

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 2504 Seq: 1 Gender: M

Reported: 05/11/1990 Weight:

Hospitalisation: Hospitalisation prolonged
Onset Date: 31/10/1990
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Symptomatic support in icu. ventilation and isotrope support

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

200.0 Milligram Total

Batch: Started: 26/10/1990 **Stopped:** 27/10/1990

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. Case Sequenced to: 68180/2

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 2506 Seq: 1 Gender: M

Reported: 30/10/1990 Weight: 80.00 Hospitalisation: Age: 47Y

Onset Date: 12/09/1990 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia			

Medicine Details:

COGENTIN (Other drug)	ı	Reason:	
Injection	1.0 Milligram	1 time	Intravenous
Batch:	Started: 05/09/1990	Stopped:	
DIAZEPAM (Other drug)	ı	Reason:	
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started: 11/09/1990	Stopped:	20/09/1990
COGENTIN (Other drug)	ı	Reason:	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 05/09/1990	Stopped:	21/09/1990
BIPERIDEN HYDROCHLORIDE (Oth	ner drug)	Reason:	
Tablet	3.0 Milligram	Daily	Oral
	9	•	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Case Sequenced to: 68215/2

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Medicine Details: THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application Started: 12/09/1990 Reason: Unspecified schizophrenia Oral splication Started: 12/09/1990 Stopped: Additional Information:	
Onset Date: 12/09/1990 Outcome: Recovered Causality: Causality probable paction Details: Medicine Details: THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application Started: 12/09/1990 Stopped: Started: 12/09/1990 Additional Information:	Weight: 80.00
Onset Date: 12/09/1990 DOB: Outcome: Recovered Causality: Causality probable paction Details: Medicine Details: Medicine Details: THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified schizophrenia Oral application 50.0 Milligram 1 time Oral Batch: Started: 12/09/1990 Stopped:	
Outcome: Recovered Causality: Causality probable eaction Details: Wedicine Details: THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified schizophrenia Oral application 50.0 Milligram 1 time Oral Batch: Started: 12/09/1990 Stopped:	
Medicine Details: THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application So.0 Milligram 1 time Oral Batch: Started: 12/09/1990 Stopped:	
Medicine Details: THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application Started: 12/09/1990 Batch: Started: 12/09/1990 Stopped: Additional Information:	,
THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application Started: 12/09/1990 Stopped: Additional Information:	
THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application Started: 12/09/1990 Reason: Unspecified schizophrenia Oral application Stopped: Stopped: aboratory Investigations:	
THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application 50.0 Milligram 1 time Oral Batch: Started: 12/09/1990 Stopped:	
THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application Started: 12/09/1990 Stopped: Started: 12/09/1990 Additional Information:	
THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application 50.0 Milligram 1 time Oral Batch: Started: 12/09/1990 Stopped:	
THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application Started: 12/09/1990 Stopped: Started: 12/09/1990 Additional Information:	
THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application Started: 12/09/1990 Stopped: Started: 12/09/1990 Additional Information:	
THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application Started: 12/09/1990 Stopped: Started: 12/09/1990 Additional Information:	
THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application Started: 12/09/1990 Stopped: Started: 12/09/1990 Additional Information:	
THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application Started: 12/09/1990 Stopped: Started: 12/09/1990 Additional Information:	
THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application Started: 12/09/1990 Stopped: Laboratory Investigations: Additional Information:	
Oral application 50.0 Milligram 1 time Oral	
THIORIDAZINE HYDROCHLORIDE (Suspected) Oral application Started: 12/09/1990 Stopped: Laboratory Investigations: Additional Information:	
Oral application 50.0 Milligram 1 time Oral Batch: Started: 12/09/1990 Stopped: -aboratory Investigations: Additional Information:	
Batch: Started: 12/09/1990 Stopped: -aboratory Investigations: Additional Information:	
aboratory Investigations:	50.0 Milligram 1 time Oral
Additional Information:	Started : 12/09/1990 Stopped :
Additional Information:	
Case Sequenced to: 68215/2	

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Causality: Causality possible

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 52892
 Seq: 1
 Gender:
 F

 Reported:
 14/06/1988
 Weight:
 84.00

 Hospitalisation:
 Age: 71Y

Onset Date: DOB:

Outcome: Death, maybe drug

Reaction Details:

•	todotion Details.			
	Preferred Term	Severity	Report Description	Treatment
	Cardiac failure			
	Cardiomyopathy			
	Electrocardiogram abnormal			

Medicine Details:

LAROXYL (Suspected)		Reason:	Depression	
Tablet	150.0 Milligram	Daily		Oral
Batch:	Started: 01/01/1970		Stopped:	13/06/1988
THIORIDAZINE HYDROCHLORIDE (S	Suspected)	Reason:	Anxiety neuros	sis
Oral application	75.0 Milligram	Daily		Oral
Batch:	Started: 01/01/1974		Stopped:	28/05/1988
DIGOXIN (Suspected)		Reason:	Congestive he	art failure
	125.0 Microgram	Daily		
Batch:	Started: 07/03/1987		Stopped:	13/06/1988
LASIX (Suspected)		Reason:	Congestive he	art failure
	40.0 Milligram	Daily		
Batch:	Started: 28/10/1986		Stopped:	13/06/1988

Laboratory Investigations:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

 Case Number:
 52892
 Seq:
 1
 Gender:
 F

 Reported:
 14/06/1988
 Weight:
 84.00

 Hospitalisation:
 Age:
 71Y

Onset Date: DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Medicine Details:

MODURETIC (Suspected) Reason: Congestive heart failure

1.0 Dose Unspecified Daily

Batch: Started: 19/05/1988 Stopped: 13/06/1988

CAPTOPRIL (Suspected) Reason: Congestive heart failure

37.0 Milligram Daily

Batch: Started: 30/03/1988 Stopped: 13/06/1988

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

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 55211 Reported: 11/07/1988 Hospitalisation: Onset Date: 28/05/1988 Outcome: Recovered Reaction Details:	Seq: 1			Gender: M Weight: 63.00 Age: 27Y DOB: ausality: Causality probable
Preferred Term	Severity	Report De	escription	Treatment
Dry skin		·	•	
Libido decreased				
Semen abnormal				Cessation of melleril and observe.
Medicine Details: VALIUM (Other drug)		Possoni	Anxiety nourse	io.
VALIUM (Other drug)	0.0	Reason:	Anxiety neuros	IS
Batch:	Started:		Stopped:	24/06/1988
MELLERIL (Suspected)		Reason:	Other paranoid	states
	100.0 Mill	ligram Daily		
Batch:	Started: 27/04/1	988	Stopped:	27/05/1988
MELLERIL (Suspected)		Reason:	Other paranoid	states
	75.0 Mill	-		
Batch:	Started: 27/05/1	988	Stopped:	09/06/1988
Laboratory Investigatio Date Type	ns: Range Date Tested	Result		Details
Additional Information:				

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

se Number:	55497	Seq: 1					Gender:	M
	05/08/1988						Weight:	
italisation:							Age:	27Y
Onset Date:							DOB:	
	Death, mayb	e drug				Ca		Causality possible
ction Deta								
	ed Term	Seve	rity	Rep	ort Desc	ription		Treatment
uroleptic mali	gnant syndron	ne						
edicine Det					ason:			
Tablet			50.0 Millio	gram	Daily		Oral	
Batch:		Start	ea:			Stopped:	01/08/1988	
aboratory Ir Date	nvestigation Type		ate Tