGOT	0-30 U/L	03/07/1993	666	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 86089	Seq: 1	Gender: F
Reported: 16/07/1993		Weight:
Hospitalisation: Admitted to hospital		Age: 72Y
Onset Date: 03/07/1993		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
75.0 Milligram Daily	
Batch:	Started: 10/05/1993 Stopped: 03/07/1993
OROXINE (Suspected)	Reason: Myxedema
100.0 Microgram Daily	
Batch:	Started: L TERM Stopped:
NITRADISC (Suspected)	Reason: Chron isch heart dis no hyper
5.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
CARDIZEM (Suspected)	Reason: Chron isch heart dis no hyper
120.0 Milligram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	0-30 U/L	06/07/1993	155	
	AST = SGOT	0-30 U/L	08/07/1993	55	
	AST = SGOT	0-30 U/L	07/07/1993	86	
	AST = SGOT	0-30 U/L	05/07/1993	388	
	AST = SGOT	0-30 U/L	04/07/1993	809	
	Bilirubin	0-17 UMMOL/L	03/07/1993	25	
	Bilirubin	0-17 UMMOL/L	04/07/1993	45	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 86089	Seq: 1	Gender: F
Reported: 16/07/1993		Weight:
Hospitalisation: Admitted to hospital		Age: 72Y
Onset Date: 03/07/1993		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
75.0 Milligram Daily	
Batch:	Started: 10/05/1993 Stopped: 03/07/1993
OROXINE (Suspected)	Reason: Myxedema
100.0 Microgram Daily	
Batch:	Started: L TERM Stopped:
NITRADISC (Suspected)	Reason: Chron isch heart dis no hyper
5.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
CARDIZEM (Suspected)	Reason: Chron isch heart dis no hyper
120.0 Milligram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	0-17 UMMOL/L	05/07/1993	11	
	Bilirubin	0-17 UMMOL/L	06/07/1993	9	
	Bilirubin	0-17 UMMOL/L	07/07/1993	9	
	Bilirubin	0-17 UMMOL/L	08/07/1993	7	
	GGT = SGGT =	7-32 U/L	03/07/1993	286	
	GGT = SGGT =	7-32 U/L	06/07/1993	338	
	GGT = SGGT =	7-32 U/L	07/07/1993	293	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 86089	Seq: 1	Gender: F
Reported: 16/07/1993		Weight:
Hospitalisation: Admitted to hospital		Age: 72Y
Onset Date: 03/07/1993		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 10/05/1993 Stopped: 03/07/1993
OROXINE (Suspected)	Reason: Myxedema
100.0 Microgram	Daily
Batch:	Started: L TERM Stopped:
NITRADISC (Suspected)	Reason: Chron isch heart dis no hyper
5.0 Milligram	Daily
Batch:	Started: L TERM Stopped:
CARDIZEM (Suspected)	Reason: Chron isch heart dis no hyper
120.0 Milligram	Daily
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =	7-32 U/L	05/07/1993	396	
	GGT = SGGT =	7-32 U/L	04/07/1993	433	
	GGT = SGGT =	7-32 U/L	08/07/1993	252	
	SAP = ALP	30-115 U/L	03/07/1993	210	
	SAP = ALP	30-115 U/L	04/07/1993	344	
	SAP = ALP	30-115 U/L	05/07/1993	315	
	SAP = ALP	30-115 U/L	06/07/1993	271	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 86089	Seq: 1	Gender: F
Reported: 16/07/1993		Weight:
Hospitalisation: Admitted to hospital		Age: 72Y
Onset Date: 03/07/1993		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 10/05/1993 Stopped: 03/07/1993
OROXINE (Suspected)	Reason: Myxedema
100.0 Microgram	Daily
Batch:	Started: L TERM Stopped:
NITRADISC (Suspected)	Reason: Chron isch heart dis no hyper
5.0 Milligram	Daily
Batch:	Started: L TERM Stopped:
CARDIZEM (Suspected)	Reason: Chron isch heart dis no hyper
120.0 Milligram	Daily
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	30-115 U/L	07/07/1993	231	
	SAP = ALP	30-115 U/L	08/07/1993	210	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 86223	Seq: 1	Gender: F
Reported: 23/07/1993		Weight: 66.00
Hospitalisation:		Age: 75Y
Onset Date: 12/06/1993		DOB:
Outcome: Recovered		Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			

Medicine Details:

NAPROSYN (Other drug)	Reason:	
0.0		
Batch:	Started: 01/01/1985	Stopped:
SANDOCAL 1000 (Other drug)	Reason:	
0.0		
Batch:	Started: 01/01/1985	Stopped:
SEREPAX (Other drug)	Reason:	
0.0	As necessary	
Batch:	Started:	Stopped:
CAPOTEN (Other drug)	Reason: Congestive heart failure	
1.5 Gram	Daily	
Batch:	Started: 01/01/1984	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction recurred on rechallenge of prothiaden. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 86223	Seq: 1	Gender: F
Reported: 23/07/1993		Weight: 66.00
Hospitalisation:		Age: 75Y
Onset Date: 12/06/1993		DOB:
Outcome: Recovered		Causality: Causality certain

Reaction Detail

Medicine Details:

LASIX (Other drug)	Reason: Congestive heart failure
40.0 Milligram Daily	
Batch:	Started: 01/01/1993 Stopped:
LANOXIN (Other drug)	Reason: Congestive heart failure
1.0 Dose Unspecified Daily	
Batch:	Started: 01/01/1982 Stopped:
TEGRETOL (Other drug)	Reason: Herpes zoster
400.0 Milligram Daily	
Batch:	Started: 01/06/1992 Stopped:
PROTHIADEN (Suspected)	Reason: Otr&unsp forms neuralg&neurit
25.0 Milligram Daily	
Batch:	Started: 01/05/1992 Stopped: 28/07/1992

Laboratory Investigations:

Additional Information:

Reaction recurred on rechallenge of prothiaden. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 86693	Seq: 1	Gender: F
Reported: 10/08/1993		Weight:
Hospitalisation:		Age: 44Y
Onset Date: 02/06/1993		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

OXAZEPAM (Other drug)	Reason:	
30.0 Milligram	Daily	
Batch:	Started: 24/02/1993	Stopped: CONTIN
LACTULOSE (Other drug)	Reason:	
40.0 Milligram	Daily	
Batch:	Started: 18/05/1993	Stopped: CONTIN
WARFARIN SODIUM (Other drug)	Reason: Prophylaxis	
8.0 Milligram	Daily	
Batch:	Started:	Stopped: CONTIN
PROPYLTHIOURACIL (Suspected)	Reason: Toxic diffuse goiter	
400.0 Milligram	Daily	
Batch:	Started: 24/02/1993	Stopped: 23/06/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	8 - 29 U/L	19/03/1993	22	
	ALT = SGPT	8 - 29 U/L	02/06/1993	138	
	ALT = SGPT	8 - 29 U/L	30/06/1993	142	
	ALT = SGPT	8 - 29 U/L	18/06/1993	167	
	ALT = SGPT	8 - 29 U/L	30/07/1993	88	
	AST = SGOT	10 - 28 U/L	19/03/1993	19	
	AST = SGOT	10 - 28 U/L	30/07/1993	42	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 86693 **Seq:** 1 **Gender:** F
Reported: 10/08/1993 **Weight:**
Hospitalisation: **Age:** 44Y
Onset Date: 02/06/1993 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected)	Reason: Depression
20.0 Milligram Daily	
Batch:	Started: 21/04/1993 Stopped: 08/06/1993
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
150.0 Milligram Daily	
Batch:	Started: Stopped: 20/04/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	10 - 28 U/L	30/06/1993	70	
	AST = SGOT	10 - 28 U/L	02/06/1993	59	
	AST = SGOT	10 - 28 U/L	18/06/1993	97	
	Bilirubin	6 - 24 UMOL/L	19/03/1993	7	
	Bilirubin	6 - 24 UMOL/L	02/06/1993	8	
	Bilirubin	6 - 24 UMOL/L	18/06/1993	13	
	Bilirubin	6 - 24 UMOL/L	30/07/1993	10	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 86693	Seq: 1	Gender: F
Reported: 10/08/1993		Weight:
Hospitalisation:		Age: 44Y
Onset Date: 02/06/1993		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Medicine Details:

OXAZEPAM (Other drug)	Reason:	
30.0 Milligram	Daily	
Batch:	Started: 24/02/1993	Stopped: CONTIN
LACTULOSE (Other drug)	Reason:	
40.0 Milligram	Daily	
Batch:	Started: 18/05/1993	Stopped: CONTIN
WARFARIN SODIUM (Other drug)	Reason: Prophylaxis	
8.0 Milligram	Daily	
Batch:	Started:	Stopped: CONTIN
PROPYLTHIOURACIL (Suspected)	Reason: Toxic diffuse goiter	
400.0 Milligram	Daily	
Batch:	Started: 24/02/1993	Stopped: 23/06/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	6 - 24 UMOL/L	30/06/1993	10	
	Prolactin	65 - 80 G/L	19/03/1993	1	
	Prolactin	65 - 80 G/L	02/06/1993	69	
	Prolactin	65 - 80 G/L	18/06/1993	75	
	Prolactin	65 - 80 G/L	30/06/1993	77	
	Prolactin	65 - 80 G/L	30/07/1993	69	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 86693

Seq: 1

Gender: F

Reported: 10/08/1993

Weight:

Hospitalisation:

Age: 44Y

Onset Date: 02/06/1993

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected)	Reason: Depression
20.0 Milligram	Daily
Batch:	Started: 21/04/1993
	Stopped: 08/06/1993
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
150.0 Milligram	Daily
Batch:	Started:
	Stopped: 20/04/1993

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 86926 **Seq:** 1 **Gender:** M
Reported: 20/08/1993 **Weight:** 88.00
Hospitalisation: **Age:** 64Y
Onset Date: 31/08/1992 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia			

Medicine Details:

TOFRANIL (Suspected)	Reason: Depression		
0.0			
Batch:	Started:	Stopped: 31/01/1988	
PROTHIADEN (Suspected)	Reason: Depression		
Capsule	250.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1988	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 87488 **Seq:** 1 **Gender:** M
Reported: 06/09/1993 **Weight:** 80.00
Hospitalisation: **Age:** 43Y
Onset Date: 16/08/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neuropathy peripheral			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	150.0 Milligram Daily Oral
Batch:	Started: 20/07/1993 Stopped: 20/08/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 87583	Seq: 1	Gender: M
Reported: 10/09/1993		Weight: 55.00
Hospitalisation:		Age: 30Y
Onset Date: 16/06/1993		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Leukopenia			

Medicine Details:

BACTRIM DS (Suspected)	Reason:
Oral application	6.0 Dose Unspecified Weekly Oral
Batch:	Started: 22/12/1992 Stopped: CONTIN
ZIDOVUDINE (Suspected)	Reason: Hiv infection
Oral application	600.0 Milligram Daily Oral
Batch:	Started: 07/04/1993 Stopped: CONTIN
KETOCONAZOLE (Suspected)	Reason: Moniliasis
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 25/08/1992 Stopped: CONTIN
PROTHIADEN (Suspected)	Reason: Depression
Oral application	5.0 Milligram Daily Oral
Batch:	Started: 19/02/1993 Stopped: 14/07/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		16/06/1993	1.8	
	White blood cells		11/08/1993	1.8	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 87634	Seq: 1	Gender: F
Reported: 13/09/1993		Weight: 36.00
Hospitalisation:		Age: 60Y
Onset Date: 31/07/1993		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

VENTOLIN (Other drug)	Reason: Asthma
Inhalation	0.0 As necessary Inhalation
Batch:	Started: L TERM Stopped:
BECOTIDE (Other drug)	Reason: Asthma
Inhalation	2.0 Dose Unspecified Daily Inhalation
Batch:	Started: L TERM Stopped:
PRIMOLUT-N (Other drug)	Reason: Osteoporosis
Tablet	0.5 Dose Unspecified Daily Oral
Batch:	Started: 01/01/1991 Stopped: CONTIN
CALCITRIOL (Other drug)	Reason: Osteoporosis
	1.0 Dose Unspecified Daily
Batch:	Started: 01/01/1991 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 87634

Seq: 1

Gender: F

Reported: 13/09/1993

Weight: 36.00

Hospitalisation:

Age: 60Y

Onset Date: 31/07/1993

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)

Reason: Depression

50.0 Milligram

Daily

Batch:

Started: 27/05/1993

Stopped: 26/08/1993

Laboratory Investigations:

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 87734	Seq: 1	Gender: M
Reported: 15/09/1993		Weight:
Hospitalisation:		Age: 65Y
Onset Date: 25/08/1993		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Enanthema			
Rash maculo-papular			

Medicine Details:

DILTIAZEM HYDROCHLORIDE (Suspected)	0.0	Reason:
Batch:	Started:	Stopped:
METOPROLOL TARTRATE (Suspected)	200.0 Milligram	Daily
Batch:	Started:	Stopped:
	L TERM	
DOTHIEPIN HYDROCHLORIDE (Suspected)	50.0 Milligram	Daily
Batch:	Started:	Stopped:
	L TERM	
ASPIRIN (Suspected)	150.0 Milligram	Daily
Batch:	Started:	Stopped:
	L TERM	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 87735 **Seq:** 1 **Gender:** M
Reported: 15/09/1993 **Weight:**
Hospitalisation: **Age:** 65Y
Onset Date: 25/08/1993 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			

Medicine Details:

VERAPAMIL HYDROCHLORIDE (Suspected)	Reason:			
Batch:	0.0	Started:	Stopped:	
METOPROLOL TARTRATE (Suspected)	Reason:			
Batch:	200.0 Milligram	Daily	Started:	Stopped:
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason:			
Batch:	50.0 Milligram	Daily	Started:	Stopped:
ASPIRIN (Suspected)	Reason:			
Batch:	150.0 Milligram	Daily	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 88509 **Seq:** 1 **Gender:** M
Reported: 13/10/1993 **Weight:** 85.00
Hospitalisation: **Age:** 55Y
Onset Date: 27/10/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Anxiety neurosis
Capsule	75.0 Milligram Daily Oral
Batch:	Started: 24/09/1993 Stopped: 01/10/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 89424	Seq: 1	Gender: F
Reported: 26/11/1993		Weight: 50.00
Hospitalisation:		Age: 45Y
Onset Date: 27/10/1993		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria			

Medicine Details:

SEREPAX (Other drug)	Reason: Anxiety neurosis
Tablet	90.0 Milligram Daily Oral
Batch:	Started: 01/01/1980 Stopped: CONTIN
CATOVIT (Other drug)	Reason: Debility&undue fatigue
Oral application	2.0 Dose Unspecified Daily Oral
Batch:	Started: 01/01/1986 Stopped: CONTIN
STEMETIL (Other drug)	Reason: Meniere's disease
Tablet	10.0 Milligram Daily Oral
Batch:	Started: 01/01/1980 Stopped: CONTIN
PREMARIN (Other drug)	Reason: Menopausal symptoms
Tablet	625.0 Microgram Daily Oral
Batch:	Started: 11/05/1993 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 89424

Seq: 1

Gender: F

Reported: 26/11/1993

Weight: 50.00

Hospitalisation:

Age: 45Y

Onset Date: 27/10/1993

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

PROVERA (Other drug)	Reason: Menopausal symptoms		
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 11/05/1993	Stopped:	CONTIN
PROTHIADEN (Suspected)	Reason: Depression		
Oral application	50.0 Milligram	Daily	Oral
Batch:	Started: 07/10/1993	Stopped:	28/10/1993

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 89459	Seq: 1	Gender: F
Reported: 30/11/1993		Weight: 44.00
Hospitalisation:		Age: 38Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia			Benztropine 2mg im stat.

Medicine Details:

DROPERIDOL (Suspected)		Reason:	
Injection	10.0 Milligram	1 time	Intramuscular
Batch:	Started: 24/11/1993	Stopped:	
PETHIDINE HYDROCHLORIDE (Suspected)		Reason:	
Injection	20.0 Milligram	1 time	Intramuscular
Batch:	Started:	Stopped:	
PROMETHAZINE HYDROCHLORIDE (Suspected)		Reason:	
Injection	50.0 Milligram	As necessary	Intramuscular
Batch:	Started:	Stopped:	
DIAZEPAM (Suspected)		Reason:	
Injection	10.0 Milligram	As necessary	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 89459

Seq: 1

Gender: F

Reported: 30/11/1993

Weight: 44.00

Hospitalisation:

Age: 38Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)	Reason:
150.0 Milligram	Daily
Batch:	Started: Stopped:
ROHYPNOL (Suspected)	Reason:
1.0 Dose Unspecified	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 89476 **Seq:** 1 **Gender:** M
Reported: 30/11/1993 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: 31/12/1993 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis	Severe		

Medicine Details:

ANATENSOL (Suspected)	Reason:
10.0 Milligram Daily Oral	
Batch:	Started: Stopped: 28/10/1993
PROTHIADEN (Suspected)	Reason:
Oral application 25.0 Milligram Daily Oral	
Batch:	Started: 01/07/1989 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	0-40	15/03/1993	148	
	ALT = SGPT	0-40	13/07/1993	219	
	ALT = SGPT	0-40	24/08/1993	265	
	ALT = SGPT	0-40	23/09/1993	166	
	AST = SGOT	0-40	15/03/1993	NORMAL	
	AST = SGOT	0-40	13/07/1993	86	
	AST = SGOT	0-40	24/08/1993	106	

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 89476 Seq: 1

Gender: M

Reported: 30/11/1993

Weight:

Hospitalisation:

Age: 34Y

Onset Date: 31/12/1993

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ANATENSOL (Suspected)		Reason:	
10.0 Milligram	Daily	Oral	
Batch:	Started:	Stopped:	28/10/1993
PROTHIADEN (Suspected)		Reason:	
Oral application	25.0 Milligram	Daily	Oral
Batch:	Started: 01/07/1989	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	0-40	23/09/1993	66	
	LDH	>225	15/03/1993	NORMAL	
	LDH	>225	13/07/1993	NORMAL	
	LDH	>225	24/08/1993	248	

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 89577 **Seq:** 1 **Gender:** F
Reported: 01/12/1993 **Weight:** 59.00
Hospitalisation: **Age:** 41Y
Onset Date: 17/11/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Acne			
Pruritus			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
25.0 Milligram	Daily
Batch:	Started: 16/11/1993 Stopped: 20/11/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had no known previous allergies.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 89727 **Seq:** 1 **Gender:** M
Reported: 02/12/1993 **Weight:** 64.00
Hospitalisation: **Age:** 21Y
Onset Date: 17/11/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Lymphadenopathy		Swollen glands	
Neutropenia			
Pharyngitis			
Pruritus			
Rash erythematous			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 03/11/1993 Stopped: 17/11/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils	2.0 - 7.8	28/10/1993	3.78	
	Neutrophils	2.0 - 7.8	17/11/1993	1.9 57%	
	Neutrophils	2.0 - 7.8	26/11/1993	5.8 63%	
	White blood cells	4.0 - 11.0	28/10/1993	7.5	
	White blood cells	4.0 - 11.0	17/11/1993	3.3	
	White blood cells	4.0 - 11.0	26/11/1993	9.2	

Additional Information:

Patient has had no known previous allergies.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 90025 **Seq:** 1 **Gender:** F
Reported: 24/12/1993 **Weight:**
Hospitalisation: **Age:** 26Y
Onset Date: 03/12/1993 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			
Rash maculo-papular			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
25.0 Milligram	1 time
Batch:	Started: 02/12/1993 Stopped: 03/12/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient tried prothiaden again on 17.12.93 and same reaction occurred



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 90453 **Seq:** 1 **Gender:** F
Reported: 13/01/1994 **Weight:**
Hospitalisation: Treated in outpatient department only. **Age:** 21Y
Onset Date: 25/12/1993 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			
Electroencephalogram abnormal			
Leukopenia			

Medicine Details:

PROTHIADEN (Suspected)		Reason:
Tablet	25.0 Milligram	Oral
Batch:	Started:	Stopped:
PROZAC (Suspected)		Reason: Feeding disturbances
	20.0 Milligram	Daily
Batch:	Started:	Stopped: 25/12/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells	4.0 - 11.1	25/12/1993	2.7	
	White blood cells	4.0 - 11.1	26/12/1993	2.5	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 90470	Seq: 1	Gender: M
Reported: 13/01/1994		Weight: 98.00
Hospitalisation:		Age: 56
Onset Date: 09/12/1993		DOB: 17/09/1937
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Dyskinesia			
Insomnia			
Nightmare			

Medicine Details:

LOPID (Other drug)	Reason: Congestive heart failure
2.0 Dose Unspecified Daily	
Batch:	Started: L TERM Stopped:
CARDIZEM (Other drug)	Reason: Congestive heart failure
2.0 Dose Unspecified Daily	
Batch:	Started: 01/10/1993 Stopped:
IMDUR (Other drug)	Reason: Congestive heart failure
2.0 Dose Unspecified Daily	
Batch:	Started: 01/10/1993 Stopped:
DOTHEP (Suspected)	Reason: Depression
175.0 Milligram Daily	
Batch:	Started: 05/07/1992 Stopped: 15/12/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 90471 **Seq:** 1 **Gender:** M
Reported: 13/01/1994 **Weight:** 86.00
Hospitalisation: **Age:** 39
Onset Date: 07/12/1993 **DOB:** 31/03/1954
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Fatigue Hyperhidrosis Insomnia Muscle spasms Nightmare			

Medicine Details:

DOTHEP (Suspected)	Reason: Depression
275.0 Milligram Daily	
Batch: Started: 01/06/1992 Stopped: 15/12/1993	
ZANTAC (Suspected)	Reason:
300.0 Milligram Daily	
Batch: Started: 01/10/1993 Stopped:	
MOTILIUM (Suspected)	Reason:
1.0 Dose Unspecified Daily	
Batch: Started: 01/10/1993 Stopped: 08/12/1993	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 91157	Seq: 1	Gender: M
Reported: 18/02/1994		Weight: 68.00
Hospitalisation:		Age: 23Y
Onset Date: 08/02/1994		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia Dystonia	Severe	Muscle spasm in jaw, back, arms & legs.	Cogentin 2mg/im 2 doses.

Medicine Details:

LARGACTIL (Suspected)	Reason: Depression
Tablet	400.0 Milligram
	Daily
	Oral
Batch:	Started: 21/01/1994
	Stopped:
PROTHIADEN (Suspected)	Reason: Depression
Capsule	300.0 Milligram
	Daily
	Oral
Batch:	Started: 21/01/1994
	Stopped:
SERENACE (Suspected)	Reason: Depression
Tablet	5.0 Milligram
	Daily
	Oral
Batch:	Started: 06/02/1994
	Stopped: 09/02/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 91287	Seq: 1	Gender: M
Reported: 25/02/1994		Weight:
Hospitalisation: Admitted to hospital		Age: 69
Onset Date: 10/02/1994		DOB: 01/03/1924
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arrhythmia			
Bone marrow failure			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	75.0 Milligram Daily Oral
Batch:	Started: 26/01/1994 Stopped: 14/02/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 91515 **Seq:** 1 **Gender:** M
Reported: 11/03/1994 **Weight:** 120.00
Hospitalisation: **Age:** 28Y
Onset Date: 19/02/1994 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Affect lability		Uncontrollable mirth	

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 19/02/1994 Stopped: 07/03/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction recurred after every morning dose



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 91519 **Seq:** 1 **Gender:** M
Reported: 10/03/1994 **Weight:**
Hospitalisation: **Age:** 63
Onset Date: 26/11/1993 **DOB:** 14/04/1930
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Dystonia		Tingling mouth and lips.	Cogentin.

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected)	Reason: Depression
Oral application 75.0 Milligram Daily Oral	
Batch: Started: 24/11/1993 Stopped: 26/11/1993	
PROTHIADEN (Suspected)	Reason: Depression
150.0 Milligram Daily	
Batch: Started: 15/11/1993 Stopped: CONTIN	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 91554 **Seq:** 1 **Gender:** F
Reported: 14/03/1994 **Weight:** 70.00
Hospitalisation: **Age:** 59Y
Onset Date: 04/03/1994 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache			
Muscle spasms			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
Oral application	25.0 Milligram Daily Oral
Batch:	Started: 03/03/1994 Stopped: 07/03/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 91582	Seq: 1	Gender: F
Reported: 11/03/1994		Weight: 61.00
Hospitalisation:		Age: 83Y
Onset Date: 04/03/1994		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pancytopenia			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	100.0 Milligram Daily Oral
Batch:	Started: 01/08/1992 Stopped: 04/03/1994
SINEMET (Suspected)	Reason: Paralysis agitans
	4.0 Dose Unspecified Daily
Batch:	Started: 01/08/1992 Stopped:
PARLODEL (Suspected)	Reason:
	2.5 Milligram Daily
Batch:	Started: 01/08/1992 Stopped:
SENOKOT (Suspected)	Reason:
Tablet	1.0 Dose Unspecified Daily Oral
Batch:	Started: 01/08/1992 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haemoglobin		04/03/1994	7.5	
	Neutrophils		04/03/1994	63	
	Platelets		04/03/1994	37,000	
	Red blood cells		04/03/1994	3.0	
	White blood cells		04/03/1994	2.1	

Additional Information:

Patient has had no known previous allergies. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 91846	Seq: 1	Gender: F
Reported: 24/03/1994		Weight: 40.00
Hospitalisation:		Age: 86Y
Onset Date: 30/05/1993		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression			
Confusional state			Largactil

Medicine Details:

DIAZEPAM (Other drug)	Reason: Depression
Oral application	5.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped: CONTIN
ORUDIS SR (Other drug)	Reason: Osteoarthritis
Capsule	200.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped: CONTIN
LANOXIN (Other drug)	Reason: Congestive heart failure
Oral application	125.0 Microgram Daily Oral
Batch:	Started: L TERM Stopped: CONTIN
FRUSEMIDE (Other drug)	Reason: Congestive heart failure
Oral application	20.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Urea	2.0-7.5 MMOL/L	30/05/1993	19.4	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 91846

Seq: 1

Gender: F

Reported: 24/03/1994

Weight: 40.00

Hospitalisation:

Age: 86Y

Onset Date: 30/05/1993

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

SLOW-K (Other drug)	Reason: Congestive heart failure
Tablet, modified release	1.0 Dose Unspecified Daily Oral
Batch:	Started: L TERM Stopped: CONTIN
MORPHINE NOS (Suspected)	Reason: Pain
Solution	60.0 Milligram Daily Oral
Batch:	Started: 25/05/1993 Stopped: 30/05/1993
PROTHIADEN (Suspected)	Reason: Depression
Oral application	25.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped: 01/06/1993

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 91918 **Seq:** 1 **Gender:** M
Reported: 31/03/1994 **Weight:**
Hospitalisation: **Age:** 52Y
Onset Date: 07/03/1994 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus	Severe		

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 05/03/1994 Stopped: 07/03/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Severe increase in tinnitus. patient had an underlying low grade deafness and tinnitus.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 92084 **Seq:** 1 **Gender:** F
Reported: 08/04/1994 **Weight:** 75.00
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			
Hot flush			
Hyperhidrosis			

Medicine Details:

PROZAC (Suspected)		Reason: Depression
Capsule	20.0 Milligram	Daily Oral
Batch:	Started: 03/09/1993	Stopped: 07/02/1994
PROTHIADEN (Suspected)		Reason: Depression
Capsule	150.0 Milligram	Daily Oral
Batch:	Started: 03/09/1993	Stopped: 07/02/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT		31/01/1994	74	
	AST = SGOT		22/02/1994	NORMAL	
	GGT = SGGT =		31/01/1994	72	
	GGT = SGGT =		22/02/1994	NORMAL	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 93008	Seq: 1	Gender: M
Reported: 16/05/1994		Weight:
Hospitalisation:		Age: 42Y
Onset Date: 03/05/1994		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Hyperreflexia Tremor		Jerking movements of arms and legs	Valium 10mg nocte

Medicine Details:

PROZAC (Suspected)		Reason: Depression
Capsule	20.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 02/05/1994
PROTHIADEN (Suspected)		Reason: Depression
Oral application	25.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 02/05/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 93198	Seq: 1	Gender: M
Reported: 26/05/1994		Weight:
Hospitalisation:		Age: 29Y
Onset Date: 16/05/1994		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Congestion on chest, unable to breathe.	

Medicine Details:

VALIUM (Other drug)		Reason:	
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	CONTIN
PANADEINE FORTE (Other drug)		Reason:	
Capsule	1.0 Dose Unspecified	As necessary	Oral
Batch:	Started:	Stopped:	
PROTHIADEN (Suspected)		Reason:	
Capsule	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 93438 **Seq:** 1 **Gender:** F
Reported: 02/06/1994 **Weight:** 59.00
Hospitalisation: **Age:** 64Y
Onset Date: 22/08/1993 **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		(symptomatic) - dizziness.	

Medicine Details:

FOLIC ACID (Other drug)	Reason:
Tablet 5.0 Milligram Weekly Oral	
Batch: Started: Stopped:	
VERAPAMIL HYDROCHLORIDE (Other drug)	Reason: Chron isch heart dis no hyper
Oral application 120.0 Milligram Daily Oral	
Batch: Started: Stopped:	
DIAZEPAM (Other drug)	Reason:
Oral application 5.0 Milligram Daily Oral	
Batch: Started: Stopped:	
CALCIUM CARBONATE (Other drug)	Reason:
Oral application 1.5 Gram Daily Oral	
Batch: Started: Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 93438

Seq: 1

Gender: F

Reported: 02/06/1994

Weight: 59.00

Hospitalisation:

Age: 64Y

Onset Date: 22/08/1993

DOB:

Outcome: Unknown

Causality: Causality probable

Reaction Detail

Medicine Details:

DIGOXIN (Other drug)	Reason:
Tablet	1.0 Dose Unspecified Alternate days Oral
Batch:	Started: Stopped:
PROTHIADEN (Suspected)	Reason: Depression
Oral application	75.0 Milligram Daily Oral
Batch:	Started: 16/08/1993 Stopped: 23/08/1993

Laboratory Investigations:

Additional Information:

See original report for other drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 93917	Seq: 1	Gender: M
Reported: 24/06/1994		Weight:
Hospitalisation:		Age: 63Y
Onset Date: 12/04/1994		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety			
Depression			
Drug ineffective			

Medicine Details:

PROZAC (Other drug)	Reason: Depression
Capsule	20.0 Milligram Daily Oral
Batch:	Started: Stopped: CONTIN
PROTHIADEN (Suspected)	Reason: Depression
	25.0 Milligram Daily
Batch:	Started: 10/04/1994 Stopped: 12/04/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 94191	Seq: 1	Gender: F
Reported: 04/07/1994		Weight:
Hospitalisation:		Age: 76Y
Onset Date: 03/05/1994		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Gtn solution prn, lactilase, chloral hydrate prn.

Medicine Details:

OXAZEPAM (Other drug)		Reason:	
Tablet	15.0 Milligram	As necessary	Oral
Batch:	Started: 08/04/1994	Stopped:	
HALOPERIDOL (Other drug)		Reason:	
	0.0	As necessary	
Batch:	Started:	Stopped:	
THYROXINE SODIUM (Other drug)		Reason: Myxedema	
Tablet	150.0 Microgram	Daily	Oral
Batch:	Started: 07/04/1994	Stopped:	CONTIN
TEMAZEPAM (Other drug)		Reason: Specific disorders of sleep	
Capsule	20.0 Milligram	Daily	Oral
Batch:	Started: 02/05/1994	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	134 - 146	08/04/1994	143	
	Sodium	134 - 146	05/05/1994	119	
	Sodium	134 - 146	07/05/1994	117	
	Sodium	134 - 146	09/05/1994	126	
	Sodium	134 - 146	23/05/1994	138	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 94191 **Seq:** 1 **Gender:** F
Reported: 04/07/1994 **Weight:**
Hospitalisation: **Age:** 76Y
Onset Date: 03/05/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

TIMOLOL MALEATE (Other drug)	Reason: Unspecified glaucoma
Eye Drops 2.0 Dose Unspecified Daily Ophthalmic	
Batch: Started: Stopped: CONTIN	
PROPINE (Other drug)	Reason: Unspecified glaucoma
Eye Drops 2.0 Dose Unspecified Daily Ophthalmic	
Batch: Started: Stopped: CONTIN	
PAROXETINE HYDROCHLORIDE (Suspected)	Reason: Depression
Oral application 20.0 Milligram Daily Oral	
Batch: Started: 03/05/1994 Stopped: 05/05/1994	
MODURETIC (Suspected)	Reason:
Tablet 1.0 Dose Unspecified Daily Oral	
Batch: Started: 08/04/1994 Stopped: 04/05/1994	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 94191

Seq: 1

Gender: F

Reported: 04/07/1994

Weight:

Hospitalisation:

Age: 76Y

Onset Date: 03/05/1994

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)

Reason:

Oral application

25.0 Milligram

Daily

Oral

Batch:

Started: 29/04/1994

Stopped: 03/05/1994

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 94790	Seq: 1	Gender: F
Reported: 03/08/1994		Weight:
Hospitalisation:		Age: 62Y
Onset Date: 31/03/1994		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hair texture abnormal Alopecia		Hair lifeless	

Medicine Details:

ASPIRIN (Suspected)	Reason:
0.0	
Batch:	Started:
	Stopped:
PROZAC (Suspected)	Reason: Depression
Capsule	20.0 Milligram Daily Oral
Batch:	Started: 01/11/1993
	Stopped: 28/03/1994
PROTHIADEN (Suspected)	Reason: Depression
	25.0 Milligram Daily
Batch:	Started: 01/01/1991
	Stopped:
ZOCOR (Suspected)	Reason: Othr&unspec metabolic diseases
Tablet	10.0 Milligram Daily Oral
Batch:	Started: 01/09/1993
	Stopped: 28/03/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 94790 **Seq:** 1 **Gender:** F
Reported: 03/08/1994 **Weight:**
Hospitalisation: **Age:** 62Y
Onset Date: 31/03/1994 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

PROVERA (Suspected)	Reason: Menopausal symptoms
Tablet 5.0 Milligram Daily Oral	
Batch: Started: Stopped:	
OGEN (Suspected)	Reason: Menopausal symptoms
Tablet 937.0 Microgram Daily Oral	
Batch: Started: Stopped:	
CALCIUM CARBONATE (Suspected)	Reason: Menopausal symptoms
Oral application 600.0 Milligram Daily Oral	
Batch: Started: Stopped:	

Laboratory Investigations:

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 94793	Seq: 1	Gender: F
Reported: 03/08/1994		Weight:
Hospitalisation:		Age: 30Y
Onset Date: 15/04/1994		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Feeling drunk	
Agitation			
Anxiety			
Insomnia			
Nausea			

Medicine Details:

DOTHEP (Suspected)		Reason: Transient situational disturb	
Oral application	25.0 Milligram	As necessary	Oral
Batch:	Started: 15/04/1994	Stopped:	25/04/1994
MULTI-B FORTE (Suspected)		Reason:	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started: 15/04/1994	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 94810 **Seq:** 1 **Gender:** M
Reported: 01/08/1994 **Weight:** 0.00
Hospitalisation: **Age:** 54Y
Onset Date: 31/12/1992 **DOB:**
Outcome: Death, maybe drug 30/06/1994 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bronchioloalveolar carcinoma		Extensive brochoalveolar cell carcinoma of lung, with aspiration pneumonia, COPD and chronic schizophrenia	

Medicine Details:

ROXIAM (Suspected)	Reason: Unspecified schizophrenia
150.0 Milligram Daily Oral	
Batch: Started: 01/08/1993 Stopped: 28/06/1994	
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
100.0 Milligram Daily Oral	
Batch: Started: 01/11/1993 Stopped: 28/06/1994	
BENZTROPINE MESYLATE (Suspected)	Reason: Abnormal involuntary movement
1.0 Milligram Daily Oral	
Batch: Started: Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not accurate but indicates that onset occurred sometime during the year. The dosage start and stop dates are not necessarily accurate but indicates that start and stop occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 95235 **Seq:** 1 **Gender:** F
Reported: 22/08/1994 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: 31/05/1994 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tongue discolouration		Black furry tongue lasting over 4 weeks	Nilstat oral drops and fungilin lozenges.

Medicine Details:

AUGMENTIN (Suspected)	Reason:
Oral application	0.0 Daily Oral
Batch:	Started: Stopped:
TEMAZEPAM (Suspected)	Reason:
	20.0 Milligram Daily
Batch:	Started: Stopped:
DIAZEPAM (Suspected)	Reason:
	50.0 Milligram Daily
Batch:	Started: Stopped:
PROTHIADEN (Suspected)	Reason:
	150.0 Milligram Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 96060	Seq: 1	Gender: M
Reported: 26/09/1994		Weight: 120.00
Hospitalisation:		Age: 46Y
Onset Date: 04/09/1994		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tongue oedema Diarrhoea Nausea		Dry thick tongue	

Medicine Details:

PANADEINE FORTE (Other drug)	0.0	Reason:
Batch:	Started:	L TERM Stopped:
ZESTRIL (Other drug)	20.0 Milligram	Daily
Batch:	Started:	L TERM Stopped:
ALDOMET (Other drug)	750.0 Milligram	Daily
Batch:	Started:	L TERM Stopped:
DIABEX (Other drug)	2.0 Dose Unspecified	Daily
Batch:	Started:	L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 96060

Seq: 1

Gender: M

Reported: 26/09/1994

Weight: 120.00

Hospitalisation:

Age: 46Y

Onset Date: 04/09/1994

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

MINIPRESS (Other drug)	Reason:	
2.0 Milligram	Daily	
Batch:	Started: L TERM	Stopped:
INSULIN MONOTARD (Other drug)	Reason:	
55.0 Unit	Daily	
Batch:	Started: L TERM	Stopped:
PROTHIADEN (Suspected)	Reason: Depression	
100.0 Milligram	Daily	
Batch:	Started: 01/09/1994	Stopped: 11/09/1994

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 96856 **Seq:** 1 **Gender:** F
Reported: 01/11/1994 **Weight:** 51.00
Hospitalisation: **Age:** 74Y
Onset Date: 06/10/1994 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema		Swelling of cheeks.	

Medicine Details:

OROXINE (Other drug)	Reason:
1.0 Dose Unspecified Daily	
Batch:	Started: 01/01/1980 Stopped: CONTIN
PROTHIADEN (Suspected)	Reason: Specific disorders of sleep
25.0 Milligram Daily	
Batch:	Started: 01/01/1993 Stopped: 14/10/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient took another prothiaden and reaction reccured. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 97092 **Seq:** 1 **Gender:** U
Reported: 15/11/1994 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 01/10/1994 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Tingling in both feet.	

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 19/09/1994 Stopped: 14/10/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Tingling and paraesthesia in both feet, increasing over two weeks. took two more weeks after cessation to resolve.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 97400 **Seq:** 1 **Gender:** F
Reported: 28/11/1994 **Weight:** 90.00
Hospitalisation: **Age:** 38Y
Onset Date: 19/11/1994 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema			

Medicine Details:

ZOLOFT (Suspected)	Reason:
Batch:	1.0 Dose Unspecified Daily
Started:	Stopped:
PROTHIADEN (Suspected)	Reason:
Batch:	150.0 Milligram Daily
Started:	Stopped:
MODURETIC (Suspected)	Reason:
Batch:	1.0 Dose Unspecified Daily
Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 97712 **Seq:** 1 **Gender:** F
Reported: 12/12/1994 **Weight:** 65.00
Hospitalisation: **Age:** 33Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intra-uterine death			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression		
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1992	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Macerated male fetus 16 weeks gestation outwardly normal appearance. fetal death picked up on routine 18 weeks scan.

Additional Information:

Fetal death in utero at 16 weeks on prothiaden 75mg x 3 tablets nocte prior to conception. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 97742	Seq: 1	Gender: F
Reported: 05/12/1994		Weight: 64.00
Hospitalisation:		Age: 39Y
Onset Date: 16/11/1994		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Acne	Severe	Acneform rash, pruritus, excoriation, post.	
Pruritus	Severe		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression
Oral application	50.0 Milligram	Daily Oral
Batch:	Started: 13/11/1994	Stopped: 18/11/1994
DOTHIEPIN HYDROCHLORIDE (Suspected)		Reason: Depression
Oral application	125.0 Milligram	Daily Oral
Batch:	Started: 01/01/1992	Stopped: 20/10/1994
DIAZEPAM (Suspected)		Reason:
Oral application	5.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 15/11/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Similar reaction to a chemically dissimilar s.s.r.i. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 98701 **Seq:** 1 **Gender:** F
Reported: 03/02/1995 **Weight:** 80.00
Hospitalisation: **Age:** 72Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Disturbance of sleep
25.0 Milligram	Daily
Batch:	Started: 23/01/1995 Stopped: 27/01/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 99043	Seq: 1	Gender: M
Reported: 20/02/1995		Weight: 81.00
Hospitalisation:		Age: 36Y
Onset Date: 29/01/1995		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Urticaria over neck, buttocks & chest	

Medicine Details:

PANADEINE FORTE (Other drug)		Reason:	
Oral application	2.0 Dose Unspecified	As necessary	Oral
Batch:	Started: 01/10/1984	Stopped:	CONTIN
PROTHIADEN (Suspected)		Reason: Depression	
Oral application	75.0 Milligram	Daily	Oral
Batch:	Started: 18/01/1995	Stopped:	04/02/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had no known previous allergies. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 99099 **Seq:** 1 **Gender:** M
Reported: 24/02/1995 **Weight:**
Hospitalisation: **Age:** 52Y
Onset Date: 22/07/1994 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus		Pruritus back of kness, thighs & back	Calamine lotion

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
Oral application	75.0 Milligram Daily Oral
Batch:	Started: 21/07/1994 Stopped: 18/08/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 99389	Seq: 1	Gender: F
Reported: 08/03/1995		Weight: 93.00
Hospitalisation:		Age: 85Y
Onset Date: 23/02/1995		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache			
Nausea	Severe		

Medicine Details:

GLIMEL (Other drug)	Reason: Diabetes mellitus
Tablet	5.0 Milligram Daily Oral
Batch:	Started: 01/01/1992 Stopped:
LANOXIN (Other drug)	Reason: Congestive heart failure
Oral application	125.0 Microgram Daily Oral
Batch:	Started: 01/01/1992 Stopped:
DYAZIDE (Other drug)	Reason: Congestive heart failure
Tablet	1.0 Dose Unspecified Daily Oral
Batch:	Started: 01/01/1992 Stopped:
ZOLOFT (Suspected)	Reason:
	0.0
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had no known previous allergies. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 99389

Seq: 1

Gender: F

Reported: 08/03/1995

Weight: 93.00

Hospitalisation:

Age: 85Y

Onset Date: 23/02/1995

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression		
Oral application	25.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1992	Stopped: 23/02/1995	

Laboratory Investigations:

Additional Information:

Patient has had no known previous allergies. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 99786 **Seq:** 1 **Gender:** F
Reported: 24/03/1995 **Weight:** 54.00
Hospitalisation: **Age:** 52Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight decreased			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
125.0 Milligram	Daily
Batch:	Started: 01/09/1989 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 99835	Seq: 1	Gender: F
Reported: 27/03/1995		Weight: 53.00
Hospitalisation: Admitted to hospital		Age: 41Y
Onset Date: 13/03/1995		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Had a fit	Oxygen
Apnoea		Stopped breathing	
Amnesia			
Coma			
Hypertonia			
Tremor			

Medicine Details:

PROZAC (Other drug)		Reason: Depression
Capsule	40.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
XANAX (Other drug)		Reason:
Tablet	4.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
PROTHIADEN (Suspected)		Reason:
Oral application	150.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 16/03/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 100006	Seq: 1	Gender: F
Reported: 03/04/1995		Weight:
Hospitalisation:		Age: 61Y
Onset Date: 07/03/1995		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Nausea			

Medicine Details:

TRANSIDERM-NITRO (Other drug)	Reason: Angina pectoris w/o hyperten
1.0 Dose Unspecified Daily	
Batch:	Started: 10/01/1994 Stopped:
ASPIRIN (Other drug)	Reason: Angina pectoris w/o hyperten
0.5 Dose Unspecified Daily	
Batch:	Started: 01/01/1993 Stopped:
SLOW-K (Other drug)	Reason:
1.0 Dose Unspecified Daily	
Batch:	Started: 01/01/1988 Stopped:
VENTOLIN (Other drug)	Reason: Asthma
4.0 Dose Unspecified Daily	
Batch:	Started: 01/01/1960 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 100006

Seq: 1

Gender: F

Reported: 03/04/1995

Weight:

Hospitalisation:

Age: 61Y

Onset Date: 07/03/1995

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

BECOTIDE (Other drug)	Reason: Asthma	
400.0 Microgram	Daily	
Batch:	Started: 01/01/1960	Stopped:
DOTHEP (Suspected)	Reason:	
0.0		
Batch:	Started:	Stopped: 01W

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIPIEN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 100026 **Seq:** 1 **Gender:** F
Reported: 04/04/1995 **Weight:** 80.00
Hospitalisation: **Age:** 57Y
Onset Date: **DOB:**
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

PROTHIADEN (Interaction)	Reason: Depression
Tablet 75.0 Milligram Daily Oral	
Batch: Started: 01/09/1993 Stopped:	
PROTHIADEN (Interaction)	Reason: Depression
Capsule 25.0 Milligram Daily Oral	
Batch: Started: 01/09/1993 Stopped:	
DOLOXENE (Interaction)	Reason: Pain
Capsule 300.0 Milligram Daily Oral	
Batch: Started: 01/08/1994 Stopped:	
VALIUM (Other drug)	Reason: Anxiety neurosis
Tablet 5.0 Milligram Daily Oral	
Batch: Started: 01/01/1985 Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				High level of dothiepin in liver 23mg/kg

Additional Information:

Patient died 4/11/94 cause of death stated as toxicity to dothiepin. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 100026

Seq: 1

Gender: F

Reported: 04/04/1995

Weight: 80.00

Hospitalisation:

Age: 57Y

Onset Date:

DOB:

Outcome: Death

Causality: Causality possible

Reaction Detail

Medicine Details:

EUHYPNOS (Other drug)	Reason: Specific disorders of sleep		
10.0 Milligram	Daily		
Batch:	Started: 01/01/1993	Stopped:	
MORPHINE NOS (Other drug)	Reason: Headache		
Injection	15.0 Milligram	Daily	Intramuscular
Batch:	Started: 03/11/1994	Stopped: 03/11/1994	

Laboratory Investigations:

Additional Information:

Patient died 4/11/94 cause of death stated as toxicity to dothiepin. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 100357 **Seq:** 1 **Gender:** F
Reported: 24/04/1995 **Weight:** 87.00
Hospitalisation: **Age:** 76Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance			

Medicine Details:

SEREPAX (Other drug)	Reason: Specific disorders of sleep
500.0 Microgram	As necessary
Batch:	Started: L TERM Stopped:
DOTHEP (Suspected)	Reason:
1.0 Dose Unspecified	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 100535	Seq: 1	Gender: F
Reported: 01/05/1995		Weight: 51.00
Hospitalisation:		Age: 37Y
Onset Date: 08/03/1995		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria			

Medicine Details:

MICROGYNON (Other drug)	Reason:
0.0	
Batch:	Started: L TERM Stopped:
TRITACE (Other drug)	Reason:
5.0 Milligram	Daily
Batch:	Started: 23/09/1993 Stopped: CONTIN
PROTHIADEN (Suspected)	Reason: Depression
25.0 Milligram	Daily
Batch:	Started: 16/02/1995 Stopped: 10/04/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 100665 **Seq:** 1 **Gender:** F
Reported: 08/05/1995 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: **DOB:** 12/09/1941
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
150.0 Milligram	Daily
Batch:	Started: 01/01/1990 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 100673	Seq: 1	Gender: M
Reported: 08/05/1995		Weight: 70.00
Hospitalisation:		Age: 57Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia			

Medicine Details:

RENITEC (Suspected)	Reason: Essential benign hypertension
10.0 Milligram Daily	
Batch:	Started: Stopped:
PROTHIADEN (Suspected)	Reason: Depression
150.0 Milligram Daily	
Batch:	Started: Stopped:
MELLERIL (Suspected)	Reason:
75.0 Milligram Daily	
Batch:	Started: Stopped:
ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergic to penicillin



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 100673

Seq: 1

Gender: M

Reported: 08/05/1995

Weight: 70.00

Hospitalisation:

Age: 57Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

TEMAZEPAM (Suspected)

Reason: Specific disorders of sleep

10.0 Milligram

Daily

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

Allergic to penicillin



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 100883 **Seq:** 1 **Gender:** M
Reported: 17/05/1995 **Weight:** 70.00
Hospitalisation: **Age:** 38Y
Onset Date: 08/05/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination		Visual and auditory hallucinations	

Medicine Details:

LOSEC (Interaction) Capsule Batch:	20.0 Milligram Started: 04/05/1995	Reason: Otr disorders stomach function Daily Stopped: 08/05/1995	Oral
PROTHIADEN (Interaction) Batch:	150.0 Milligram Started: 04/03/1995	Reason: Depression Daily Stopped:	CONTIN
TEMAZEPAM (Interaction) Batch:	10.0 Milligram Started: 04/05/1995	Reason: Specific disorders of sleep Daily Stopped: 08/05/1995	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient took all the medication together, usually took the losec much earlier. began to hallucinate auditorially and visually about 30 minutes later, behaviour became uncontrollable and bizarre over the next 4-6 hours. given a further 150mg prothiaden which seemed to settle him.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 101083 **Seq:** 1 **Gender:** F
Reported: 23/05/1995 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Severe		

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	25.0 Milligram Daily Oral
Batch:	Started: 12/05/1995 Stopped: 14/05/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 101118	Seq: 1	Gender: F
Reported: 29/05/1995		Weight:
Hospitalisation:		Age: 86Y
Onset Date: 18/04/1995		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state			

Medicine Details:

ASPIRIN (Other drug)	Reason: Prophylaxis
150.0 Milligram Daily	
Batch:	Started: Stopped: CONTIN
THYROXINE SODIUM (Other drug)	Reason:
50.0 Microgram Alternate days	
Batch:	Started: 17/04/1995 Stopped: CONTIN
PROTHIADEN (Suspected)	Reason: Depression
25.0 Milligram Daily	
Batch:	Started: 13/04/1995 Stopped: 24/04/1995
STEMETIL (Suspected)	Reason: Nausea and vomiting
15.0 Milligram Daily	
Batch:	Started: 11/04/1995 Stopped: 24/04/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 101118

Seq: 1

Gender: F

Reported: 29/05/1995

Weight:

Hospitalisation:

Age: 86Y

Onset Date: 18/04/1995

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

TRIMETHOPRIM (Suspected)

Reason:

300.0 Milligram

Daily

Batch:

Started: 11/04/1995

Stopped: 24/04/1995

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 101322 **Seq:** 1 **Gender:** F
Reported: 05/06/1995 **Weight:**
Hospitalisation: **Age:** 22Y
Onset Date: 24/05/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia			

Medicine Details:

ZOLOFT (Other drug)	Reason: Premedication
100.0 Milligram Daily	
Batch: Started: Stopped:	
PROTHIADEN (Suspected)	Reason: Depression
Capsule 50.0 Milligram Daily Oral	
Batch: Started: 24/05/1995 Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 101693	Seq: 1	Gender: F
Reported: 22/06/1995		Weight: 65.00
Hospitalisation:		Age: 28Y
Onset Date: 28/04/1995		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			
Neurosis			

Medicine Details:

AROPAX (Suspected)		Reason: Depression
Tablet	20.0 Milligram	Daily Oral
Batch:	Started: 27/04/1995	Stopped: 28/04/1995
DOTHIEPIN HYDROCHLORIDE (Suspected)		Reason: Depression
Oral application	150.0 Milligram	Daily Oral
Batch:	Started: 23/06/1994	Stopped: 23/03/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 101801 **Seq:** 1 **Gender:** M
Reported: 27/06/1995 **Weight:**
Hospitalisation: **Age:** 14Y
Onset Date: 17/02/1995 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Nausea			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
Oral application	150.0 Milligram Daily Oral
Batch:	Started: 16/01/1995 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	(0-55)	17/02/1995	150	
	Bilirubin	(6-24)	17/02/1995	50	
	GGT = SGGT =	(0-60)	17/02/1995	249	
	SAP = ALP	(30-110)	17/02/1995	183	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 102535	Seq: 1	Gender: F
Reported: 31/07/1995		Weight:
Hospitalisation:		Age: 16Y
Onset Date: 24/08/1994		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

DOTHEP (Suspected)		Reason: Depression	
Oral application	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	24/08/1994

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 103034 **Seq:** 1 **Gender:** F
Reported: 23/08/1995 **Weight:** 63.00
Hospitalisation: **Age:** 43Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain	Severe		

Medicine Details:

INSULATARD (NORDISK) (Other drug)	Reason:	
0.0		
Batch:	Started:	Stopped:
VELOSULIN (NORDISK) (Other drug)	Reason:	
0.0		
Batch:	Started:	Stopped:
PROTHIADEN (Suspected)	Reason: Depression	
75.0 Milligram	Daily	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 103369	Seq: 1	Gender: F
Reported: 05/09/1995		Weight: 73.00
Hospitalisation:		Age: 41Y
Onset Date: 07/08/1995		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Immunoglobulins decreased		Hypogammaglobulinemia	

Medicine Details:

IMURAN (Suspected)	Reason: Systemic lupus erythematosus
150.0 Milligram	Daily
Batch:	Started: 01/03/1993 Stopped: 07/08/1995
RANITIDINE (Suspected)	Reason: Gastritis&duodenitis
Tablet	150.0 Milligram
	Daily
Batch:	Started: Stopped: CONTIN
PROTHIADEN (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 21/02/1994 Stopped: CONTIN
NAPROXEN (Suspected)	Reason: Systemic lupus erythematosus
1.0 Gram	Daily
Batch:	Started: Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 103991 **Seq:** 1 **Gender:** F
Reported: 12/10/1995 **Weight:** 65.00
Hospitalisation: **Age:** 30Y
Onset Date: 15/09/1995 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram Daily	
Batch:	Started: 15/09/1995 Stopped:
PROTHIADEN (Suspected)	Reason: Depression
150.0 Milligram Daily	
Batch:	Started: 01/02/1995 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 104790 **Seq:** 1 **Gender:** F
Reported: 21/11/1995 **Weight:** 38.00
Hospitalisation: **Age:** 32Y
Onset Date: 02/10/1995 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

ZOLOFT (Suspected)	Reason:		
Batch:	0.0	Started:	Stopped:
PROTHIADEN (Suspected)	Reason:		
Batch:	0.0	Started:	Stopped:
MOCLOBEMIDE (Suspected)	Reason:		
Batch:	0.0	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 104993	Seq: 1	Gender: F
Reported: 30/11/1995		Weight: 38.00
Hospitalisation:		Age: 85Y
Onset Date: 12/09/1995		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination		Auditory hallucination	

Medicine Details:

ISOPTIN (Other drug)	Reason: Essential benign hypertension
40.0 Milligram Daily	
Batch:	Started: 01/01/1990 Stopped:
THYROXINE SODIUM (Other drug)	Reason: Myxedema
100.0 Microgram Daily	
Batch:	Started: 01/01/1988 Stopped:
TEMAZEPAM (Other drug)	Reason: Specific disorders of sleep
10.0 Milligram Daily	
Batch:	Started: 01/01/1988 Stopped:
LASIX (Other drug)	Reason: Congestive heart failure
80.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 104993

Seq: 1

Gender: F

Reported: 30/11/1995

Weight: 38.00

Hospitalisation:

Age: 85Y

Onset Date: 12/09/1995

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

CAPOTEN (Other drug)	25.0 Milligram	Daily	Reason: Congestive heart failure
Batch:	Started:	Stopped:	
PROTHIADEN (Suspected)	25.0 Milligram	Daily	Reason:
Batch:	Started:	Stopped: 13/11/1995	

Laboratory Investigations:

Additional Information:

See original report for other drugs the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 105180	Seq: 1	Gender: F
Reported: 07/12/1995		Weight:
Hospitalisation: Admitted to hospital		Age: 90
Onset Date: 16/07/1995		DOB: 20/02/1905
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastric ulcer perforation			Ranitidine started and oversewing of ulcer.

Medicine Details:

PANADOL (Suspected)				Reason:	
Oral application	0.0	As necessary	Oral		
Batch:	Started:		Stopped:		
ORUDIS SR (Suspected)				Reason:	
Tablet	1.0 Dose Unspecified	Daily	Oral		
Batch:	Started:		Stopped:	17/07/1995	
PROTHIADEN (Suspected)				Reason:	
Oral application	75.0 Milligram	Daily	Oral		
Batch:	Started:		Stopped:	17/07/1995	
COLOXYL WITH SENNA (Suspected)				Reason:	
Tablet	2.0 Dose Unspecified	Daily	Oral		
Batch:	Started:		Stopped:	17/07/1995	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 105180 **Seq:** 1 **Gender:** F
Reported: 07/12/1995 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 90
Onset Date: 16/07/1995 **DOB:** 20/02/1905
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

TEMAZEPAM (Suspected)		Reason:	
Oral application	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	17/07/1995
LACTULOSE (Suspected)		Reason:	
Oral application	15.0 Millilitre	Daily	Oral
Batch:	Started:	Stopped:	17/07/1995

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 105797	Seq: 1	Gender: F
Reported: 10/01/1996		Weight: 65.00
Hospitalisation: Admitted to hospital		Age: 73Y
Onset Date: 08/12/1995		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Orthostatic hypotension			

Medicine Details:

THYROXINE SODIUM (Other drug)	Reason: Myxedema
50.0 Microgram Daily	
Batch:	Started: 01/01/1994 Stopped: CONTIN
PROZAC (Suspected)	Reason: Depression
Oral application 40.0 Milligram Daily Oral	
Batch:	Started: 04/09/1995 Stopped: 08/12/1995
PROTHIADEN (Suspected)	Reason: Depression
Oral application 150.0 Milligram Daily Oral	
Batch:	Started: 04/09/1995 Stopped: 08/12/1995
EPILIM (Suspected)	Reason: Depression
1.0 Gram Daily	
Batch:	Started: 06/12/1995 Stopped: 08/12/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 106396 **Seq:** 1 **Gender:** M
Reported: 12/02/1996 **Weight:**
Hospitalisation: **Age:** 24Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			
Visual disturbance			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
25.0 Milligram	Daily
Batch:	Started: 01/02/1996 Stopped: 05/02/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 106493 **Seq:** 1 **Gender:** F
Reported: 16/02/1996 **Weight:** 80.00
Hospitalisation: **Age:** 63Y
Onset Date: 31/01/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysphonia Laryngitis			

Medicine Details:

TEMAZEPAM (Other drug)	Reason:		
10.0 Milligram	Daily		
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Other drug)	Reason:		
375.0 Milligram	Daily		
Batch:	Started:	Stopped:	
NAPROXEN (Other drug)	Reason:		
1.0 Gram	Daily		
Batch:	Started:	Stopped:	
PROTHIADEN (Suspected)	Reason:		
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient changed from prothiaden tabs to caps. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 106519	Seq: 1	Gender: F
Reported: 19/02/1996		Weight: 71.00
Hospitalisation:		Age: 51Y
Onset Date: 18/01/1996		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			
Rash			Aristocort cream, canestan.

Medicine Details:

PROTHIADEN (Suspected)	Reason: Specific disorders of sleep
25.0 Milligram	Daily
Batch:	Started: 27/12/1995 Stopped: 20/01/1996
FEFOL (Suspected)	Reason: Iron deficiency anemias
1.0 Dose Unspecified	Daily
Batch:	Started: 27/12/1995 Stopped: 20/01/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 106659 **Seq:** 1 **Gender:** F
Reported: 26/02/1996 **Weight:** 70.00
Hospitalisation: **Age:** 26Y
Onset Date: 31/01/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia			
Disturbance in attention			

Medicine Details:

AROPAX (Suspected)	Reason: Depression
Tablet 30.0 Milligram Daily Oral	
Batch:	Started: 01/12/1995 Stopped:
PROTHIADEN (Suspected)	Reason: Depression
Oral application 75.0 Milligram Daily Oral	
Batch:	Started: 01/05/1995 Stopped: 28/02/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Chronic cannabinoid effect. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 106665	Seq: 1	Gender: F
Reported: 26/02/1996		Weight: 63.00
Hospitalisation:		Age: 28Y
Onset Date: 31/08/1995		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia Thinking abnormal			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
200.0 Milligram	Daily
Batch:	Started: 01/08/1995 Stopped: 28/10/1995
PROTHIADEN (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 01/08/1995 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 107100 **Seq:** 1 **Gender:** U
Reported: 15/03/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/07/1994 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Skin discolouration			

Medicine Details:

OROXINE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
LEDERMycin (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
MINIPRESS (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
PROTHIADEN (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 107100 Seq: 1

Gender: U

Reported: 15/03/1996

Weight:

Hospitalisation:

Age:

Onset Date: 31/07/1994

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ZYLOPRIM (Suspected)	Reason:	
0.0		
Batch:	Started:	Stopped:
COLGOUT (Suspected)	Reason:	
0.0		
Batch:	Started:	Stopped:
DAPA-TABS (Suspected)	Reason:	
0.0		
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 107129 **Seq:** 1 **Gender:** F
Reported: 20/03/1996 **Weight:**
Hospitalisation: **Age:** 52Y
Onset Date: 08/03/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			

Medicine Details:

PROTHIADEN (Suspected)	Reason:
Batch:	50.0 Milligram Daily
Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient re-commenced on morphine with no further problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 107422 **Seq:** 1 **Gender:** F
Reported: 29/03/1996 **Weight:** 70.00
Hospitalisation: **Age:** 48Y
Onset Date: 04/03/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia Dermatitis bullous Pharyngitis Pyrexia			

Medicine Details:

PROPRANOLOL HYDROCHLORIDE (Other drug)	Reason: Myxedema
1.0 Dose Unspecified Daily	
Batch:	Started: 05/02/1996 Stopped: 16/03/1996
MENOREST (Other drug)	Reason: Menopausal symptoms
Cream 37.5 Microgram Daily Transdermal	
Batch:	Started: 01/01/1996 Stopped:
PROTHIADEN (Suspected)	Reason: Depression
Tablet 25.0 Milligram Daily Oral	
Batch:	Started: 04/03/1996 Stopped: 06/03/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 108317	Seq: 1	Gender: F
Reported: 06/05/1996		Weight: 43.00
Hospitalisation:		Age: 19Y
Onset Date: 02/04/1996		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia			
Arthralgia			
Fatigue			
Headache			
Hepatitis			
Hyperhidrosis			
Influenza like illness			
Myalgia			

Medicine Details:

ROACCUTANE (Suspected)	Reason:
0.0	
Batch:	Started: 08/02/1995 Stopped: 08/02/1996
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Myxedema
Oral application	150.0 Milligram Daily Oral
Batch:	Started: 22/02/1996 Stopped: 19/04/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	0 - 50 U/L	17/04/1996	136	
	ALT = SGPT	0 - 50 U/L	01/05/1996	39	
	AST = SGOT	11 - 33 U/L	17/04/1996	40	
	AST = SGOT	11 - 33 U/L	01/05/1996	23	
	GGT = SGGT =	0 - 50 U/L	17/04/1996	695	
	GGT = SGGT =	0 - 50 U/L	01/05/1996	319	
	GGT = SGGT =	0 - 50 U/L	10/05/1996	201	

Additional Information:

Alcohol intake occasionally. while patient was taking roaccutane serial lft's and lipids were normal, apart from a consistently mildly elevated ggt (60 - 70).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 108317 Seq: 1

Gender: F

Reported: 06/05/1996

Weight: 43.00

Hospitalisation:

Age: 19Y

Onset Date: 02/04/1996

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ROACCUTANE (Suspected)	Reason:
0.0	
Batch:	Started: 08/02/1995 Stopped: 08/02/1996
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Myxedema
Oral application	150.0 Milligram Daily Oral
Batch:	Started: 22/02/1996 Stopped: 19/04/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	30 - 120 U/L	17/04/1996	217	
	SAP = ALP	30 - 120 U/L	01/05/1996	109	

Additional Information:

Alcohol intake occasionally. while patient was taking roaccutane serial lft's and lipids were normal, apart from a consistently mildly elevated ggt (60 - 70).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 108480 **Seq:** 1 **Gender:** F
Reported: 15/05/1996 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 39Y
Onset Date: 04/03/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Migraine			
Orthostatic hypotension			
Quadriplegia			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: Stopped: 05/02/1996
PROZAC (Suspected)	Reason: Depression
40.0 Milligram Daily	
Batch:	Started: Stopped: 14/02/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Fell down a spiral staircase as a result of which she sustained a very severe fracture of the neck and she is quadriplegic. she may have had a viral infection.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 108734 **Seq:** 1 **Gender:** F
Reported: 27/05/1996 **Weight:**
Hospitalisation: **Age:** 76Y
Onset Date: 31/01/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			Topical therapy

Medicine Details:

PROTHIADEN (Suspected)	Reason:		
Batch:	Started: 0.0	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIPI
HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 108817	Seq: 1	Gender: M
Reported: 29/05/1996		Weight: 75.00
Hospitalisation: Admitted to hospital		Age: 73Y
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Dyspnoea Tremor			

Medicine Details:

SINEMET CR (Suspected)		Reason: Paralysis agitans
Tablet	1.0 Dose Unspecified 1 time	Oral
Batch:	Started: 01/01/1993	Stopped: 20/05/1996
SINEMET (Suspected)		Reason: Paralysis agitans
Tablet	1.0 Dose Unspecified Daily	Oral
Batch:	Started:	Stopped:
SINEMET (Suspected)		Reason: Paralysis agitans
Tablet	1.0 Dose Unspecified Daily	Oral
Batch:	Started: 01/01/1994	Stopped: 28/02/1996
DOTHIPIPI HYDROCHLORIDE (Suspected)		Reason: Depression
Tablet	200.0 Milligram Daily	Oral
Batch:	Started: 01/03/1996	Stopped: 19/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 108817	Seq: 1	Gender: M
Reported: 29/05/1996		Weight: 75.00
Hospitalisation: Admitted to hospital		Age: 73Y
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)	Reason:		
100.0 Milligram	Daily		
Batch:	Started: 01/01/1996	Stopped:	CONTIN

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 109021	Seq: 1	Gender: F
Reported: 07/06/1996		Weight: 110.00
Hospitalisation:		Age: 41Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			Rivotril
Tremor			

Medicine Details:

INDERAL (Other drug)	Reason: Essential benign hypertension
Tablet	40.0 Milligram Daily Oral
Batch:	Started: 01/06/1995 Stopped:
ALDACTONE (Other drug)	Reason: Diseases of hair&hair follicle
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 01/01/1991 Stopped:
FELDENE (Other drug)	Reason: Unspecified arthritis
Oral application	10.0 Milligram Daily Oral
Batch:	Started: 01/01/1990 Stopped:
ZOLOFT (Suspected)	Reason: Depression
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 01/02/1995 Stopped: 30/04/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 109021

Seq: 1

Gender: F

Reported: 07/06/1996

Weight: 110.00

Hospitalisation:

Age: 41Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)

Reason: Specific disorders of sleep

Oral application

25.0 Milligram

Daily

Oral

Batch:

Started: 01/01/1996

Stopped: 28/04/1996

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 109114 **Seq:** 1 **Gender:** F
Reported: 13/06/1996 **Weight:** 65.00
Hospitalisation: **Age:** 52Y
Onset Date: 07/06/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Spaced out	
Coordination abnormal		Unable to drive, writing difficulty.	

Medicine Details:

TELDANE (Suspected)	Reason:
Batch:	2.0 Dose Unspecified Daily
Started: 07/06/1996	Stopped: 08/06/1996
PROTHIADEN (Suspected)	Reason: Depression
Batch:	2.0 Dose Unspecified Daily
Started: 07/06/1996	Stopped: 08/06/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 109267 **Seq:** 1 **Gender:** F
Reported: 17/06/1996 **Weight:**
Hospitalisation: **Age:** 76
Onset Date: 31/05/1996 **DOB:** 11/04/1920
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cerebellar syndrome Extrapyramidal disorder Gait disturbance Hypercalcaemia Orthostatic hypotension			

Medicine Details:

PRAMIN (Other drug)	Reason:
Tablet 30.0 Milligram Daily Oral	
Batch:	Started: 09/05/1996 Stopped: 14/05/1996
MOTILIUM (Other drug)	Reason:
Tablet 30.0 Milligram Daily Oral	
Batch:	Started: 14/05/1996 Stopped:
COLOXYL WITH SENNA (Other drug)	Reason:
Tablet 1.0 Dose Unspecified Daily Oral	
Batch:	Started: Stopped:
RIVOTRIL (Other drug)	Reason:
Oral application 500.0 Microgram Daily Oral	
Batch:	Started: Stopped: 07/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 109267 **Seq:** 1 **Gender:** F
Reported: 17/06/1996 **Weight:**
Hospitalisation: **Age:** 76
Onset Date: 31/05/1996 **DOB:** 11/04/1920
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

ASPIRIN (Other drug)	Reason:
Oral application 300.0 Milligram Daily Oral	
Batch: Started: Stopped: 07/05/1996	
MYSOLINE (Suspected)	Reason:
500.0 Milligram Daily	
Batch: Started: Stopped:	
LITHIUM CARBONATE (Suspected)	Reason:
500.0 Milligram Daily	
Batch: Started: Stopped:	
CHLOTRIDE (Suspected)	Reason: Essential benign hypertension
Tablet 500.0 Milligram Daily Oral	
Batch: Started: Stopped:	

Laboratory Investigations:

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 109267 **Seq:** 1

Gender: F

Reported: 17/06/1996

Weight:

Hospitalisation:

Age: 76

Onset Date: 31/05/1996

DOB: 11/04/1920

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	75.0 Milligram Daily Oral
Batch:	Started: Stopped: 06/05/1996
RENITEC (Suspected)	Reason: Essential benign hypertension
Tablet	20.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 109694	Seq: 1	Gender: F
Reported: 03/07/1996		Weight:
Hospitalisation:		Age: 29Y
Onset Date: 04/04/1996		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

OXAZEPAM (Other drug) Batch:	30.0 Milligram Started: 01/04/1996	Reason: Daily Stopped:
PROTHIADEN (Suspected) Batch:	200.0 Milligram Started:	Reason: Daily Stopped: 07/04/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		04/04/1996	852	
	ALT = SGPT		09/04/1996	1086	
	ALT = SGPT		15/04/1996	1941	
	ALT = SGPT		22/04/1996	852	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 110150	Seq: 1	Gender: F
Reported: 23/07/1996		Weight: 95.00
Hospitalisation:		Age: 36Y
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Hepatocellular damage Malaise			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 01/01/1988 Stopped: 05/07/1996
DOTHEP (Suspected)	Reason:
150.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP				Sap, alt and ggt were raised.

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 110208 **Seq:** 1 **Gender:** F
Reported: 24/07/1996 **Weight:** 53.00
Hospitalisation: **Age:** 68Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		Decreased platelets	
Hepatic function abnormal		Increased ggt, ast and alt	

Medicine Details:

LAMISIL (Suspected)	Reason: Dermatophytosis
Tablet	1.0 Dose Unspecified Daily Oral
Batch:	Started: 19/04/1996 Stopped: 28/06/1996
PROTHIADEN (Suspected)	Reason:
	25.0 Milligram Daily
Batch:	Started: 15/03/1996 Stopped: 28/06/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 110415	Seq: 1	Gender: F
Reported: 01/08/1996		Weight: 70.00
Hospitalisation:		Age: 52Y
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety		Believed she was dying.	
Headache		Constant and severe pain at base of skull.	
Nervousness		Constant trembling	
Malaise		Health deteriorated	
Coordination abnormal		Needed help to walk and shower.	
Visual disturbance		Unable to judge distance	
Depression			
Dizziness			

Medicine Details:

ESTRADERM (Other drug)	Reason: Menopausal symptoms
100.0 Milligram Weekly	
Batch:	Started: 01/01/1990 Stopped: 10/03/1996
MOGADON (Other drug)	Reason: Specific disorders of sleep
1.0 Dose Unspecified As necessary	
Batch:	Started: 01/01/1990 Stopped: 10/03/1996
PROVERA (Other drug)	Reason: Menopausal symptoms
1.0 Dose Unspecified Fortnightly	
Batch:	Started: 01/01/1990 Stopped: 10/03/1996
ZOTON (Other drug)	Reason:
1.0 Dose Unspecified Daily	
Batch:	Started: 01/01/1990 Stopped: 10/03/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of chronic dizziness the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 110415 **Seq:** 1

Gender: F

Reported: 01/08/1996

Weight: 70.00

Hospitalisation:

Age: 52Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)

Reason:

75.0 Milligram

Daily

Batch:

Started: 16/03/1996

Stopped: 07/05/1996

Laboratory Investigations:

Additional Information:

History of chronic dizziness the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 111029 **Seq:** 1 **Gender:** M
Reported: 20/08/1996 **Weight:** 70.00
Hospitalisation: **Age:** 27Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			Changed back to prothiaden.

Medicine Details:

DOTHEP (Suspected)	Reason: Depression
Batch:	Started: 0.0
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 111818	Seq: 1	Gender: F
Reported: 25/09/1996		Weight: 52.00
Hospitalisation:		Age: 54Y
Onset Date: 19/08/1996		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Constipation			
Dizziness			
Dry mouth			
Flushing			
Headache			
Somnolence			

Medicine Details:

AMFAMOX (Suspected)		Reason: Ulcer of stomach w/o ment perf
Tablet	80.0 Milligram	Daily Oral
Batch:	Started: 19/08/1996	Stopped:
PROTHIADEN (Suspected)		Reason: Depression
Oral application	100.0 Milligram	Daily Oral
Batch:	Started: 19/08/1996	Stopped:
MOGADON (Suspected)		Reason: Specific disorders of sleep
Tablet	5.0 Milligram	Daily Oral
Batch:	Started: 19/08/1996	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 111881 **Seq:** 1 **Gender:** F
Reported: 27/09/1996 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 17/04/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			

Medicine Details:

TRIQUILAR ED (Other drug)	Reason: Contraception
Oral application 0.0 Oral	
Batch: Started: Stopped:	
PROTHIADEN (Suspected)	Reason: Depression
Oral application 125.0 Milligram Daily Oral	
Batch: Started: 01/02/1995 Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 111886 **Seq:** 1 **Gender:** F
Reported: 27/09/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Black curtain before the eyes	The medication was changed to amitriptyline
Hypertension		Blood pressure went up	
Headache		Massive bursting sensation, burning in	
Hypoaesthesia			
Insomnia			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
0.0	
Batch:	Started: 01/01/1993 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 112406 **Seq:** 1 **Gender:** M
Reported: 21/10/1996 **Weight:** 79.00
Hospitalisation: **Age:** 67Y
Onset Date: 15/10/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itchy skin rash	
Rash			

Medicine Details:

DOTHEP (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
PENICILLIN NOS (Suspected)	Reason:
Oral application	0.0 Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Changed from prothiaden to dothep and itchy skin rash developed.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 112639 **Seq:** 1 **Gender:** M
Reported: 30/10/1996 **Weight:** 75.00
Hospitalisation: Admitted to hospital **Age:** 25Y
Onset Date: 18/10/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypersensitivity		Carbamazepine induced immune/hypersensitivity reac	Steroids, inpatient admission

Medicine Details:

TEGRETOL (Suspected)	Reason: Depression
600.0 Milligram Daily	
Batch:	Started: 16/09/1996 Stopped: 17/10/1996
PROTHIADEN (Suspected)	Reason: Otr spec symp psychopathol nec
225.0 Milligram Daily	
Batch:	Started: 01/03/1996 Stopped: 17/10/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 112678	Seq: 1	Gender: F
Reported: 30/10/1996		Weight: 53.00
Hospitalisation: Admitted to hospital		Age: 33Y
Onset Date: 17/08/1996		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Hyperhidrosis Muscle spasms Tachycardia Tremor			lv diazepam

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 12/08/1996 Stopped:
PROTHIADEN (Suspected)	Reason: Depression
Oral application	300.0 Milligram
Daily	Oral
Batch:	Started: 01/07/1996 Stopped: 11/08/1996
TEMAZEPAM (Suspected)	Reason: Specific disorders of sleep
30.0 Milligram	Daily
Batch:	Started: 01/07/1996 Stopped: 22/08/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 113429	Seq: 1	Gender: F
Reported: 26/11/1996		Weight:
Hospitalisation:		Age: 76Y
Onset Date: 24/10/1996		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

VENTOLIN (Other drug)	Reason:	
0.0	As necessary	
Batch:	Started: 24/10/1996	Stopped:
ATROVENT (Other drug)	Reason:	
0.0	As necessary	
Batch:	Started: 24/10/1996	Stopped:
NICOTINIC ACID (Other drug)	Reason:	Othr&unspec metabolic diseases
250.0 Milligram	Daily	
Batch:	Started: 24/10/1996	Stopped:
F.G.F. (Other drug)	Reason:	
1.0 Dose Unspecified	Daily	
Batch:	Started: 24/10/1996	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		25/10/1996	119	
	Sodium		26/10/1996	120	
	Sodium		08/11/1996	130	
	Sodium		14/11/1996	128	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 113429

Seq: 1

Gender: F

Reported: 26/11/1996

Weight:

Hospitalisation:

Age: 76Y

Onset Date: 24/10/1996

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

CHLORVESCENT (Other drug)	Reason:
1.0 Dose Unspecified Daily	
Batch:	Started: 24/10/1996 Stopped:
PANADOL (Other drug)	Reason:
8.0 Dose Unspecified Daily	
Batch:	Started: 24/10/1996 Stopped:
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
150.0 Milligram Daily	
Batch:	Started: 24/10/1996 Stopped: 06/11/1996

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 113717 **Seq:** 1 **Gender:** M
Reported: 06/12/1996 **Weight:** 60.00
Hospitalisation: **Age:** 35Y
Onset Date: 22/11/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Constipation			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 20/11/1996 Stopped: 30/11/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 113853	Seq: 1	Gender: M
Reported: 09/12/1996		Weight:
Hospitalisation:		Age:
Onset Date: 31/07/1994		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Light flashes before eyes	
Agitation			
Confusional state			

Medicine Details:

PROTHIADEN (Suspected)		Reason:	
Capsule	50.0 Milligram	Daily	Oral
Batch:	Started: 01/07/1994	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 114052 **Seq:** 1

Gender: M

Reported: 20/12/1996

Weight: 86.00

Hospitalisation:

Age: 52Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)		Reason:	Unspecifid affective psychosis	
Oral application	75.0 Milligram	Daily	Oral	
Batch:	Started:	Stopped:		
TEGRETOL (Suspected)		Reason:	Unspecifid affective psychosis	
Oral application	300.0 Milligram	Daily	Oral	
Batch:	Started: 01/10/1996	Stopped:		

Laboratory Investigations:

Additional Information:

Cirrhosis with ductopenia and massive bile ductule proliferation, normal ercp. previous history of chlorpromazine induced jaundice 1962. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 114659	Seq: 1	Gender: M
Reported: 21/01/1997		Weight: 60.00
Hospitalisation:		Age: 36Y
Onset Date: 13/01/1997		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood folate abnormal			

Medicine Details:

METHOTREXATE (Suspected)	Reason:
7.5 Gram	Weekly
Batch:	Started: 01/06/1996 Stopped: 14/01/1997
FELDENE (Suspected)	Reason:
20.0 Milligram	Daily
Batch:	Started: 01/06/1996 Stopped: CONTIN
ZANTAC (Suspected)	Reason:
300.0 Milligram	Daily
Batch:	Started: 01/06/1996 Stopped: CONTIN
PROTHIADEN (Suspected)	Reason: Depression
150.0 Milligram	Daily
Batch:	Started: 01/01/1992 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				Serum b12 40 omol/l (150-700)13/1/97 rbc folate 205 nmol/l(250-1030)13/1/97

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 114780 **Seq:** 1 **Gender:** F
Reported: 28/01/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

DOTHEP (Suspected)	Reason: Depression
Batch:	Started: 0.0 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient noticed a difference in efficacy when she switched from prothiaden to dothep - her depression relapsed.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 115365	Seq: 1	Gender: F
Reported: 17/02/1997		Weight:
Hospitalisation:		Age: 56Y
Onset Date: 18/01/1997		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Hypoxic fit	
Syncope		Loss of consciousness	
Electrocardiogram abnormal			
Torsade de pointes			Amiodarone, lignocaine.

Medicine Details:

ASPIRIN (Other drug)	Reason:	
100.0 Milligram	Daily	
Batch:	Started:	Stopped:
GEMFIBROZIL (Other drug)	Reason: Othr&unspec metabolic diseases	
1.2 Gram	Daily	
Batch:	Started:	Stopped:
MELLERIL (Suspected)	Reason: Unspecified schizophrenia	
600.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 18/01/1997
PROTHIADEN (Suspected)	Reason: Unspecified schizophrenia	
150.0 Milligram	Daily	
Batch:	Started: 18/01/1997	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Ecg: anterolateral st-t wave changes suggestive cardiac

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 115581 **Seq:** 1 **Gender:** F
Reported: 26/02/1997 **Weight:** 70.00
Hospitalisation: **Age:** 31Y
Onset Date: 28/12/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion Syncope			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	150.0 Milligram Daily Oral
Batch:	Started: 02/10/1996 Stopped: 23/01/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electroencephalog				Eeg and ct brain - normal.

Additional Information:

No past history or family history of epilepsy. neurologist opinion: only identifiable precipitating factor is prothiaden.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 115850 **Seq:** 1 **Gender:** F
Reported: 12/03/1997 **Weight:** 60.00
Hospitalisation: **Age:** 70Y
Onset Date: 29/01/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bradycardia			Atropine , saline. commenced on amiodarone

Medicine Details:

DIGOXIN (Suspected)	Reason: Otr&nos disord of heart rhythm
250.0 Microgram Daily	
Batch:	Started: 28/01/1997 Stopped: 29/01/1997
KINIDIN DURULES (Suspected)	Reason:
4.0 Dose Unspecified Daily	
Batch:	Started: Stopped: 29/01/1997
ATENOLOL (Suspected)	Reason:
25.0 Milligram Daily	
Batch:	Started: Stopped: 29/01/1997
AMLODIPINE (Suspected)	Reason:
10.0 Milligram Daily	
Batch:	Started: Stopped: 29/01/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 115850

Seq: 1

Gender: F

Reported: 12/03/1997

Weight: 60.00

Hospitalisation:

Age: 70Y

Onset Date: 29/01/1997

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)

Reason:

75.0 Milligram

Daily

Batch:

Started:

Stopped: 29/01/1997

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 115987 **Seq:** 1 **Gender:** F
Reported: 12/03/1997 **Weight:**
Hospitalisation: **Age:** 34
Onset Date: 15/02/1997 **DOB:** 12/02/1963
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			
Muscle spasms			Quinine bi-sou.

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	150.0 Milligram Daily Oral
Batch:	Started: 01/02/1997 Stopped: 22/02/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced similar reaction to prothiaden previously.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 116582 **Seq:** 1 **Gender:** F
Reported: 09/04/1997 **Weight:** 58.00
Hospitalisation: **Age:** 33Y
Onset Date: 04/04/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sensory disturbance Paraesthesia Flushing Headache Nausea		Decreased sensation on neurological Left side of face, arm and hand	

Medicine Details:

PROTHIADEN (Suspected)	Reason:
Oral application	50.0 Milligram Daily Oral
Batch:	Started: 12/03/1997 Stopped: 04/04/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 117111 **Seq:** 1 **Gender:** M
Reported: 28/04/1997 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dry mouth			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
150.0 Milligram	Daily
Batch:	Started:
	Stopped: 6M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 117262	Seq: 1	Gender: F
Reported: 05/05/1997		Weight:
Hospitalisation:		Age: 92
Onset Date: 24/02/1997		DOB: 16/10/1904
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypothyroidism			

Medicine Details:

NEO-MERCAZOLE (Suspected)	Reason: Thyrotoxicosis w/o ment goiter
17.5 Milligram	Daily
Batch:	Started:
Stopped:	
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason:
50.0 Milligram	Daily
Batch:	Started:
Stopped:	
GLICLAZIDE (Suspected)	Reason: Diabetes mellitus
80.0 Milligram	Daily
Batch:	Started:
Stopped:	
PARACETAMOL (Suspected)	Reason: Pain
6.0 Gram	Daily
Batch:	Started: 23/02/1997
Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 117262

Seq: 1

Gender: F

Reported: 05/05/1997

Weight:

Hospitalisation:

Age: 92

Onset Date: 24/02/1997

DOB: 16/10/1904

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

HEPARIN SODIUM (Suspected)

Reason:

Injection

10.0 Thousand Internat Daily

Subcutaneous

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 117389	Seq: 1	Gender: M
Reported: 08/05/1997		Weight: 103.00
Hospitalisation:		Age: 32Y
Onset Date: 31/12/1995		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			

Medicine Details:

STEMETIL (Suspected)	Reason:
5.0 Milligram	As necessary
Batch:	Started: L TERM Stopped:
COLOXYL (Suspected)	Reason:
240.0 Milligram	As necessary
Batch:	Started: L TERM Stopped:
PROTHIADEN (Suspected)	Reason: Depression
150.0 Milligram	Daily
Batch:	Started: 01/01/1995 Stopped: 08/08/1996
METHADONE HYDROCHLORIDE (Suspected)	Reason: Pain
80.0 Milligram	Daily
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 117389

Seq: 1

Gender: M

Reported: 08/05/1997

Weight: 103.00

Hospitalisation:

Age: 32Y

Onset Date: 31/12/1995

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

CATAPRES (Suspected)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
ALPHA-TOCOPHEROL (Suspected)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 118425 **Seq:** 1 **Gender:** M
Reported: 20/06/1997 **Weight:** 70.00
Hospitalisation: **Age:** 28Y
Onset Date: 31/03/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia Amnesia Libido decreased Somnolence		Heart racing	

Medicine Details:

DOTHEP (Suspected)	Reason: Depression
150.0 Milligram	1 time
Batch:	Started: 01/03/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been on prothiaden 2 years ago and stable on 150rg. changed to dothep in march 97 and experienced reaction, so changed back to prothiaden. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 118960	Seq: 1	Gender: M
Reported: 10/07/1997		Weight:
Hospitalisation:		Age: 49
Onset Date: 19/02/1997		DOB: 25/07/1947
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itch->feet/groin/hands/back. visible rash	Phenergan 25mg im inj given and prothiaden ceased

Medicine Details:

METHADONE HYDROCHLORIDE (Other drug)	Reason:
Oral application	80.0 Milligram Daily Oral
Batch:	Started: Stopped:
COLOXYL (Other drug)	Reason:
Tablet	2.0 Dose Unspecified Daily Oral
Batch:	Started: Stopped:
MAXOLON (Other drug)	Reason:
	30.0 Milligram Daily
Batch:	Started: 16/02/1997 Stopped:
PETHIDINE HYDROCHLORIDE (Other drug)	Reason:
Injection	600.0 Milligram Daily Intramuscular
Batch:	Started: 16/02/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 118960 **Seq:** 1 **Gender:** M
Reported: 10/07/1997 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: 19/02/1997 **DOB:** 25/07/1947
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

COTAZYM-S FORTE (Other drug)		Reason:	
Capsule	9.0 Dose Unspecified	Daily	Oral
Batch:	Started: 17/02/1997	Stopped:	
RANITIDINE (Other drug)		Reason:	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 19/02/1997	Stopped:	
PROTHIADEN (Suspected)		Reason:	
Capsule	75.0 Milligram	1 time	Oral
Batch:	Started: 19/02/1997	Stopped: 19/02/1997	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 119483 **Seq:** 1 **Gender:** F
Reported: 28/07/1997 **Weight:**
Hospitalisation: **Age:** 73Y
Onset Date: 25/06/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Hallucination Headache			Prothiaden ceased

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 23/04/1997 Stopped: 29/07/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 120096 **Seq:** 1 **Gender:** M
Reported: 18/08/1997 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 45Y
Onset Date: 31/08/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal Extrasystoles Palpitations Ventricular tachycardia		St wave changes Ventricular ectopic beats, 3 beats salvos.	

Medicine Details:

PROTHIADEN (Interaction)	Reason:
50.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
ZOLOFT (Interaction)	Reason: Depression
Tablet 25.0 Milligram Daily Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient discontinued protiaden and after 2-3 day washout commenced zoloft. after increasing dose, experienced reaction. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 120495 **Seq:** 1 **Gender:** F
Reported: 03/09/1997 **Weight:**
Hospitalisation: **Age:** 77Y
Onset Date: 27/08/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			

Medicine Details:

NORVASC (Suspected)	Reason: Essential benign hypertension	
Tablet	0.0	Oral
Batch:	Started:	Stopped:
PHENOBARBITONE (Suspected)	Reason:	
Oral application	0.0	Oral
Batch:	Started:	Stopped:
NAPROSYN (Suspected)	Reason: Unspecified arthritis	
Oral application	0.0	As necessary Oral
Batch:	Started:	Stopped:
PROTHIADEN (Suspected)	Reason: Depression	
Oral application	0.0	As necessary Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 120495 **Seq:** 1

Gender: F

Reported: 03/09/1997

Weight:

Hospitalisation:

Age: 77Y

Onset Date: 27/08/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

LIPEX (Suspected)	Reason: Othr&unspec metabolic diseases
Tablet	0.0 As necessary Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 120629 **Seq:** 1 **Gender:** F
Reported: 09/09/1997 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: 01/09/1997 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence			Dothep ceased prothiaden recommenced.

Medicine Details:

PROTHIADEN (Other drug)	Reason: Specific disorders of sleep
Capsule 25.0 Milligram Daily Oral	
Batch: Started: Stopped: 01/09/1997	
DOTHEP (Suspected)	Reason: Specific disorders of sleep
Capsule 25.0 Milligram Daily Oral	
Batch: Started: 01/09/1997 Stopped: 03/09/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been taking prothiaden for years. medication changed to dothep 25mg. patient took dothep on 2 evenings but found they caused her to be drowsy - much more than prothiaden. first dose caused patient to sleep until 1pm the next day. second dose was better but still caused excessive drowsiness



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 120880	Seq: 1	Gender: F
Reported: 15/09/1997		Weight: 76.00
Hospitalisation:		Age: 69Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression			Therapy changed back to
Drug ineffective			

Medicine Details:

LITHICARB (Other drug)	Reason: Depression
Tablet	500.0 Milligram
	Daily
	Oral
Batch:	Started: 01/01/1993
	Stopped:
COVERSYL (Other drug)	Reason: Essential benign hypertension
Tablet	4.0 Milligram
	Daily
	Oral
Batch:	Started: 01/01/1993
	Stopped:
OROXINE (Other drug)	Reason: Myxedema
Tablet	150.0 Microgram
	Daily
	Oral
Batch:	Started: 01/01/1994
	Stopped:
AGON (Other drug)	Reason: Essential benign hypertension
Tablet	10.0 Milligram
	Daily
	Oral
Batch:	Started: 01/01/1993
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred when patient changed therapy from prothiaden to generic brand of dothep. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 120880
Reported: 15/09/1997
Hospitalisation:
Onset Date:
Outcome: Recovered

Seq: 1

Gender: F
Weight: 76.00
Age: 69Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

TAZAC (Other drug)	Reason: Other diseases of esophagus		
Capsule	300.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1993	Stopped:	
PREMARIN (Other drug)	Reason: Menopausal symptoms		
Tablet	625.0 Microgram	Daily	Oral
Batch:	Started: 01/01/1989	Stopped:	
DOTHEP (Suspected)	Reason: Depression		
	0.0		
Batch:	Started: 07/06/1997	Stopped:	

Laboratory Investigations:

Additional Information:

Reaction occurred when patient changed therapy from prothiaden to generic brand of dothep. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 121012	Seq: 1	Gender: F
Reported: 22/09/1997		Weight:
Hospitalisation:		Age: 15Y
Onset Date: 19/11/1996		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence			Paracetamol, iv fluids. referred to adolescent psych services.
Urinary incontinence			

Medicine Details:

AMOXYCILLIN TRIHYDRATE (Other drug)	Reason: Ac upr resp inf,mult,unsp stes
0.0	
Batch:	Started: 15/11/1996 Stopped:
PROTHIADEN (Suspected)	Reason: Depression
Oral application	50.0 Milligram
	Daily
	Oral
Batch:	Started: 01/09/1996 Stopped:
PROTHIADEN (Suspected)	Reason:
Oral application	75.0 Milligram
	Daily
	Oral
Batch:	Started: 15/11/1996 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 121366 **Seq:** 1 **Gender:** M
Reported: 07/10/1997 **Weight:** 71.00
Hospitalisation: Admitted to hospital **Age:** 49Y
Onset Date: 05/09/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Capsule	150.0 Milligram Daily Oral
Batch:	Started: 08/08/1997 Stopped: 19/09/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft - sore gums



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 122309	Seq: 1	Gender: F
Reported: 12/11/1997		Weight:
Hospitalisation:		Age: 63Y
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pseudolymphoma			

Medicine Details:

RITALIN (Suspected)	0.0	Reason:
Batch:	Started:	Stopped:
OGEN (Suspected)	0.0	Reason:
Batch:	Started: 01/01/1989	Stopped: 31/01/1996
PROGESTERONE (Suspected)	0.0	Reason:
Batch:	Started:	Stopped:
DERALIN (Suspected)		Reason: Anxiety neurosis
Tablet	240.0 Milligram	Daily Oral
Batch:	Started: 01/01/1989	Stopped: 31/01/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 122309 **Seq:** 1 **Gender:** F
Reported: 12/11/1997 **Weight:**
Hospitalisation: **Age:** 63Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

DERALIN (Suspected)	Reason: Anxiety neurosis
Tablet	120.0 Milligram Daily Oral
Batch:	Started: 01/01/1993 Stopped: 31/01/1996
PROTHIADEN (Suspected)	Reason:
Oral application	25.0 Milligram Daily Oral
Batch:	Started: Stopped: 31/01/1996
MELLERIL (Suspected)	Reason:
Oral application	1.0 Dose Unspecified Daily Oral
Batch:	Started: Stopped: 31/01/1996

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 122750 **Seq:** 1 **Gender:** F
Reported: 25/11/1997 **Weight:** 62.00
Hospitalisation: **Age:** 49Y
Onset Date: 31/08/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			

Medicine Details:

TRISEQUENS FORTE (Other drug)	Reason: Menopausal symptoms
0.0	
Batch:	Started: 01/01/1996 Stopped:
VERACAPS SR (Other drug)	Reason: Essential benign hypertension
Capsule 160.0 Milligram Daily Oral	
Batch:	Started: 01/01/1994 Stopped:
DOTHEP (Suspected)	Reason: Anxiety neurosis
150.0 Milligram Daily	
Batch:	Started: 01/01/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

When patient changed from prothiaden to dothep brand symptoms were experienced and settled when returned to prothiaden. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 122896	Seq: 1	Gender: F
Reported: 01/12/1997		Weight: 100.00
Hospitalisation:		Age: 33Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Insomnia			Dose of prothiaden reduced to

Medicine Details:

PROTHIADEN (Suspected)	Reason: Anxiety neurosis
225.0 Milligram	Daily
Batch:	Started: 01/06/1997
	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 123033	Seq: 1	Gender: M
Reported: 03/12/1997		Weight:
Hospitalisation:		Age: 66Y
Onset Date: 14/06/1997		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haematemesis Melaena			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	150.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:
POTASSIUM CHLORIDE (Suspected)	Reason:
Oral application	2.0 Dose Unspecified Daily Oral
Batch:	Started: L TERM Stopped:
LASIX (Suspected)	Reason:
Tablet	40.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:
NAPROXEN (Suspected)	Reason: Pain
Oral application	1.0 Gram Daily Oral
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 123033 **Seq:** 1 **Gender:** M
Reported: 03/12/1997 **Weight:**
Hospitalisation: **Age:** 66Y
Onset Date: 14/06/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

FENTANYL CITRATE (Suspected)	Reason: Pain
Oral application	300.0 Microgram Daily Oral
Batch:	Started: L TERM Stopped:
COLOXYL WITH SENNA (Suspected)	Reason:
Tablet	4.0 Dose Unspecified Daily Oral
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 123118	Seq: 1	Gender: U
Reported: 08/12/1997		Weight:
Hospitalisation:		Age: 45
Onset Date: 31/03/1997		DOB: 29/02/1952
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aortic valve incompetence			
Retroperitoneal fibrosis			Prednisolone

Medicine Details:

PROTHIADEN (Suspected)	Reason:	0.0
Batch:	Started:	Stopped:
ROHYPNOL (Suspected)	Reason:	0.0
Batch:	Started:	Stopped:
MERSYNDOL FORTE (Suspected)	Reason:	0.0
Batch:	Started:	Stopped:
DESERIL (Suspected)	Reason: Migraine	
Tablet	4.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 28/08/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 123253	Seq: 1	Gender: F
Reported: 10/12/1997		Weight:
Hospitalisation:		Age: 67Y
Onset Date: 08/10/1997		DOB:
Outcome: Death, maybe drug		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination Confusional state		Visual hallucinations	Ceased ritalin and changed to morphine mix.

Medicine Details:

MAXOLON (Other drug)	Reason: Nausea and vomiting
Tablet	40.0 Milligram
Daily	Oral
Batch:	Started: 02/10/1997
	Stopped: 12/10/1997
DEXAMETHASONE (Other drug)	Reason: Nausea and vomiting
Oral application	2.0 Milligram
Daily	Oral
Batch:	Started: 03/10/1997
	Stopped: 10/10/1997
CIPROFLOXACIN (Suspected)	Reason: Unspecified septicemia
Tablet	1.5 Gram
Daily	Oral
Batch:	Started: 29/09/1997
	Stopped: 08/10/1997
RITALIN (Suspected)	Reason:
Tablet	10.0 Milligram
Daily	Oral
Batch:	Started: 07/10/1997
	Stopped: 08/10/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 12/10/97.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 123253 **Seq:** 1 **Gender:** F
Reported: 10/12/1997 **Weight:**
Hospitalisation: **Age:** 67Y
Onset Date: 08/10/1997 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Medicine Details:

MS CONTIN (Suspected)	Reason: Pain
Tablet	40.0 Milligram Daily Oral
Batch:	Started: 29/09/1997 Stopped: 08/10/1997
SLOW-K (Suspected)	Reason:
	2.0 Dose Unspecified Daily
Batch:	Started: 29/09/1997 Stopped: 08/10/1997
COLOXYL WITH SENNA (Suspected)	Reason: Constipation
Tablet	4.0 Dose Unspecified Daily Oral
Batch:	Started: 29/09/1997 Stopped: 08/10/1997
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason:
	75.0 Milligram Daily
Batch:	Started: 19/09/1997 Stopped: 08/10/1997

Laboratory Investigations:

Additional Information:

Patient died 12/10/97.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 123253 **Seq:** 1

Gender: F

Reported: 10/12/1997

Weight:

Hospitalisation:

Age: 67Y

Onset Date: 08/10/1997

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Detail

Medicine Details:

PANADOL (Suspected)	Reason: Pain
Oral application	4.0 Gram Daily Oral
Batch:	Started: 30/09/1997 Stopped: 08/10/1997
GASTROGEL (Suspected)	Reason: Nausea and vomiting
	3.0 Dose Unspecified Daily
Batch:	Started: 06/10/1997 Stopped: 09/10/1997
XYLOCAINE JELLY (Suspected)	Reason: Otr&unspec oral soft tissu dis
Gel	3.0 Dose Unspecified Daily Topical
Batch:	Started: 06/10/1997 Stopped: 09/10/1997

Laboratory Investigations:

Additional Information:

Patient died 12/10/97.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 123642 **Seq:** 1 **Gender:** M
Reported: 24/12/1997 **Weight:**
Hospitalisation: **Age:** A4
Onset Date: 31/12/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain			Chest pain treated with

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression		
Batch:	Started:	L TERM	Stopped:
0.0			
MELLERIL (Suspected)	Reason:		
Batch:	Started:		Stopped:
0.0			
ZOLOFT (Suspected)	Reason: Depression		
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 124416 **Seq:** 1 **Gender:** F
Reported: 28/01/1998 **Weight:** 60.00
Hospitalisation: **Age:** 37Y
Onset Date: 01/12/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Congenital foot malformation		Megadactyly affecting great toe of one foot.	

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression		
Capsule	75.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1994	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Baby born with megadactyly affecting great toe of one foot. mother taking prothiaden continuously from and before conception and throughout pregnancy. 2 previous babies without defects. no family history or other illness. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 124898	Seq: 1	Gender: F
Reported: 12/02/1998		Weight: 94.00
Hospitalisation:		Age: 58Y
Onset Date: 23/01/1998		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis		Increased bilirubin, ast, alt, ggt	

Medicine Details:

COVERSYL (Suspected)	0.0	Reason:
Batch:	Started:	Stopped:
NITRADISC (Suspected)	0.0	Reason:
Batch:	Started:	Stopped:
NOROXIN (Suspected)	0.0	Reason:
Batch:	Started:	Stopped:
PROTHIADEN (Suspected)	0.0	Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 124898 **Seq:** 1

Gender: F

Reported: 12/02/1998

Weight: 94.00

Hospitalisation:

Age: 58Y

Onset Date: 23/01/1998

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PRAVACHOL (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
NIZORAL (Suspected)	Reason: Unspecified systemic mycosis
Tablet 200.0 Milligram Daily Oral	
Batch:	Started: 20/01/1998 Stopped: 23/01/1998
ZOTON (Suspected)	Reason: Otr intestne&peritoneum dsease
Capsule 30.0 Milligram Daily Oral	
Batch:	Started: 20/01/1998 Stopped: 23/01/1998

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 125858 **Seq:** 1 **Gender:** M
Reported: 17/03/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/03/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia	Required Specialist Consultation		Prothiaden ceased, zolofl commenced

Medicine Details:

PROTHIADEN (Suspected)	Reason: Anxiety neurosis
Oral application	150.0 Milligram Daily Oral
Batch:	Started: 01/07/1997 Stopped: 28/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 127125 **Seq:** 1 **Gender:** M
Reported: 04/05/1998 **Weight:**
Hospitalisation: **Age:** 20Y
Onset Date: 27/04/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			

Medicine Details:

FLORINEF (Suspected) Tablet Batch:	0.1 Milligram Started: 23/02/1998	Daily Stopped: 30/04/1998	Oral
SLOW-K (Suspected) Batch:	600.0 Milligram Started: 23/02/1998	Daily Stopped: 30/04/1998	
PROTHIADEN (Suspected) Batch:	25.0 Milligram Started:	Daily Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 127464	Seq: 1	Gender: F
Reported: 18/05/1998		Weight: 60.00
Hospitalisation: Admitted to hospital		Age: 50Y
Onset Date: 28/02/1998		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Catatonia Confusional state Coordination abnormal Hyponatraemia Polydipsia Polyuria			

Medicine Details:

TEGRETOL (Other drug)	Reason:
1.2 Gram	Daily
Batch:	Started: L TERM Stopped:
MELLERIL (Other drug)	Reason:
300.0 Milligram	Daily
Batch:	Started: L TERM Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
750.0 Milligram	Daily
Batch:	Started: L TERM Stopped:
VALIUM (Other drug)	Reason:
4.0 Milligram	Daily
Batch:	Started: 01/01/1998 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine Electrolytes		28/02/1998	.14 - .17	Hyponatremia 117 - 129 - 131, urine sodium <30 repeatedly.

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 127464 **Seq:** 1 **Gender:** F
Reported: 18/05/1998 **Weight:** 60.00
Hospitalisation: Admitted to hospital **Age:** 50Y
Onset Date: 28/02/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

THYROXINE SODIUM (Other drug)	Reason: Thyrotoxicosis w/o ment goiter
50.0 Milligram	Daily
Batch:	Started: 01/01/1996 Stopped:
PROTHIADEN (Suspected)	Reason: Specific disorders of sleep
50.0 Milligram	Daily
Batch:	Started: 01/01/1998 Stopped: 28/03/1998

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 128713 **Seq:** 1 **Gender:** F
Reported: 26/06/1998 **Weight:** 61.00
Hospitalisation: **Age:** 40Y
Onset Date: 20/06/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety		Anxious	
Insomnia		Unsettled	
Palpitations			

Medicine Details:

DOTHEP (Suspected)	Reason: Specific disorders of sleep
Tablet	75.0 Milligram Daily Oral
Batch:	Started: 20/06/1998 Stopped: 21/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 128943	Seq: 1	Gender: M
Reported: 06/07/1998		Weight: 90.00
Hospitalisation:		Age: 47Y
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast pain			
Gynaecomastia			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	250.0 Milligram Daily Oral
Batch:	Started: 01/07/1996 Stopped: 28/06/1998
MORPHINE NOS (Suspected)	Reason: Pain
Oral application	30.0 Milligram Daily Oral
Batch:	Started: 01/09/1995 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 129267	Seq: 1	Gender: F
Reported: 17/07/1998		Weight:
Hospitalisation:		Age: 56Y
Onset Date: 16/05/1998		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus	Required Visit to Doctor		Cephalosporin changed to flucloxacillin. given promethazine iv and po
Rash	Required Visit to Doctor		

Medicine Details:

EPREX (Suspected)		Reason:	
Injection	4.0 Thousand Internat Weekly	Subcutaneous	
Batch:	Started:	Stopped:	
DYMADON (Suspected)		Reason:	
Tablet	2.0 Dose Unspecified As necessary	Oral	
Batch:	Started:	Stopped:	
CEPHAZOLIN SODIUM (Suspected)		Reason: Unspecified septicemia	
Injection	3.0 Gram Daily	Intravenous	
Batch:	Started: 08/05/1998	Stopped: 16/05/1998	
CALTRATE (Suspected)		Reason:	
Tablet	6.0 Dose Unspecified Daily	Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 129267 **Seq:** 1 **Gender:** F
Reported: 17/07/1998 **Weight:**
Hospitalisation: **Age:** 56Y
Onset Date: 16/05/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

VITAMIN B-COMPLEX FORTE (Suspected)	Reason:
Tablet 1.0 Dose Unspecified Daily Oral	
Batch:	Started: Stopped:
FERRO-GRADUMET (Suspected)	Reason:
Tablet 2.0 Dose Unspecified Daily Oral	
Batch:	Started: Stopped:
DOTHEP (Suspected)	Reason:
Oral application 25.0 Milligram Daily Oral	
Batch:	Started: Stopped:
ADALAT OROS (Suspected)	Reason:
Tablet 30.0 Milligram Daily Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 130136 **Seq:** 1 **Gender:** F
Reported: 14/08/1998 **Weight:** 58.00
Hospitalisation: **Age:** 26Y
Onset Date: 06/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			Drug ceased

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
175.0 Milligram	Daily
Batch:	Started: 07/07/1998 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 130442 **Seq:** 1 **Gender:** F
Reported: 25/08/1998 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 03/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Skin exfoliation		Red peeling pustules on hands and feet.	

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Batch:	Started: 23/06/1998 Stopped: 18/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 130546	Seq: 1	Gender: F
Reported: 25/08/1998		Weight:
Hospitalisation:		Age: AD
Onset Date: 26/06/1998		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			
Drug withdrawal syndrome neonatal			
Fatigue			
Feeding disorder neonatal			
Respiratory disorder			

Medicine Details:

DOXEPIN HYDROCHLORIDE (Suspected)	Reason:
0.0	
Batch:	Started:
	Stopped:
PROTHIADEN (Suspected)	Reason:
0.0	
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Doxepin and prothiaden administered to the mother in pregnancy and puerperium. symptoms suggestive of drug withdrawal. tachypnoea and abnormal jerky jittery movements starting soon after birth, followed after some days by lethargy, poor feeding, failure to gain weight on breast feeds. baby improved markedly when formula fed. long term outcome unknown.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 130740	Seq: 1	Gender: F
Reported: 02/09/1998		Weight:
Hospitalisation:		Age: 63Y
Onset Date: 23/08/1998		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia		Aching pain in legs	
Paraesthesia			

Medicine Details:

LARGACTIL (Suspected)	Reason:
100.0 Milligram	Daily
Batch:	Started: 01/08/1998 Stopped: CONTIN
PROTHIADEN (Suspected)	Reason:
150.0 Milligram	Daily
Batch:	Started: 01/08/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 130901 **Seq:** 1 **Gender:** F
Reported: 08/09/1998 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Multiple congenital abnormalities		Bifid uvula	

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
Oral application	125.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Baby was born with bifid uvula, mother was taking prothiaden. 1st male child 2 yrs ago - normal



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 131100 **Seq:** 1 **Gender:** F
Reported: 04/09/1998 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: 20/08/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare		"nightmares and hallucinations"	
Depersonalisation		Feels extremely scared & disorientated.	
Confusional state		Feels in a strange environment.	
Hallucination			

Medicine Details:

METOPROLOL TARTRATE (Other drug)	Reason:
200.0 Milligram	Daily
Batch:	Started: 01/10/1997 Stopped:
PROTHIADEN (Suspected)	Reason:
75.0 Milligram	Daily
Batch:	Started: 01/07/1998 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Barlow's syndrome. back pain (degeneration of vertebrae affecting the nerves. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 131108 **Seq:** 1 **Gender:** F
Reported: 11/09/1998 **Weight:**
Hospitalisation: **Age:** 79Y
Onset Date: 06/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania		Acute hypomania	Ceased dothep

Medicine Details:

PROPRANOLOL HYDROCHLORIDE (Other drug)	Reason: Abnormal involuntary movement
80.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
GLICLAZIDE (Other drug)	Reason: Diabetes mellitus
240.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
TRANDOLAPRIL (Other drug)	Reason: Congestive heart failure
500.0 Microgram Daily	
Batch:	Started: L TERM Stopped:
DIGOXIN (Other drug)	Reason: Congestive heart failure
187.5 Microgram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 131108
Reported: 11/09/1998
Hospitalisation:
Onset Date: 06/08/1998
Outcome: Recovered

Seq: 1

Gender: F
Weight:
Age: 79Y
DOB:
Causality: Causality probable

Reaction Detail

Medicine Details:

NITROFURANTOIN (Other drug)	Reason: Prophylaxis
100.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
XANAX (Other drug)	Reason: Anxiety neurosis
2.5 Milligram Daily	
Batch:	Started: L TERM Stopped:
OXAZEPAM (Other drug)	Reason: Specific disorders of sleep
30.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
WARFARIN SODIUM (Other drug)	Reason: Otr&nos disord of heart rhythm
2.0 Milligram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 131108

Seq: 1

Gender: F

Reported: 11/09/1998

Weight:

Hospitalisation:

Age: 79Y

Onset Date: 06/08/1998

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

DOTHEP (Suspected)

Reason: Depression

Oral application

25.0 Milligram

Daily

Oral

Batch:

Started: 05/08/1998

Stopped: 06/08/1998

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 131796 **Seq:** 1 **Gender:** F
Reported: 06/10/1998 **Weight:**
Hospitalisation: **Age:** 44Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)		Reason:
Batch:	0.0	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 131861	Seq: 1	Gender: F
Reported: 08/10/1998		Weight:
Hospitalisation:		Age: 64Y
Onset Date: 05/07/1998		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Talking faster than she is thinking	

Medicine Details:

LARGACTIL (Suspected)	Reason:
100.0 Milligram	Daily
Batch:	Started: 05/07/1998 Stopped: CONTIN
PROTHIADEN (Suspected)	Reason:
150.0 Milligram	Daily
Batch:	Started: Stopped: CONTIN
TEMAZEPAM (Suspected)	Reason:
20.0 Milligram	Daily
Batch:	Started: Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 132715	Seq: 1	Gender: M
Reported: 02/11/1998		Weight: 104.00
Hospitalisation:		Age: 57Y
Onset Date: 14/10/1998		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Enteritis		Salmonella enteritis	
Bacterial infection			

Medicine Details:

TIMOPTOL (Other drug)	Reason: Unspecified glaucoma
Eye Drops	0.0 Ophthalmic
Batch:	Started:
Batch:	Stopped:
DIAMICRON (Other drug)	Reason: Diabetes mellitus
160.0 Milligram	Daily
Batch:	Started: 01/01/1990
Batch:	Stopped:
AMILORIDE HYDROCHLORIDE (Other drug)	Reason: Adrenal cortical hyperfunction
10.0 Milligram	Daily
Batch:	Started: 01/01/1990
Batch:	Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
1.0 Gram	Daily
Batch:	Started: L TERM
Batch:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Microbiology				Salmonella enteritis/enteric fever.

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 132715 **Seq:** 1 **Gender:** M
Reported: 02/11/1998 **Weight:** 104.00
Hospitalisation: **Age:** 57Y
Onset Date: 14/10/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

ZYLOPRIM (Other drug)	Reason: Gout
300.0 Milligram	Daily
Batch:	Started: 01/01/1990 Stopped:
ULTRATARD HM (Suspected)	Reason: Diabetes mellitus
Injection	60.0 Unit Daily Subcutaneous
Batch:	Started: 01/01/1997 Stopped:
LOSEC (Suspected)	Reason: Other diseases of esophagus
40.0 Milligram	Daily
Batch:	Started: 01/01/1996 Stopped:
LIPEX (Suspected)	Reason: Othr&unspec metabolic diseases
20.0 Milligram	Daily
Batch:	Started: 01/01/1996 Stopped:

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 132715
Reported: 02/11/1998
Hospitalisation:
Onset Date: 14/10/1998
Outcome: Recovered

Seq: 1

Gender: M
Weight: 104.00
Age: 57Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

EFEXOR (Suspected)	Reason: Depression
37.5 Milligram	Daily
Batch:	Started: 01/01/1998 Stopped:
DOTHEP (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 133490	Seq: 1	Gender: F
Reported: 19/11/1998		Weight:
Hospitalisation:		Age: 68Y
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

FLUNITRAZEPAM (Suspected)	Reason:	
0.0		
Batch:	Started:	Stopped: CONTIN
DOTHIEPIN HYDROCHLORIDE (Suspected)		
Reason:		
0.0		
Batch:	Started: 01/01/1998	Stopped: CONTIN
ZOCOR (Suspected)		
Reason: Othr&unspec metabolic diseases		
Tablet	10.0 Milligram	Daily Oral
Batch:	Started: 01/01/1994	Stopped: CONTIN
SOTALOL HYDROCHLORIDE (Suspected)		
Reason:		
160.0 Milligram	Daily	
Batch:	Started:	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 133490

Seq: 1

Gender: F

Reported: 19/11/1998

Weight:

Hospitalisation:

Age: 68Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

OESTROGENS CONJUGATED (Suspected)

Reason:

300.0 Microgram Daily

Batch:

Started:

Stopped:

CONTIN

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 134759 **Seq:** 1 **Gender:** M
Reported: 04/01/1999 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: 31/10/1998 **DOB:** 29/12/1947
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			Ceased prothiaden

Medicine Details:

PROTHIADEN (Suspected)	Reason:
Batch:	Started: 0.0 L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 135360	Seq: 1	Gender: F
Reported: 27/01/1999		Weight:
Hospitalisation:		Age: 69Y
Onset Date: 29/12/1998		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			

Medicine Details:

DAONIL (Other drug)	Reason:
0.0	
Batch:	Started: L TERM Stopped: CONTIN
ADALAT OROS (Other drug)	Reason:
30.0 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN
INDERAL (Other drug)	Reason:
80.0 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN
MINIPRESS (Other drug)	Reason:
2.5 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils				Neutrophils falling to 0.1 by 04/01/99.

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 135360

Seq: 1

Gender: F

Reported: 27/01/1999

Weight:

Hospitalisation:

Age: 69Y

Onset Date: 29/12/1998

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

ZYLOPRIM (Other drug)	Reason:	
300.0 Milligram	Daily	
Batch:	Started: L TERM	Stopped: CONTIN
PROTHIADEN (Suspected)	Reason: Depression	
100.0 Milligram	Daily	
Batch:	Started: 01/11/1998	Stopped: 31/12/1998

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 136607	Seq: 1	Gender: F
Reported: 24/02/1999		Weight: 63.00
Hospitalisation:		Age: 51Y
Onset Date: 10/01/1999		DOB:
Outcome: Recovered		Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Confusional state			

Medicine Details:

DIAZEPAM (Other drug)	Reason:
2.5 Milligram	Daily
Batch:	Started: 01/01/1997 Stopped: CONTIN
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced same reaction on two occasions when taking dothiepin. took dothiepin in 1998 for three months with no reaction. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 137507 **Seq:** 1 **Gender:** F
Reported: 18/03/1999 **Weight:** 62.00
Hospitalisation: **Age:** 80Y
Onset Date: **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myopathy		Proximal myopathy.	Ceased prothiaden
Asthenia		Weakness upper & lower limb.	

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
125.0 Milligram	Daily
Batch:	Started: 01/11/1997 Stopped: 28/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original for other drug details - lithcarb. increasing proximal myopathy, rapidly reversed when drug stopped. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 139424 **Seq:** 1 **Gender:** F
Reported: 12/05/1999 **Weight:** 78.00
Hospitalisation: **Age:** 61Y
Onset Date: 31/08/1997 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Lichenoid keratosis			Ceased dothep 75

Medicine Details:

DOTHEP (Suspected)	Reason:
Oral application	1.0 Dose Unspecified Daily Oral
Batch:	Started: 01/01/1994 Stopped: 15/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Tissue biopsy				Lichenoid dermatitis on biopsy.

Additional Information:

Reaction cleared when dothep was ceased and recurred when it was resumed twice - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 140381	Seq: 1	Gender: F
Reported: 09/06/1999		Weight: 79.00
Hospitalisation:		Age: 64Y
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus			Prothiaden ceased.

Medicine Details:

PROTHIADEN (Suspected)		Reason: Depression
Capsule	25.0 Milligram	Daily Oral
Batch:	Started: 01/08/1998	Stopped: 28/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drug. - panadeine forte. reaction occurred after 2 1/2 weeks of prothiaden use: 1st week: 1x25mg; 2nd week 2x25mg and 3rd week 3x25mg. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 141148	Seq: 1	Gender: F
Reported: 02/07/1999		Weight: 56.00
Hospitalisation:		Age: 49Y
Onset Date: 31/03/1999		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia			
Nightmare			

Medicine Details:

DOTHEP (Suspected)		Reason: Depression	
Capsule	25.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1999	Stopped:	28/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - microgynon. this appears to be a drug brand problems. the patient was previously on prothiaden (2 years) 25mg-50mg with no adverse effects. patient has returned to prothiaden and has had no further problems. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 141149	Seq: 1	Gender: F
Reported: 02/07/1999		Weight: 75.00
Hospitalisation:		Age: 67Y
Onset Date: 04/06/1999		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare Insomnia		Continued after waking & getting back to	

Medicine Details:

DOTHEP (Suspected)		Reason: Depression
Capsule	25.0 Milligram	Daily Oral
Batch: 9B021	Started: 04/06/1999	Stopped: 10/06/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - zoton, lescol, premarin & panamax. this appears to be a drug brand problem. the patient was previously on prothiaden (6 weeks) with no adverse effect (25mg-50mg) and has since continued with this brand with none of the above mentioned effects. dothep 25 batch no 9b021



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 141867	Seq: 1	Gender: F
Reported: 22/07/1999		Weight:
Hospitalisation:		Age: 37Y
Onset Date: 16/06/1999		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state		Mental confusion	
Thirst			Reduce dosage to 100mg at
Tremor			

Medicine Details:

NICORETTE PATCH (Suspected)		Reason: Smoker
Cream	15.0 Milligram	Daily Transdermal
Batch:	Started: 08/06/1999	Stopped: 16/06/1999
PROTHIADEN (Suspected)		Reason: Depression
Oral application	150.0 Milligram	Daily Oral
Batch:	Started: 01/01/1996	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The symptoms resolved within 4 days of the dosage reduction being initiated. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 144889 **Seq:** 1 **Gender:** M
Reported: 19/10/1999 **Weight:**
Hospitalisation: **Age:** 61Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Persistent rash on abdomen and trunk for 6	Ceased dothiepin. topical steroids and moisturisers.

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Specific disorders of sleep
Oral application	50.0 Milligram Daily Oral
Batch:	Started: Stopped: 23/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Skin biopsy				Skin biopsy confirmed a drug eruption.

Additional Information:

See original report for details of other drugs - bromocriptine, coloxyl with senna, rhinocort.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 147685 **Seq:** 1 **Gender:** F
Reported: 06/01/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Dry mouth Therapeutic response decreased			Changed afternoon dosing of singularair to the morning.

Medicine Details:

SINGULAIR (Suspected)	Reason: Asthma		
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/11/1999	Stopped:	CONTIN
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason:		
	25.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking salbutamol sulfate, fluticasone propionate, nifedipine nedocromil sodium. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 147997 **Seq:** 1 **Gender:** M
Reported: 14/01/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Patient experienced a tingling sensation in	

Medicine Details:

PROTHIADEN (Interaction)	Reason:
Capsule 0.0 Daily Oral	
Batch: Started: Stopped:	
CELEBREX (Interaction)	Reason:
Capsule 0.0 Daily Oral	
Batch: Started: Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was stabilised on prothiaden (taken at night) and commenced on celebrex (taken each morning). the patient complained of a tingling sensation in the skin which commenced after taking the prothiaden dose.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 148426 **Seq:** 1 **Gender:** F
Reported: 31/01/2000 **Weight:** 70.00
Hospitalisation: **Age:** 41Y
Onset Date: 24/12/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

DOTHEP (Suspected)	Reason: Depression
300.0 Milligram	Daily
Batch:	Started: 14/12/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Dothiepin dose previous to 14/12/99 was 75mg nocte. this reaction was noticed within 10 days of a significant dose increase. patient also taking diazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 149776	Seq: 1	Gender: F
Reported: 01/03/2000		Weight: 57.00
Hospitalisation:		Age: 44Y
Onset Date: 11/02/2000		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Antinuclear antibody positive Arthralgia Chills Constipation Flushing Hyperhidrosis Pyrexia Red blood cell abnormality Red blood cell sedimentation rate			

Medicine Details:

PROTHIADEN (Suspected)		Reason:	
Oral application	100.0 Milligram	Daily	Oral
Batch:	Started: 21/12/1999	Stopped:	22/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Antinuclear factor Erythrocyte Other data				Ana = 200 Esr = 38 Mild macrocytosis

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 154362 **Seq:** 1 **Gender:** M
Reported: 04/07/2000 **Weight:** 102.00
Hospitalisation: **Age:** 52
Onset Date: 28/06/2000 **DOB:** 19/11/1947
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia			Required a visit to doctor.

Medicine Details:

INDOCID (Suspected)	Reason: Otr&unsp vertebrogen pain synd
4.0 Dose Unspecified Daily	
Batch:	Started: 05/04/2000 Stopped: 30/06/2000
PROTHIADEN (Suspected)	Reason: Specific disorders of sleep
225.0 Milligram Daily	
Batch:	Started: 10/05/2000 Stopped: 30/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

2nd case seen by the doctor in relation to prothiaden.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 154403 **Seq:** 1 **Gender:** F
Reported: 03/07/2000 **Weight:** 82.00
Hospitalisation: **Age:** 47
Onset Date: **DOB:** 09/12/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Agitation			
Headache			
Muscle spasms			
Pharyngitis			
Visual disturbance			

Medicine Details:

DOTHEP (Suspected)	Reason:
Batch:	25.0 Milligram Daily
Started: 24/06/2000	Stopped: 28/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking ogen, noten, agon. patient has multiple sensitivities



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 157333	Seq: 1	Gender: F
Reported: 04/09/2000		Weight:
Hospitalisation:		Age: 73
Onset Date: 25/08/2000		DOB: 03/01/1927
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anaemia Confusional state Hepatic function abnormal Pyrexia Red blood cell sedimentation rate			Patient admitted to hospital, all therapy ceased.

Medicine Details:

SINEMET (Other drug)	Reason:	
0.0		
Batch:	Started:	Stopped: CONTIN
RIVOTRIL (Other drug)	Reason:	
0.0		
Batch:	Started:	Stopped:
ARICEPT (Suspected)	Reason:	
0.0		
Batch:	Started:	Stopped: 25/08/2000
SELEGILINE HYDROCHLORIDE (Suspected)	Reason:	
0.0		
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	5 - 55	28/08/2000	38	
	ALT = SGPT	5 - 55	30/08/2000	56	
	Albumin	33 - 50	28/08/2000	30	
	Albumin	33 - 50	30/08/2000	34	
	Bilirubin	2 - 20	28/08/2000	11	
	Bilirubin	2 - 20	30/08/2000	9	
	GGT = SGGT =	12 - 43	28/08/2000	378	

Additional Information:

Patient also taking doxepin, levodopa, benzodiazepine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 157333 **Seq:** 1 **Gender:** F
Reported: 04/09/2000 **Weight:**
Hospitalisation: **Age:** 73
Onset Date: 25/08/2000 **DOB:** 03/01/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

CABASER (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
DOXEPIN HYDROCHLORIDE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
LEVODOPA (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
PROTHIADEN (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =	12 - 43	30/08/2000	359	
	SAP = ALP	20 - 110	28/08/2000	285	
	SAP = ALP	20 - 110	30/08/2000	265	

Additional Information:

Patient also taking doxepin, levodopa, benzodiazepine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 157333

Seq: 1

Gender: F

Reported: 04/09/2000

Weight:

Hospitalisation:

Age: 73

Onset Date: 25/08/2000

DOB: 03/01/1927

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

COMTAN (Suspected)	Reason: Paralysis agitans		
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 17/07/2000	Stopped: 25/08/2000	

Laboratory Investigations:

Additional Information:

Patient also taking doxepin, levodopa, benzodiazepine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 157516 **Seq:** 1 **Gender:** M
Reported: 07/09/2000 **Weight:**
Hospitalisation: **Age:** 79
Onset Date: **DOB:** 28/04/1921
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal distension		Abdominal distension could not eat a meal	
Depersonalisation		Felt queer	
Suicide attempt		Felt suicidal.	
Paranoia			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
25.0 Milligram Daily	
Batch:	Started: 26/08/2000 Stopped: 29/08/2000
SEREPAX (Suspected)	Reason:
15.0 Milligram Daily	
Batch:	Started: 01/04/2000 Stopped: 24/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking monoproil, betaloc, astrix, antenex patient recovered 29/8/00.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 158906 **Seq:** 1 **Gender:** M
Reported: 30/10/2000 **Weight:**
Hospitalisation: **Age:** 88
Onset Date: **DOB:** 07/08/1912
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Duodenal ulcer haemorrhage		Bleeding duodenal ulcer.	

Medicine Details:

CELECOXIB (Suspected) Capsule Batch: Started: Stopped:	500.0 Milligram	Daily	Oral
PROTHIADEN (Suspected) Oral application Batch: Started: Stopped:	75.0 Milligram	Daily	Oral
OXAZEPAM (Suspected) Tablet Batch: Started: Stopped:	60.0 Milligram	Daily	Oral
RAMIPRIL (Suspected) Tablet Batch: Started: Stopped:	2.5 Milligram	Daily	Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Past history of peptic ulcer disease in 1985.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 159502 **Seq:** 1 **Gender:** F
Reported: 23/11/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

DOTHEP (Suspected)	Reason:
Batch:	Started: 0.0 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient on prothiaden 75mg 2 nocte for many years. given dothep brand and got depressed over the 2 months she was on it.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 159513 **Seq:** 1 **Gender:** M
Reported: 24/11/2000 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dry mouth Pharyngitis Tongue oedema Visual disturbance			

Medicine Details:

OMEPRAZOLE (Interaction)	Reason: Otr&nos infec¶sit diseases
20.0 Milligram Daily	
Batch:	Started: 13/11/2000 Stopped: 14/11/2000
PROTHIADEN (Interaction)	Reason: Anxiety neurosis
25.0 Milligram Daily	
Batch:	Started: L TERM Stopped: 15/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Regime used 31/10 also with similar reactions. no problem with years of use of prothiaden with no problem of cholinergic effects.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 159647 **Seq:** 1 **Gender:** F
Reported: 30/11/2000 **Weight:** 64.00
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 22/08/1967
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Electric shocks lasted six months.	
Muscle twitching		Muscle twitching	Required a visit to doctor.
Drug withdrawal syndrome			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
300.0 Milligram	Daily
Batch:	Started: 01/01/1998 Stopped: 28/04/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Transfer from prothiaden to paroxetine after a two week withdrawal period of the prothiaden, patient experienced symptoms. alternative sri's zoloft and also efexor increased the muscle twitching. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 160041 **Seq:** 1 **Gender:** M
Reported: 13/12/2000 **Weight:** 70.00
Hospitalisation: **Age:** 40
Onset Date: 01/12/2000 **DOB:** 28/09/1960
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression			Required a visit to doctor. date of recovery 04/12/00. rulide

Medicine Details:

RULIDE (Interaction)	Reason: Otr loc skin&subcut tis infect
300.0 Milligram	Daily
Batch:	Started: 30/11/2000 Stopped: 02/12/2000
PROTHIADEN (Interaction)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 06/11/2000 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 162618 **Seq:** 1 **Gender:** F
Reported: 13/03/2001 **Weight:** 98.00
Hospitalisation: **Age:** 51
Onset Date: **DOB:** 21/03/1949
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Ceased prothiaden (dothiepin).

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
Oral application	150.0 Milligram Daily Oral
Batch:	Started: Stopped: 12/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		08/02/2001	98	
	ALT = SGPT		12/02/2001	558	
	ALT = SGPT		13/02/2001	552	
	AST = SGOT		08/02/2001	164	
	AST = SGOT		12/02/2001	288	
	AST = SGOT		13/02/2001	281	
	GGT = SGGT =		08/02/2001	356	

Additional Information:

Patient also taking - nitrazepam and warfarin. no known lft's before the 02/2001.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 162618

Seq: 1

Gender: F

Reported: 13/03/2001

Weight: 98.00

Hospitalisation:

Age: 51

Onset Date:

DOB: 21/03/1949

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)		Reason:	Depression	
Oral application	150.0 Milligram	Daily	Oral	
Batch:	Started:	Stopped:	12/02/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =		12/02/2001	1420	
	GGT = SGGT =		13/02/2001	1511	
	SAP = ALP		08/02/2001	160	
	SAP = ALP		12/02/2001	345	
	SAP = ALP		13/02/2001	371	

Additional Information:

Patient also taking - nitrazepam and warfarin. no known lft's before the 02/2001.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 164200 **Seq:** 1 **Gender:** F
Reported: 03/05/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 33Y
Onset Date: 14/04/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations		Heart rate of > 200.	Pt hospitalised
Hypoxia		Oxygen level in blood decreased.	

Medicine Details:

NORIMIN (Other drug)	Reason: Contraception	
0.0		
Batch:	Started:	Stopped:
PROTHIADEN (Suspected)	Reason:	
225.0 Milligram	Daily	
Batch:	Started: 15/01/2001	Stopped: 15/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

P/h of palpitations.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 164234	Seq: 1	Gender: F
Reported: 03/05/2001		Weight:
Hospitalisation:		Age: 58Y
Onset Date: 27/01/2001		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Conjunctivitis Xerophthalmia			Prothiaden ceased. lubricant eye drops/gel/ointment. 26.3.01 insertion of ductal plugs in both tear ducts

Medicine Details:

CELLUFRESH (Other drug)	0.0	Reason: Otr&unsp difuse connec tis dis
Batch:	Started:	Stopped: CONTIN
VISCOTEARS (Other drug)	0.0	Reason:
Batch:	Started:	Stopped: CONTIN
LACRI-LUBE (Other drug)	0.0	Reason:
Batch:	Started:	Stopped:
SANDRENA (Other drug)	3.0 Dose Unspecified Weekly	Reason:
Batch:	Started:	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of sjogrens syndrome and ra since 1993 and anlclosing spondylitis since 1995.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 164234 **Seq:** 1 **Gender:** F
Reported: 03/05/2001 **Weight:**
Hospitalisation: **Age:** 58Y
Onset Date: 27/01/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

PANADEINE FORTE (Other drug)	Reason: Other rheumatoid arthritis	
1.0 Dose Unspecified As necessary		
Batch:	Started:	Stopped: CONTIN
CELEBREX (Other drug)	Reason: Other rheumatoid arthritis	
400.0 Milligram Daily		
Batch:	Started:	Stopped: CONTIN
PROTHIADEN (Suspected)	Reason: Depression	
150.0 Milligram Daily		
Batch:	Started: 25/01/2001	Stopped: 18/04/2001

Laboratory Investigations:

Additional Information:

History of sjogrens syndrome and ra since 1993 and anlclosing spondylitis since 1995.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 165006	Seq: 1	Gender: F
Reported: 31/05/2001		Weight: 60.00
Hospitalisation:		Age:
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety			Diazepam 5mg short-term

Medicine Details:

MENOREST (Suspected)	Reason: Menopausal symptoms
50.0 Milligram Fortnightly	
Batch:	Started:
Stopped:	
ZYBAN SR (Suspected)	Reason: Smoker
150.0 Milligram Daily	
Batch:	Started:
Stopped:	
DOTHEP (Suspected)	Reason: Depression
75.0 Milligram Daily	
Batch:	Started:
Stopped:	
DOTHEP (Suspected)	Reason:
50.0 Milligram Daily	
Batch:	Started:
Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 165006 **Seq:** 1

Gender: F

Reported: 31/05/2001

Weight: 60.00

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

INDERAL (Suspected)	Reason: Migraine
30.0 Milligram	Daily
Batch:	Started: Stopped:
RANI 2 (Suspected)	Reason:
600.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 165076 **Seq:** 1 **Gender:** F
Reported: 01/06/2001 **Weight:** 84.00
Hospitalisation: **Age:** 46Y
Onset Date: 15/05/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Generalised bruising both legs, thighs.	Ceased celeberx, prothiaden, natures own l-lysine. treated with telfast and elocon cream.
Urticaria		Generalised welts both legs, thigh.	
Flushing		Hot and flushed generally.	
Pyrexia			

Medicine Details:

CELEBREX (Suspected)	Reason:
Capsule 200.0 Milligram Daily Oral	
Batch: Started: 09/01/2000 Stopped: 15/05/2001	
PROTHIADEN (Suspected)	Reason:
Tablet 75.0 Milligram Daily Oral	
Batch: Started: 18/11/2000 Stopped: 15/05/2001	
NATURE'S OWN L-LYSINE (Suspected)	Reason:
Oral application 1.0 Gram Daily Oral	
Batch: Started: 11/05/2001 Stopped: 15/05/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 165425 **Seq:** 1 **Gender:** F
Reported: 12/06/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 61
Onset Date: 25/05/2001 **DOB:** 12/05/1940
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug level increased			
Orthostatic hypotension			Patient hospitalised

Medicine Details:

ZYBAN SR (Interaction)	Reason: Smoker
1.0 Dose Unspecified Daily	
Batch:	Started: 01/04/2000 Stopped: CONTIN
NALTREXONE HYDROCHLORIDE (Interaction)	Reason: Alcoholism
1.0 Dose Unspecified Daily	
Batch:	Started: 18/05/2001 Stopped: CONTIN
DOTHIEPIN HYDROCHLORIDE (Interaction)	Reason: Depression
2.0 Dose Unspecified Daily	
Batch:	Started: 01/05/2001 Stopped: 25/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level		25/05/2001	1848	Dothiepin level was very high.
	Serum drug level		26/05/2001	1422	Dothiepin level was very high.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 165932 **Seq:** 1 **Gender:** F
Reported: 28/06/2001 **Weight:** 60.00
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain		Painful breast nipples.	

Medicine Details:

PROTHIADEN (Suspected)	Reason:
Batch:	75.0 Milligram Daily
Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Note side affect developed and worsening with increased dosage.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 166049 **Seq:** 1 **Gender:** F
Reported: 02/07/2001 **Weight:**
Hospitalisation: **Age:** 70
Onset Date: **DOB:** 02/01/1931
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination		Hallucinations of scutling spiders	Prothiaden dose decreased.

Medicine Details:

PROTHIADEN (Suspected)	Reason:
Batch:	150.0 Milligram Daily
Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient on prothiaden from december 2000. no reaction when on this dose 12 months ago. dose reduced to 100mg daily and hallucinations virtually disappeared.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 166105 **Seq:** 1 **Gender:** M
Reported: 02/07/2001 **Weight:**
Hospitalisation: **Age:** A4
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Conjunctivitis		Red eyes.	Prothiaden withdrawal.
Testicular disorder		Testicular shrinkage.	
Photophobia			
Visual disturbance			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
25.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Relevant medical history - lazer surgery.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 168228 **Seq:** 1 **Gender:** M
Reported: 06/09/2001 **Weight:** 65.00
Hospitalisation: Admitted to hospital **Age:** 46
Onset Date: 19/07/2001 **DOB:** 17/01/1955
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain		Colic spasm	Patient admitted to hospital. surgical review - cystourethoscopy. given buscopan and colofac
Dysuria		Difficulty passing urine	
Abdominal pain			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
0.0	
Batch:	Started: Stopped: 19/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 169568	Seq: 1	Gender: M
Reported: 27/09/2001		Weight:
Hospitalisation:		Age: 34Y
Onset Date: 26/06/2001		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Delirium			
Hyperhidrosis			

Medicine Details:

PROTHIADEN (Suspected)	Reason:
0.0	
Batch:	Started:
	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 21/06/2001
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Self-medicating with other unknown medications. the patient's dose had gradually been increased by 25mg daily, reaching 100mg daily on 26.6.01. for the 2 nights that the patient was on 100mg, he experienced the reactions one hour after the dose. this settled down promptly when the dose was stopped for one day, then reduced to 50mg daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 170412	Seq: 1	Gender: F
Reported: 29/11/2001		Weight:
Hospitalisation:		Age: 91Y
Onset Date: 08/01/2001		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills			
Cognitive disorder			
Tremor			Zoloft ceased. given

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
0.0	
Batch:	Started: 01/12/2000 Stopped: 04/01/2001
DOTHEP (Suspected)	Reason: Depression
Tablet	25.0 Milligram As necessary Oral
Batch:	Started: 04/01/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 170413	Seq: 1	Gender: F
Reported: 29/11/2001		Weight:
Hospitalisation:		Age: 91Y
Onset Date: 07/01/2001		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal Tachycardia			Zoloft ceased. given aspirin

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
0.0	
Batch:	Started: 01/12/2000 Stopped: 04/01/2001
DOTHEP (Suspected)	Reason: Depression
Tablet	25.0 Milligram As necessary Oral
Batch:	Started: 04/01/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 171051 **Seq:** 1 **Gender:** F
Reported: 17/12/2001 **Weight:**
Hospitalisation: **Age:** 63
Onset Date: 28/10/2001 **DOB:** 06/09/1938
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Parkinsonian effects.	Required a visit to doctor.

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
150.0 Milligram	Daily
Batch:	Started: 16/10/2000 Stopped:
PRITOR (Suspected)	Reason:
80.0 Milligram	Daily
Batch:	Started: 17/10/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 172608	Seq: 1	Gender: F
Reported: 11/02/2002		Weight: 39.00
Hospitalisation: Admitted to hospital		Age: 47Y
Onset Date: 12/01/2002		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		3 x seizures.	Patient was hospitalised. given anticonvulsants.

Medicine Details:

PROTHIADEN (Interaction)	Reason:
150.0 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN
TRAMADOL HYDROCHLORIDE (Interaction)	Reason:
200.0 Milligram Daily	
Batch:	Started: 10/01/2002 Stopped: 12/01/2002
PANADEINE FORTE (Other drug)	Reason: Otr&unsp vertebrogen pain synd
2.0 Dose Unspecified Daily	
Batch:	Started: L TERM Stopped: CONTIN
HYPNODORM (Other drug)	Reason: Specific disorders of sleep
0.5 Dose Unspecified Daily	
Batch:	Started: S TERM Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 172608	Seq: 1	Gender: F
Reported: 11/02/2002		Weight: 39.00
Hospitalisation: Admitted to hospital		Age: 47Y
Onset Date: 12/01/2002		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Medicine Details:

MURELAX (Other drug)	Reason:
	1.0 Dose Unspecified Daily
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 172743	Seq: 1	Gender: M
Reported: 13/02/2002		Weight:
Hospitalisation:		Age: 31Y
Onset Date: 11/12/2001		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperreflexia Hypertension Hypertonia Hypokalaemia Hypoxia Leukocytosis Mydriasis Neuroleptic malignant syndrome Serotonin syndrome Tachycardia			Therapy ceased. supportive treatment given, rehydration, cataril, kel

Medicine Details:

CIPRAMIL (Suspected)	Reason: Depression
20.0 Milligram Daily	
Batch:	Started: Stopped: 5D
PROTHIADEN (Suspected)	Reason: Depression
150.0 Milligram Daily	
Batch:	Started: Stopped: 7D
PROZAC (Suspected)	Reason: Depression
60.0 Milligram Daily	
Batch:	Started: Stopped: 7D
PERICYAZINE (Suspected)	Reason:
20.0 Milligram Daily	
Batch:	Started: Stopped: 1M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Sao2 90% on air.
	Creatine	0 - 270 U/L	11/12/2001	689	
	Creatine	0 - 270 U/L	13/12/2001	1670	
	Creatine	0 - 270 U/L	12/12/2001	1407	
	Potassium		11/12/2001	2.7	
	White blood cells	4-11	11/12/2001	17.1	
	White blood cells	4-11	13/12/2001	11.9	

Additional Information:

Other reaction terms: creatinine phosphokinase increased, sweating increased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 173774 **Seq:** 1 **Gender:** F
Reported: 20/03/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 23
Onset Date: 12/03/2002 **DOB:** 28/04/1978
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Patient was hospitalised.

Medicine Details:

TRAMADOL HYDROCHLORIDE (Suspected) 100.0 Milligram Daily Batch: Started: 02/03/2002 Stopped: 13/03/2002 Reason: Otr&unsp vertebrogen pain synd
PAROXETINE HYDROCHLORIDE (Suspected) 10.0 Milligram Daily Batch: Started: 02/03/2002 Stopped: 13/03/2002 Reason: Depression
DOTHIEPIN HYDROCHLORIDE (Suspected) 22.0 Milligram Daily Batch: Started: Stopped: CONTIN Reason: Depression

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 13/3/02.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 174718	Seq: 1	Gender: M
Reported: 22/04/2002		Weight: 50.00
Hospitalisation:		Age: 56
Onset Date: 28/03/2002		DOB: 21/02/1946
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching Tremor		Muscle twitches and spasms	Dental treatment. required a visit to doctor.

Medicine Details:

LIPITOR (Other drug)	Reason: Othr&unspec metabolic diseases
40.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
ADALAT OROS (Other drug)	Reason: Essential benign hypertension
30.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
CARTIA (Other drug)	Reason: Chron isch heart dis no hyper
100.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
ZYBAN SR (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Shaky sweats and muscle twitches and spasms - sufficient to break a motar. the dose start date for dothep is not necessarily accurate but indicates the d rug was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 174718 **Seq:** 1

Gender: M

Reported: 22/04/2002

Weight: 50.00

Hospitalisation:

Age: 56

Onset Date: 28/03/2002

DOB: 21/02/1946

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

DOTHEP (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 01/02/1999 Stopped:

Laboratory Investigations:

Additional Information:

Shaky sweats and muscle twitches and spasms - sufficient to break a motor. the dose start date for dothep is not necessarily accurate but indicates the drug was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 175345 **Seq:** 1 **Gender:** F
Reported: 09/05/2002 **Weight:** 67.00
Hospitalisation: **Age:** 49
Onset Date: 12/04/2002 **DOB:** 04/04/1953
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Severe paraesthesia of both hands.	Prothiaden dose reduced to

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 27/02/2002 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 175359	Seq: 1	Gender: F
Reported: 10/05/2002		Weight:
Hospitalisation:		Age: 69Y
Onset Date: 27/03/2002		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema		Bilateral ankle oedema.	

Medicine Details:

PLAVIX (Other drug)	Reason:
1.0 Dose Unspecified Daily	
Batch:	Started: L TERM Stopped: CONTIN
PREMARIN (Other drug)	Reason:
0.6 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN
PROVERA (Other drug)	Reason:
5.0 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN
CARDIZEM (Other drug)	Reason:
90.0 Milligram Daily	
Batch:	Started: L TERM Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking seretide.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 175359 **Seq:** 1 **Gender:** F
Reported: 10/05/2002 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 27/03/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

VENTOLIN (Other drug)	Reason: Asthma
Inhalation 2.0 Dose Unspecified Daily Inhalation	
Batch:	Started: L TERM Stopped: CONTIN
ATROVENT (Other drug)	Reason: Asthma
Inhalation 2.0 Dose Unspecified Daily Inhalation	
Batch:	Started: L TERM Stopped: CONTIN
FOSAMAX (Suspected)	Reason:
70.0 Milligram Weekly	
Batch:	Started: 17/03/2002 Stopped: CONTIN
DOTHEP (Suspected)	Reason: Anxiety neurosis
50.0 Milligram Daily	
Batch:	Started: 01/12/2001 Stopped: CONTIN

Laboratory Investigations:

Additional Information:

Patient also taking seretide.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 175359 **Seq:** 1

Gender: F

Reported: 10/05/2002

Weight:

Hospitalisation:

Age: 69Y

Onset Date: 27/03/2002

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ALEPAM (Suspected)	Reason: Anxiety neurosis
45.0 Milligram	Daily
Batch:	Started: 01/12/2001
	Stopped: CONTIN

Laboratory Investigations:

Additional Information:

Patient also taking seretide.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 179300	Seq: 1	Gender: M
Reported: 20/09/2002		Weight:
Hospitalisation:		Age: 32
Onset Date: 30/08/2002		DOB: 17/04/1970
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			Patient was treated with dilantin 300mg daily. date of recovery: 30/8/02.

Medicine Details:

PROPOFOL (Interaction)	Reason: Depression	
0.0		
Batch:	Started:	Stopped:
TRAMADOL HYDROCHLORIDE (Interaction)	Reason: Pain	
Tablet	50.0 Milligram	As necessary Oral
Batch:	Started: 28/08/2002	Stopped: 30/08/2002
PROTHIADEN (Interaction)	Reason: Depression	
	300.0 Milligram	Daily
Batch:	Started:	Stopped:
DI-GESIC (Other drug)	Reason: Pain	
Tablet	0.0	Oral
Batch:	Started: 28/08/2002	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Chronic pain endone dependence (3-4/day for 3/12) ceased abruptly 1/52 ago from 30/8/02 no patient history of epilepsy/seizures.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 179300

Seq: 1

Gender: M

Reported: 20/09/2002

Weight:

Hospitalisation:

Age: 32

Onset Date: 30/08/2002

DOB: 17/04/1970

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PETHIDINE HYDROCHLORIDE (Other drug)	Reason: Pain
Injection 75.0 Milligram	As necessary Intravenous
Batch:	Started: 28/08/2002 Stopped:
STEMETIL FOR INJECTION (Other drug)	Reason: Nausea and vomiting
Injection 12.5 Milligram	As necessary Intramuscular
Batch:	Started: 30/08/2002 Stopped:
TEMAZEPAM (Other drug)	Reason: Depression
10.0 Milligram	As necessary
Batch:	Started: 29/08/2002 Stopped:

Laboratory Investigations:

Additional Information:

Chronic pain endone dependence (3-4/day for 3/12) ceased abruptly 1/52 ago from 30/8/02 no patient history of epilepsy/seizures.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 179894 **Seq:** 1 **Gender:** F
Reported: 21/10/2002 **Weight:** 80.00
Hospitalisation: **Age:** 40
Onset Date: 10/10/2002 **DOB:** 10/08/1962
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression			Required a visit to doctor. recovered 17/10/02.

Medicine Details:

DOTHEP (Suspected)	Reason: Migraine
Tablet	1.0 Dose Unspecified Daily Oral
Batch:	Started: 07/10/2002 Stopped: 15/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergies to penicillin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 179915	Seq: 1	Gender: F
Reported: 17/10/2002		Weight:
Hospitalisation:		Age: 55Y
Onset Date: 17/09/2002		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia Hepatic function abnormal Hyperglycaemia Nausea Vomiting			Date of recovery 23.9.02. required a visit to doctor. prothiaden ceased

Medicine Details:

BUSCOPAN (Other drug)	Reason:	As necessary
Injection	0.0	Intramuscular
Batch:	Started:	Stopped:
DUCENE (Other drug)	Reason:	Anxiety neurosis
	5.0 Milligram	As necessary
Batch:	Started:	Stopped:
BETALOC (Other drug)	Reason:	Essential benign hypertension
	50.0 Milligram	Daily
Batch:	Started:	Stopped:
PROTHIADEN (Suspected)	Reason:	Irritable colon
Tablet	100.0 Milligram	Weekly Oral
Batch:	Started: 11/09/2002	Stopped: 23/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Bsl increased to 8.7.

Additional Information:

Bsl and If now normal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 181833	Seq: 1	Gender: F
Reported: 21/01/2003		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 54Y
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal failure acute	Life	Acute renal failure and acute hepatic Initially presented with lethargy, muscle aches, weakness, confusion and jaundice.	
Lethargy	Life		
Asthenia	Life		
Confusional state	Life		
Hepatic failure	Life		
Jaundice	Life		
Myalgia	Life		

Medicine Details:

RANITIDINE (Other drug)	Reason:
Batch:	Started:
	Stopped: CONTIN
SEREPAX (Suspected)	Reason: Anxiety neurosis
Tablet	As necessary Oral
Batch:	Started:
	Stopped: 07/07/2001
MONOFEME 28 (Suspected)	Reason: Contraception
Tablet	1.0 Dose Unspecified Daily Oral
Batch:	Started:
	Stopped: 07/04/2001
PANADEINE FORTE (Suspected)	Reason: Pain
Tablet	Daily Oral
Batch:	Started:
	Stopped: 07/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/01/2003	ALT = SGPT		07/04/2001	5800	
21/01/2003	AST = SGOT				
21/01/2003	Albumin				
21/01/2003	Creatine				
21/01/2003	GGT = SGGT =		07/04/2001	296	
21/01/2003	International				
21/01/2003	Renal biopsy =				

Additional Information:

Exact amount of Paracetamol/day not known - probably at least 4gm.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 181833 **Seq:** 1 **Gender:** F
Reported: 21/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 54Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

KETOPROFEN (Suspected)	Reason: Pain
1.0 Dose Unspecified Daily	Oral
Batch:	Started: L TERM Stopped: 07/04/2001
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Anxiety neurosis
150.0 Milligram Daily	Oral
Batch:	Started: Stopped: 07/04/2001
METOCLOPRAMIDE HYDROCHLORIDE (Suspected)	Reason: Nausea and vomiting
Tablet 30.0 Milligram Daily	Oral
Batch:	Started: Stopped: 07/07/2001
TEMAZEPAM (Suspected)	Reason: Specific disorders of sleep
Daily	Oral
Batch:	Started: Stopped: 07/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/01/2003	Urea				

Additional Information:

Exact amount of Paracetamol/day not known - probably at least 4gm.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 181859	Seq: 1	Gender: F
Reported: 21/01/2003		Weight: 0.00
Hospitalisation:		Age: 99U
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective		Therapeutic inefficacy.	

Medicine Details:

HALOPERIDOL (Other drug)	Reason: Depression
Tablet	3.0 Milligram Daily Oral
Batch:	Started: Stopped:
PROTHIADEN (Suspected)	Reason:
Batch:	Started: Stopped:
PROTHIADEN (Suspected)	Reason: Depression
Tablet	Daily Oral
Batch:	Started: 02/02/2000 Stopped: 19/02/2000
PROTHIADEN (Suspected)	Reason: Depression
Tablet	150.0 Milligram Daily Oral
Batch:	Started: 19/02/2000 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 181859

Seq: 1

Gender: F

Reported: 21/01/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression		
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 21/03/2000	Stopped:	
PROTHIADEN (Suspected)	Reason: Depression		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 07/04/2000	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 181874	Seq: 1	Gender: F
Reported: 21/01/2003		Weight: 0.00
Hospitalisation:		Age: 99U
Onset Date: 15/10/1999		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Fatigue Tachycardia		Therapeutic inefficacy, tachycardia, fatigue	

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Other drug)		Reason:	
Tablet	175.0 Milligram	Daily	Oral
Batch:	Started: 15/10/1999	Stopped:	18/10/1999
DOTHIEPIN HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 24/09/1999	Stopped:	15/10/1999
DOTHIEPIN HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	175.0 Milligram	Daily	Oral
Batch:	Started: 15/10/1999	Stopped:	18/10/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 183278	Seq: 1	Gender: U
Reported: 18/12/2002		Weight: 0.00
Hospitalisation:		Age: 68Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis Myopathy		Rhabdomyolysis, necrotizing myopathy	ceased Simvastatin

Medicine Details:

VERAPAMIL HYDROCHLORIDE (Suspected)	Reason:
Batch:	Started: Stopped:
AMIODARONE HYDROCHLORIDE (Suspected)	Reason:
Batch:	Started: Stopped:
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason:
Batch:	Started: Stopped:
SIMVASTATIN (Suspected)	Reason:
Tablet	40.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/12/2002	Creatine				
18/12/2002	Histology				

Additional Information:

Literature reference: Mckelvie, P.A. Dennett, X, Myopathy associated with HMG-COA reductase inhibitors (statins): A series of 10 patients and review of the literature. j Clin neuromusc disease 3 (4): 143-148 (2002) 2002; 3 (4): 143-148, PharmLine No.: 200208963.
Time from ceasing drug to biopsy 2 days.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 184052	Seq: 1	Gender: F
Reported: 18/03/2003		Weight: 65.00
Hospitalisation: Admitted to hospital		Age: 67
Onset Date: 01/02/2003		DOB: 20/05/1935
Outcome: Recovered without treatment		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Jaundice	Caused or prolonged inpatient hospitalisation	Progressive painless jaundice, increasing yellow skin over 2-3 weeks, dark urine, decreased appetite, weight loss.	Ceased Macrochantin, Dothep, Celebrex, Premarin, Fosamax.
Chromaturia	Caused or prolonged inpatient hospitalisation		
Decreased appetite	Caused or prolonged inpatient hospitalisation		

Medicine Details:

THYROXINE SODIUM (Other drug)		Reason:	
Tablet	100.0 Microgram	Daily	Oral
Batch:	Started:	Stopped:	contin
FOSAMAX (Suspected)		Reason:	
Tablet	70.0 Milligram	Weekly	Oral
Batch:	Started:	Stopped:	20/02/2003
MACRODANTIN (Suspected)		Reason: Othr diseases of urinary tract	
Capsule	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	20/02/2003
DOTHEP (Suspected)		Reason: Depression	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	20/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/03/2003	ALT = SGPT		26/02/2003	431	
18/03/2003	AST = SGOT		26/02/2003	586	
18/03/2003	Bilirubin		26/02/2003	310	
18/03/2003	Biochemistry				
18/03/2003	GGT = SGGT =		26/02/2003	494	
18/03/2003	LDH		26/02/2003	287	
18/03/2003	SAP = ALP		26/02/2003	352	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 184052	Seq: 1	Gender: F
Reported: 18/03/2003		Weight: 65.00
Hospitalisation: Admitted to hospital		Age: 67
Onset Date: 01/02/2003		DOB: 20/05/1935
Outcome: Recovered without treatment		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic	Caused or prolonged inpatient hospitalisation		
Weight decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CELEBREX (Suspected)		Reason: Osteoporosis
Tablet	200.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 20/02/2003
PREMARIN (Suspected)		Reason: Menopausal symptoms
Tablet	625.0 Microgram	Daily Oral
Batch:	Started:	Stopped: 20/02/2003

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 185457 **Seq:** 1 **Gender:** F
Reported: 01/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 47
Onset Date: 24/01/2003 **DOB:** 30/12/1955
Outcome: Recovered 07/04/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dry mouth	Required Visit to Doctor	Urinary retention and dry mouth.	
Urinary retention	Required Visit to Doctor	Urinary retention and dry mouth.	

Medicine Details:

NEXIUM (Suspected)		Reason: Other diseases of esophagus
Tablet	40.0 Milligram	Daily Oral
Batch:	Started: 24/01/2003	Stopped: 07/04/2003
PROTHIADEN (Suspected)		Reason: Depression
Tablet	150.0 Milligram	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Inderal, Stemetil, Monocest, Ergodryl.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 186520	Seq: 1	Gender: F
Reported: 02/06/2003		Weight: 0.00
Hospitalisation:		Age: 21Y
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vision blurred		Worsened blurred vision and difficulty with near and far sight.	
Accommodation disorder			
Visual disturbance			

Medicine Details:

PROTHIADEN (Suspected)	Reason:
Batch:	Started: Stopped:
	Oral
PHENERGAN (Suspected)	Reason:
Batch:	Started: Stopped:
SEROQUEL (Suspected)	Reason:
Tablet	100.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had changed from Amisulpride to Seroquel due to hyperprolactinaemia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 186955	Seq: 1	Gender: F
Reported: 17/06/2003		Weight: 67.50
Hospitalisation:		Age: 36
Onset Date: 24/01/2000		DOB: 15/06/1963
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Communication disorder		Baby born with language disorder and	
Mental impairment		Baby born with language disorder and	

Medicine Details:

PROTHIADEN (Suspected)		Reason: Depression	
Oral application	150.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

During pregnancy patient took Prothiaden 150mg. While unlikely to be restarted given older drug being used in pregnancy. Worth notifying as possible. Dose start and stop date: 1998-2000.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 188041	Seq: 1	Gender: M
Reported: 03/07/2003		Weight: 0.00
Hospitalisation:		Age: 99u
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Speech disorder		Inability to articulate	It was recommended to stop amisulpride and valproate.
Gait disturbance		Inability to walk unaided.	
Jaundice		Jaundice, sweating increased, muscle	
Muscle spasms	Severe	Severe muscle spasm	
Aphasia	Severe		
Hyperhidrosis			

Medicine Details:

EPILIM (Suspected)	Reason:
Batch:	Started:
Batch:	Stopped:
SOLIAN (Suspected)	Reason:
Tablet	1000.0 Milligram Daily Oral
Batch:	Started:
Batch:	Stopped:
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason:
	150.0 Milligram Daily
Batch:	Started:
Batch:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of Hepatitis B



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 189091	Seq: 1	Gender: F
Reported: 30/07/2003		Weight: 70.00
Hospitalisation:		Age: 54
Onset Date: 10/07/2003		DOB: 20/05/1949
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vision blurred	Required Visit to Doctor	Blurred vision, dry mouth.	
Dry mouth	Required Visit to Doctor		

Medicine Details:

SEROQUEL (Interaction)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 26/05/2003	Stopped:	
PROTHIADEN (Interaction)		Reason:	
Capsule	25.0 Milligram	Daily	Oral
Batch:	Started: 27/02/2003	Stopped:	
PROTHIADEN (Interaction)		Reason:	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 10/07/2003	Stopped:	
RISPERDAL (Interaction)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 02/09/2002	Stopped: 03/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 189091 **Seq:** 1

Gender: F

Reported: 30/07/2003

Weight: 70.00

Hospitalisation:

Age: 54

Onset Date: 10/07/2003

DOB: 20/05/1949

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ZYPREXA (Interaction)	Reason:
Tablet	12.5 Milligram Daily Oral
Batch:	Started: 02/09/2002 Stopped: 03/06/2003

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 189993 **Seq:** 1 **Gender:** F
Reported: 01/09/2003 **Weight:** 57.60
Hospitalisation: **Age:** 60Y
Onset Date: 09/07/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Night sweats	Required Visit to Doctor	Some night sweats.	Tramadol ceased. Diltiazem started for tachycardia.
Hypotension	Required Visit to Doctor		
Tachycardia	Required Visit to Doctor		

Medicine Details:

TRAMAL (Interaction)		Reason: Pain
Capsule	50.0 Milligram	As necessary Oral
Batch:	Started: 05/07/2003	Stopped: 09/07/2003
DOTHEP (Interaction)		Reason:
Tablet	75.0 Milligram	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other medications taken: Mixtard 30/70, Daonil, Diaformin, Zocor, Tritace, Seretide, Ventolin, Aspirin. Previous allergy - sulphurs - tongue swelling.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIPIIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 190280	Seq: 1	Gender: F
Reported: 08/09/2003		Weight: 80.00
Hospitalisation: Admitted to hospital		Age: 99U
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Menstruation irregular	Caused or prolonged inpatient hospitalisation	Gradual moodiness, decreased concentration, decreased mental alertness, suicidal, menstrual irregularities - X2 seizures (2.5 hrs apart).	Tramal ceased, now on panadeine forte.
Convulsion	Caused or prolonged inpatient hospitalisation		
Disturbance in attention	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DOTHEP (Interaction)		Reason: Depression
Tablet	150.0 Milligram	Daily Oral
Batch:	Started: 26/10/2002	Stopped:
TRAMAL (Interaction)		Reason: Pain
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 17/09/2002	Stopped: 30/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Losec, Inderal. 2nd seizure precipitated by Tramal injection given in causality.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 190280 **Seq:** 1 **Gender:** F
Reported: 08/09/2003 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mood altered	Caused or prolonged inpatient hospitalisation		
Suicidal ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DOTHEP (Interaction)	Reason: Depression
Tablet 150.0 Milligram Daily Oral	
Batch:	Started: 26/10/2002 Stopped:
TRAMAL (Interaction)	Reason: Pain
Tablet 200.0 Milligram Daily Oral	
Batch:	Started: 17/09/2002 Stopped: 30/08/2003

Laboratory Investigations:

Additional Information:

Patient also taking Losec, Inderal. 2nd seizure precipitated by Tramal injection given in causality.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 191404	Seq: 1	Gender: F
Reported: 20/10/2003		Weight: 0.00
Hospitalisation:		Age: 58
Onset Date:		DOB: 15/10/1945
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis		Acute hepatitis	

Medicine Details:

Desflurane (Suspected)	Reason:
Batch:	Started: Stopped:
TRAMADOL HYDROCHLORIDE (Suspected)	Reason:
Batch:	Started: Stopped:
TAMOXIFEN CITRATE (Suspected)	Reason:
Batch:	Started: Stopped:
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/10/2003	Other data				
20/10/2003	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 191404

Seq: 1

Gender: F

Reported: 20/10/2003

Weight: 0.00

Hospitalisation:

Age: 58

Onset Date:

DOB: 15/10/1945

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

RABEPRAZOLE SODIUM (Suspected)	Reason:	
Batch:	Started:	Stopped:
IRBESARTAN-HYDROCHLOROTHIAZIDE (Suspected)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 192767	Seq: 1	Gender: F
Reported: 02/12/2003		Weight: 65.00
Hospitalisation:		Age: 37
Onset Date:		DOB: 16/12/1965
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arrhythmia	Caused or prolonged inpatient hospitalisation	Cardiac arrhythmia	

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
150.0 Milligram	
Batch:	Started:
	Stopped:
TEMAZEPAM (Suspected)	Reason: Specific disorders of sleep
10.0 Milligram	
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs used: Valtrex.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 193448 **Seq:** 1 **Gender:** F
Reported: 22/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 59Y
Onset Date: 28/09/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia		Urinary burning sensation, insomnia.	

Medicine Details:

CRANBERRY (Interaction)	Reason:
Tablet	1.0 Dose Unspecified Daily Oral
Batch:	Started: 01/09/2003 Stopped: 14/09/2003
DOTHIEPIN HYDROCHLORIDE (Interaction)	Reason: Depression
	75.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient stabilised on Dothiepin for years.
Cranberry tablets were ceased after call to AME line. Within a week of herb cessation, sleeping pattern returned to normal and insomnia disappeared.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 194792 **Seq:** 1 **Gender:** M
Reported: 20/02/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation	Syncope, loss of consciousness, non-accidental overdose, suicide attempt, lethargy, asthenia.	
Asthenia	Caused or prolonged inpatient hospitalisation		
Intentional overdose	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
300.0 Milligram	Daily
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Prazosin, Enalapril, Furosemide, Aspirin, Amlodipine, Simvastatin, Salbutamol, Ipratropium forte, Beclomethasone, Glyceryl trinitrate, Fluoxetine HCL, Paracetamol.

Patient had been hospitalised twice following intentional Paracetamol overdose from which he fully recovered.

It is unclear whether the patient was on Prothiaden at the time of the Paracetamol overdose.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 194792 **Seq:** 1 **Gender:** M
Reported: 20/02/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Lethargy	Caused or prolonged inpatient hospitalisation		
Loss of consciousness	Caused or prolonged inpatient hospitalisation		
Suicide attempt	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROTHIADEN (Suspected)	Reason: Depression
300.0 Milligram	Daily
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Additional Information:

Patient also administered: Prazosin, Enalapril, Furosemide, Aspirin, Amlodipine, Simvastatin, Salbutamol, Ipratropium forte, Beclomethasone, Glyceryl trinitrate, Fluoxetine HCL, Paracetamol.

Patient had been hospitalised twice following intentional Paracetamol overdose from which he fully recovered.

It is unclear whether the patient was on Prothiaden at the time of the Paracetamol overdose.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 198429 **Seq:** 1 **Gender:** U
Reported: 24/06/2004 **Weight:** 65.00
Hospitalisation: **Age:** 45
Onset Date: **DOB:** 10/12/1958
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anger		Rage - feeling of extreme anger to the extent of homicidal thoughts.	
Homicidal ideation			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
75.0 Milligram	Daily
Oral	
Batch:	Started: 07/05/2004
	Stopped: 09/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 198576 **Seq:** 1 **Gender:** F
Reported: 28/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 55Y
Onset Date: 10/04/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dry eye		Dry eyes.	

Medicine Details:

PROTHIADEN (Suspected)	Reason:
Batch:	150.0 Milligram Daily Oral
Started: 10/04/2004	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of cataract extractions and lens implants (bilateral) and a history of hypertension. She is also taking Coversyl and was took one dose of Zoloft, then ceased. Copy of telephone report sent to reporter by Dr Purcell.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 199266	Seq: 1	Gender: M
Reported: 21/07/2004		Weight: 0.00
Hospitalisation:		Age: 61
Onset Date:		DOB: 13/05/1943
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sunburn	Required Visit to Doctor	Whenever he went into the sun he had Sun	
Photosensitivity reaction	Required Visit to Doctor		

Medicine Details:

PROTHIADEN (Suspected)	Reason:
800.0 Milligram	Daily
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 199555	Seq: 1	Gender: M
Reported: 30/07/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 50Y
Onset Date: 15/04/2003		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia		Twitching, jerking movements and nausea.	levodopa
Dyskinesia			
Muscle twitching			

Medicine Details:

TRAMAL SR (Interaction)	Reason: Other disturbance of sensation
200.0 Milligram	Daily
Batch:	Started: 01/02/2003 Stopped: 30/03/2004 0
PROTHIADEN (Interaction)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: L TERM Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 199562 **Seq:** 1 **Gender:** F
Reported: 30/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 24
Onset Date: 15/05/2004 **DOB:** 19/02/1980
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		Withdrawal reaction, suicidal ideation.	
Suicidal ideation			

Medicine Details:

PROTHIADEN (Suspected)	Reason:		
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 202555	Seq: 1	Gender: F
Reported: 15/11/2004		Weight: 0.00
Hospitalisation:		Age: 54
Onset Date: 07/10/2004		DOB: 24/01/1950
Outcome: Not yet recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Life threatening	Out of hospital cardiac arrest - rhythm VF on arrival of QAS, prolonged QT interval, cardiomyopathy	Bystander CPR, defibrillation and withdrawal of Dothiepin.
Electrocardiogram QT prolonged	Life threatening		
Ventricular fibrillation	Life threatening		

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)		Reason: Depression
Tablet	75.0 Milligram	Daily Oral
Batch:	Started: 15/06/2004	Stopped: 07/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/11/2004	Other data				QTc 480ms @ 20:25 7/10/2004. QTc 595ms @ 09:20 8/10/2004. Cardiomyopathy diagnosed this hospital admission EF ~40%.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 203186	Seq: 1	Gender: M
Reported: 01/12/2004		Weight: 82.00
Hospitalisation: Admitted to hospital		Age: 60
Onset Date: 15/01/2004		DOB: 05/03/1943
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Life	The patient developed bad trembling, high anxiety, chills, impaired vision, sweating, depression, bad dreams, headaches, low libido and hallucinations	Hospitalisation for 3 days.
Anxiety	Life		
Chills	Life		
Depression	Life		
Hallucination	Life		
Headache	Life		
Hyperhidrosis	Life		
Loss of libido	Life		
Nightmare	Life		

Medicine Details:

AROPAX (Suspected)	Reason:
Batch:	Started: Stopped:
LOVAN (Suspected)	Reason:
Batch:	Started: Stopped:
Lexapro (Suspected)	Reason:
Batch:	Started: Stopped:
DOTHEP (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 203186 **Seq:** 1 **Gender:** M
Reported: 01/12/2004 **Weight:** 82.00
Hospitalisation: Admitted to hospital **Age:** 60
Onset Date: 15/01/2004 **DOB:** 05/03/1943
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance	Life		

Medicine Details:

VERAPAMIL HYDROCHLORIDE (Suspected)	Reason: Headache
Tablet 80.0 Milligram Daily Oral	
Batch:	Started: 15/10/2003 Stopped:
ZOLOFT (Suspected)	Reason:
Tablet 50.0 Milligram Daily Oral	
Batch:	Started: Stopped:
EFEXOR-XR (Suspected)	Reason:
Capsule 225.0 Milligram Daily Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 206398	Seq: 1	Gender: F
Reported: 31/03/2005		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 74Y
Onset Date: 01/03/2004		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fall	Caused or prolonged inpatient hospitalisation	Multiple falls and increasing debility. Recent fall resulted in fracture to right humerus	Oxazepam weaned and Dothiepin ceased.
Asthenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

WARFARIN SODIUM (Other drug)	Reason: Otr&nos disord of heart rhythm
Batch:	Started: Stopped:
PROPYLTHIOURACIL (Other drug)	Reason: Thyrotoxicosis w/o ment goiter
Batch:	Started: Stopped:
CHLORVESCENT (Other drug)	Reason: Alkalosis
Batch:	Started: Stopped:
PARACETAMOL (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 206398 **Seq:** 1 **Gender:** F
Reported: 31/03/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 74Y
Onset Date: 01/03/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

VENTOLIN (Other drug)	Reason: Otr respiratory systm diseases	
Batch:	Started:	Stopped:
FRUSEMIDE (Other drug)	Reason: No reason given	
Batch:	Started:	Stopped:
PREDNISOLONE (Other drug)	Reason: Other rheumatoid arthritis	
Batch:	Started:	Stopped:
FAMOTIDINE (Other drug)	Reason: Other diseases of esophagus	
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 206398 **Seq:** 1 **Gender:** F
Reported: 31/03/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 74Y
Onset Date: 01/03/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

FOSAMAX ONCE WEEKLY TABLETS (Other drug)	Reason: Osteoporosis
Batch:	Started: Stopped:
FOLIC ACID (Other drug)	Reason:
Batch:	Started: Stopped:
METHOTREXATE (Other drug)	Reason: Other rheumatoid arthritis
Batch:	Started: Stopped:
FERRO-GRADUMET (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 206398 **Seq:** 1 **Gender:** F
Reported: 31/03/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 74Y
Onset Date: 01/03/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

IRBESARTAN (Other drug)	Reason: Essential benign hypertension		
Batch:	Started:	Stopped:	
SIMVASTATIN (Other drug)	Reason: Othr&unspec metabolic diseases		
Batch:	Started:	Stopped:	
OXAZEPAM (Suspected)	Reason: Anxiety neurosis		
Tablet	90.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression		
	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/04/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 206398 **Seq:** 1 **Gender:** F
Reported: 31/03/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 74Y
Onset Date: 01/03/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	25.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 208608	Seq: 1	Gender: F
Reported: 09/06/2005		Weight: 79.00
Hospitalisation: Admitted to hospital		Age: 32
Onset Date: 19/05/2005		DOB: 11/02/1973
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	The patient experienced sudden onset grand mal seizure, lasting 60 seconds and causing unconsciousness. She had post-episode confusion and amnesia.	Observation and withdrawal of medication.
Amnesia	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADEINE FORTE (Other drug)	Reason: Otr&unsp vertebrogen pain synd
Tablet	As necessary Oral
Batch:	Started: L TERM Stopped:
XANAX (Other drug)	Reason: Anxiety neurosis
Tablet	2.0 Milligram Daily Oral
Batch:	Started: 24/06/2004 Stopped: 0
AVANZA (Suspected)	Reason: Depression
Tablet	30.0 Milligram Daily Oral
Batch:	Started: 05/05/2005 Stopped: 10/05/2005
PROTHIADEN (Suspected)	Reason: Depression
	225.0 Milligram Daily Oral
Batch:	Started: 04/11/2004 Stopped: 19/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 208608 **Seq:** 1 **Gender:** F
Reported: 09/06/2005 **Weight:** 79.00
Hospitalisation: Admitted to hospital **Age:** 32
Onset Date: 19/05/2005 **DOB:** 11/02/1973
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADEINE FORTE (Other drug) Tablet Batch:	Reason: Otr&unsp vertebrogen pain synd As necessary Oral Started: L TERM Stopped:
XANAX (Other drug) Tablet Batch:	Reason: Anxiety neurosis 2.0 Milligram Daily Oral Started: 24/06/2004 Stopped: 0
AVANZA (Suspected) Tablet Batch:	Reason: Depression 30.0 Milligram Daily Oral Started: 05/05/2005 Stopped: 10/05/2005
PROTHIADEN (Suspected) Batch:	Reason: Depression 225.0 Milligram Daily Oral Started: 04/11/2004 Stopped: 19/05/2005

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 209302 **Seq:** 1 **Gender:** F
Reported: 30/06/2005 **Weight:** 90.00
Hospitalisation: Required a visit to the doctor **Age:** 34
Onset Date: 06/04/2005 **DOB:** 26/07/1970
Outcome: Recovered 07/04/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Transient ischaemic attack	Caused or prolonged inpatient hospitalisation	Patient experienced transient ischaemic attack	

Medicine Details:

OLANZAPINE (Suspected)	Reason: Unspecified psychosis
10.0 Milligram Daily	
Batch:	Started: Stopped:
PROTHIADEN (Suspected)	Reason: Depression
225.0 Milligram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 209576	Seq: 1	Gender: F
Reported: 07/07/2005		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 59
Onset Date: 16/08/2004		DOB: 29/06/1945
Outcome: Recovered	04/07/2004	Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient developed neuroleptic malignant syndrome, fevers to 40 degrees, decreased level of consciousness, creatinine kinase increased, white level count increased, neutrophils increased.	Withheld Dothiepin and
Blood creatine phosphokinase in	Caused or prolonged inpatient hospitalisation		
Depressed level of consciousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DIAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
ASPIRIN (Other drug)	Reason:
Batch:	Started: Stopped:
THIAMINE (Other drug)	Reason:
Batch:	Started: Stopped:
CENTRUM TABLETS (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2005	Neutrophils				Neutrophils 10.39.
07/07/2005	White blood cells				WCC 12.4.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 209576	Seq: 1	Gender: F
Reported: 07/07/2005		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 59
Onset Date: 16/08/2004		DOB: 29/06/1945
Outcome: Recovered	04/07/2004	Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutrophil count increased	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

COLOXYL (Other drug)	Reason:
Batch:	Started: Stopped:
FRUSEMIDE (Other drug)	Reason:
Batch:	Started: Stopped:
METFORMIN HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
METOPROLOL TARTRATE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 209576 **Seq:** 1 **Gender:** F
Reported: 07/07/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 59
Onset Date: 16/08/2004 **DOB:** 29/06/1945
Outcome: Recovered 04/07/2004 **Causality:** Causality possible

Reaction Detail

Medicine Details:

PRAVACHOL (Other drug)	Reason:
Batch:	Started: Stopped:
SOMAC (Other drug)	Reason:
Batch:	Started: Stopped:
RAMIPRIL (Other drug)	Reason:
Batch:	Started: Stopped:
GLYCERYL TRINITRATE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 209576 **Seq:** 1 **Gender:** F
Reported: 07/07/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 59
Onset Date: 16/08/2004 **DOB:** 29/06/1945
Outcome: Recovered 04/07/2004 **Causality:** Causality possible

Reaction Detail

Medicine Details:

NOVORAPID (Other drug)	Reason:
Batch:	Started: Stopped:
PROTAPHANE (Other drug)	Reason:
Batch:	Started: Stopped:
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression
Tablet 25.0 Milligram Daily Oral	
Batch:	Started: Stopped: 01/07/2004
QUETIAPINE (Suspected)	Reason: Hallucinations
Tablet 50.0 Milligram Daily Oral	
Batch:	Started: Stopped: 01/07/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 210835 **Seq:** 1 **Gender:** F
Reported: 17/08/2005 **Weight:** 46.00
Hospitalisation: **Age:** 54
Onset Date: 15/06/2005 **DOB:** 18/07/1950
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations		The patient experienced palpitations, couldn't sleep and had vomiting and diarrhoea	
Diarrhoea			
Insomnia			
Vomiting			

Medicine Details:

PROTHIADEN (Suspected)	Reason: Neuroses
75.0 Milligram	Daily
Oral	
Batch:	Started: 20/05/2005
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 213589 **Seq:** 1 **Gender:** M
Reported: 18/11/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 52
Onset Date: 29/10/2005 **DOB:** 15/12/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	The patient experienced chest pain and dullness in the left arm - cardiac event.	

Medicine Details:

Peg Interferon Alfa-2B (Suspected)	Reason: Other diseases of liver
120.0 Microgram Weekly	
Batch:	Started: 18/02/2005 Stopped: 28/10/2005
RIBAVIRIN (Suspected)	Reason: Other diseases of liver
800.0 Milligram Daily	
Batch:	Started: 18/02/2005 Stopped: 31/10/2005
PROTHIADEN (Suspected)	Reason:
100.0 Milligram Daily Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 214939	Seq: 1	Gender: F
Reported: 13/01/2006		Weight: 0.00
Hospitalisation:		Age: 40
Onset Date: 01/01/2005		DOB: 26/06/1964
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	The patient experienced an unsteady gait, body shakes, falls, slurred speech, increased sweating and palpitations, increased agitation, dizziness, difficulty walking, bowels opened more often than usual, was ataxic, had tremor, hyperreflexia and increased limb tone. The patient increased her dose of Dothiepin only 4	Tramadol and Dothiepin
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MS CONTIN (Other drug)	Reason: Pain
Batch:	Started:
Stopped:	
PANADEINE FORTE (Other drug)	Reason: Pain
Batch:	Started:
Stopped:	
NITRAZEPAM (Other drug)	Reason:
Batch:	Started:
Stopped:	
DIAZEPAM (Other drug)	Reason:
Batch:	Started:
Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient states increasing the dose of Dothiepin only 4 days prior to admission.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 214939 **Seq:** 1 **Gender:** F
Reported: 13/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 40
Onset Date: 01/01/2005 **DOB:** 26/06/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal	Caused or prolonged inpatient hospitalisation		
Dizziness	Caused or prolonged inpatient hospitalisation		
Dysarthria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMADOL HYDROCHLORIDE (Suspected)	Reason: Pain	
400.0 Milligram	Daily	
Batch:	Started:	Stopped: 17/01/2005
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Pain	
150.0 Milligram	Daily	Oral
Batch:	Started: 15/11/2004	Stopped: 17/01/2005

Laboratory Investigations:

Additional Information:

Patient states increasing the dose of Dothiepin only 4 days prior to admission.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 214939 **Seq:** 1 **Gender:** F
Reported: 13/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 40
Onset Date: 01/01/2005 **DOB:** 26/06/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fall	Caused or prolonged inpatient hospitalisation		
Gait disturbance	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MS CONTIN (Other drug)	Reason: Pain	
Batch:	Started:	Stopped:
PANADEINE FORTE (Other drug)	Reason: Pain	
Batch:	Started:	Stopped:
NITRAZEPAM (Other drug)	Reason:	
Batch:	Started:	Stopped:
DIAZEPAM (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Patient states increasing the dose of Dothiepin only 4 days prior to admission.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 214939 **Seq:** 1 **Gender:** F
Reported: 13/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 40
Onset Date: 01/01/2005 **DOB:** 26/06/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperreflexia	Caused or prolonged inpatient hospitalisation		
Hypertonia	Caused or prolonged inpatient hospitalisation		
Palpitations	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMADOL HYDROCHLORIDE (Suspected)	Reason: Pain	
400.0 Milligram	Daily	
Batch:	Started:	Stopped: 17/01/2005
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Pain	
150.0 Milligram	Daily	Oral
Batch:	Started: 15/11/2004	Stopped: 17/01/2005

Laboratory Investigations:

Additional Information:

Patient states increasing the dose of Dothiepin only 4 days prior to admission.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 214939

Seq: 1

Gender: F

Reported: 13/01/2006

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date: 01/01/2005

DOB: 26/06/1964

Outcome: Recovered

Causality: Causality possible

Reaction Detail

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

Medicine Details:

MS CONTIN (Other drug)	Reason: Pain	
Batch:	Started:	Stopped:
PANADEINE FORTE (Other drug)	Reason: Pain	
Batch:	Started:	Stopped:
NITRAZEPAM (Other drug)	Reason:	
Batch:	Started:	Stopped:
DIAZEPAM (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Patient states increasing the dose of Dothiepin only 4 days prior to admission.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 214939

Seq: 1

Gender: F

Reported: 13/01/2006

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date: 01/01/2005

DOB: 26/06/1964

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

TRAMADOL HYDROCHLORIDE (Suspected)	Reason: Pain	
400.0 Milligram	Daily	
Batch:	Started:	Stopped: 17/01/2005
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Pain	
150.0 Milligram	Daily	Oral
Batch:	Started: 15/11/2004	Stopped: 17/01/2005

Laboratory Investigations:

Additional Information:

Patient states increasing the dose of Dothiepin only 4 days prior to admission.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 215402	Seq: 1	Gender: M
Reported: 31/01/2006		Weight: 94.00
Hospitalisation: Required a visit to the doctor		Age: 69
Onset Date: 03/11/2005		DOB: 21/12/1935
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Facial palsy		The patient experienced left facial Bell's palsy. He found that as he was taking Dothiepin off and on the palsy, having cleared initially, kept recurring and then stopping after stopping the Dothiepin.	Dothiepin ceased.
Drug ineffective			

Medicine Details:

LIPITOR (Other drug)	Reason: Othr&unspec metabolic diseases
Batch:	Started: Stopped:
AVAPRO (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
ISCOVER (Other drug)	Reason:
Batch:	Started: Stopped:
NEXIUM (Other drug)	Reason: Other diseases of esophagus
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 215402 **Seq:** 1 **Gender:** M
Reported: 31/01/2006 **Weight:** 94.00
Hospitalisation: Required a visit to the doctor **Age:** 69
Onset Date: 03/11/2005 **DOB:** 21/12/1935
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

BETALOC (Other drug)	Reason: Essential benign hypertension	
Batch:	Started:	Stopped:
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason:	
Batch:	75.0 Milligram Daily Oral	Stopped: 23/11/2005
Started: 17/04/2005		

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 215997	Seq: 1	Gender: F
Reported: 20/02/2006		Weight: 75.00
Hospitalisation: Required a visit to the doctor		Age: 52Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome Agitation		The patient experienced restless legs and	Dothep ceased.

Medicine Details:

LOVAN (Other drug)	Reason:	
20.0 Milligram		
Batch:	Started:	Stopped:
PREMARIN (Other drug)	Reason:	
625.0 Microgram		
Batch:	Started:	Stopped:
DOTHEP (Suspected)	Reason:	
25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 216459 **Seq:** 1 **Gender:** F
Reported: 13/03/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 48
Onset Date: **DOB:** 10/12/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Dizziness Drug therapy changed Nausea		Changed from Prothiaden to Dothep and experienced fatigue, nausea, dizzy.	Stopped Dothep and reverted back to Prothiaden.

Medicine Details:

DOTHEP (Suspected)	Reason:
Batch:	25.0 Milligram Daily
Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 218064	Seq: 1	Gender: F
Reported: 05/05/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 86Y
Onset Date: 17/01/2006		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient experienced hyponatraemia and	
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ATORVASTATIN (Other drug)		Reason: Othr&unspec metabolic diseases
Tablet	20.0 Milligram	Oral
Batch:	Started:	Stopped:
CLOPIDOGREL (Other drug)		Reason:
Tablet	75.0 Milligram	Oral
Batch:	Started:	Stopped:
OMEPRAZOLE (Other drug)		Reason: Other diseases of esophagus
Tablet	20.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
CANDESARTAN-HYDROCHLOROTHIAZIDE (Suspected)		Reason: Essential benign hypertension
Tablet		Oral
Batch:	Started:	Stopped: 17/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/05/2006	Sodium				Na was 121 on admission which improved to 131 next day.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 218064 **Seq:** 1 **Gender:** F
Reported: 05/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 86Y
Onset Date: 17/01/2006 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Depression	
Batch:	Started:	Stopped: 17/01/2006
HYOSCINE NOS (Suspected)	Reason: Diarrhea	
Tablet	Started:	Stopped: 17/01/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 219338 **Seq:** 1 **Gender:** F
Reported: 20/06/2006 **Weight:** 60.00
Hospitalisation: **Age:** 81
Onset Date: 27/03/2006 **DOB:** 02/06/1924
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
		... was re-challenged (in ICU) with fusidic acid and ciprofloxacin-this produced chest pain , paraesthesias over neck and cheek. Fusidic acid alone was given 8 hours later and within 90 mins patient developed periorbital oedema, erythema over forearms, neck and back. No further doses of fusidic acid were given. On 26/05/2006 she was given rifampicin 300mg and ciprofloxacin 500 mg at 1600 hours. Within 2 hours she developed mild erythematous rash over lower limbs, then on forearms, chest and peri-orbital area. Swelling of upper eye lids. no tongue swelling. All oral antibiotics have been ceased and now on IV vancomycin	

Medicine Details:

PROTHIADEN (Suspected)	Reason:
Capsule	25.0 Milligram 1 time Oral
Batch:	Started: 24/03/2006 Stopped: 27/03/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIPIIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 219338 **Seq:** 1 **Gender:** F
Reported: 20/06/2006 **Weight:** 60.00
Hospitalisation: **Age:** 81
Onset Date: 27/03/2006 **DOB:** 02/06/1924
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation		
Erythema	Caused or prolonged inpatient hospitalisation		
Paraesthesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RIFAMPICIN (Other drug)	Reason:
Capsule 300.0 Milligram 2 times Oral	
Batch:	Started: 24/01/2006 Stopped: 20/04/2006
PANTOPRAZOLE (Other drug)	Reason:
Capsule 40.0 Milligram 1 time Oral	
Batch:	Started: 24/01/2006 Stopped: 10/04/2006
CIPROFLOXACIN (Suspected)	Reason:
Batch:	Started: Stopped:
FUCIDIN (Suspected)	Reason:
Tablet 500.0 Milligram 3 times Oral	
Batch:	Started: 20/01/2006 Stopped: 20/04/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 219338 **Seq:** 1 **Gender:** F
Reported: 20/06/2006 **Weight:** 60.00
Hospitalisation: **Age:** 81
Onset Date: 27/03/2006 **DOB:** 02/06/1924
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Periorbital oedema	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROTHIADEN (Suspected)	Reason:
Capsule	25.0 Milligram 1 time Oral
Batch:	Started: 24/03/2006 Stopped: 27/03/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 219617	Seq: 1	Gender: M
Reported: 03/07/2006		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 99u
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cerebellar syndrome	Caused or prolonged inpatient hospitalisation	The patient was hospitalized for cerebellar symptoms described as ataxia, and disorientation	
Coordination abnormal	Caused or prolonged inpatient hospitalisation		
Disorientation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROTHIADEN (Suspected)	Reason:
225.0 Milligram	Daily
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 221271 **Seq:** 1 **Gender:** F
Reported: 01/09/2006 **Weight:** 0.00
Hospitalisation: **Age:** 46
Onset Date: 15/02/2005 **DOB:** 19/04/1958
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abscess of salivary gland	Caused or prolonged inpatient hospitalisation	Pleimorphic adenoma of the parotid gland.	due for surgery

Medicine Details:

PROTHIADEN (Suspected)	Reason: Pain		
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 221421	Seq: 1	Gender: F
Reported: 06/09/2006		Weight: 0.00
Hospitalisation:		Age: 61Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		Suspected serotonin syndrome which recurred when re-introduced	

Medicine Details:

EFEXOR-XR (Suspected)	Reason: Depression
Capsule	150.0 Milligram Daily Oral
Batch:	Started: Stopped: 0
DOTHEP (Suspected)	Reason:
	25.0 Milligram Daily Oral
Batch:	Started: Stopped:
TRAMAL SR (Suspected)	Reason:
	200.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 225104	Seq: 1	Gender: U
Reported: 25/01/2007		Weight: 0.00
Hospitalisation:		Age: 34Y
Onset Date: 09/01/2007		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		seizure	

Medicine Details:

EPILIM (Suspected)	Reason: Depression
1.0 Gram	Daily
Batch:	Started: 15/05/2005 Stopped: 15/12/2006 0
PROTHIADEN (Suspected)	Reason: Depression
150.0 Milligram	Daily Oral
Batch:	Started: 15/04/2006 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 225147 **Seq:** 1 **Gender:** M
Reported: 29/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 68Y
Onset Date: 02/01/2007 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pancytopenia		Pancytopenia, decreased WCC and decreased neutrophil count	Stopped drug and monitored.

Medicine Details:

MEROPENEM (Other drug) Injection Batch:	3.0 Gram Started: 22/12/2006	Reason: Unspecified osteomyelitis Daily Stopped:	Intravenous
VANCOMYCIN HYDROCHLORIDE (Other drug) Injection Batch:	2.0 Gram Started: 24/12/2006	Reason: Unspecified osteomyelitis Daily Stopped:	Intravenous
GABAPENTIN (Other drug) Batch:	1.2 Gram Started: 22/12/2006	Reason: Pain Daily Stopped:	Oral
IBUPROFEN (Other drug) Batch:	1.2 Gram Started: 27/12/2006	Reason: Pain Daily Stopped:	Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 225147 **Seq:** 1

Gender: M

Reported: 29/01/2007

Weight: 0.00

Hospitalisation:

Age: 68Y

Onset Date: 02/01/2007

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason: Otr periph nerve dis not auton	
25.0 Milligram	Daily	Oral
Batch:	Started: 29/12/2006	Stopped: 02/01/2007

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 225302	Seq: 1	Gender: F
Reported: 01/02/2007		Weight: 0.00
Hospitalisation:		Age: 53
Onset Date: 14/12/2006		DOB: 21/07/1953
Outcome: Death	27/12/2006	Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Death	Marked agitation and confusion.	Methylene blue, cessation of CNS active drugs.
Confusional state	Death		

Medicine Details:

IFOSFAMIDE (Suspected)	Reason: Other malign no spec of site
7.8 Gram	Daily
Batch:	Started: 13/12/2006 Stopped: 14/12/2006
ETOPOSIDE (Suspected)	Reason: Other malign no spec of site
Injection 150.0 Milligram	Daily Intravenous
Batch:	Started: 12/12/2006 Stopped: 14/12/2006
CARBOPLATIN (Suspected)	Reason: Other malign no spec of site
Injection 635.0 Milligram	Daily Intravenous
Batch:	Started: 12/12/2006 Stopped:
DOTHIEPIN HYDROCHLORIDE (Suspected)	Reason:
100.0 Milligram	Daily Oral
Batch:	Started: L TERM Stopped: 15/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient known to CNS disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 225302

Seq: 1

Gender: F

Reported: 01/02/2007

Weight: 0.00

Hospitalisation:

Age: 53

Onset Date: 14/12/2006

DOB: 21/07/1953

Outcome: Death

27/12/2006

Causality: Causality possible

Reaction Detail

Medicine Details:

FLUCONAZOLE (Suspected)	Reason: Moniliasis
100.0 Milligram	Daily
Oral	
Batch:	Started: 10/12/2006
	Stopped: 15/12/2006
CYCLIZINE (Suspected)	Reason: Nausea and vomiting
50.0 Milligram	Daily
Batch:	Started: 12/12/2006
	Stopped: 15/12/2006

Laboratory Investigations:

Additional Information:

Patient known to CNS disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 226411 **Seq:** 1 **Gender:** F
Reported: 07/03/2007 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 61Y
Onset Date: 25/01/2007 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Anger Pyrexia Restlessness		Severe agitation, restlessness as well as fever, angerness.	

Medicine Details:

DOTHEP (Suspected)	Reason: Depression
Capsule	25.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1991 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DOTHEP,DOTHIEPIN HYDROCHLORIDE,PROTHIADEN

Report Detail

Case Number: 227355 **Seq:** 1 **Gender:** F
Reported: 04/04/2007 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Patient experienced severe dizziness and tiredness when using Dothep.	Stopped Dothep, replaced with Prothiaden.
Fatigue			
Therapeutic response unexpecte			

Medicine Details:

DOTHEP (Suspected)	Reason:
Tablet	150.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information: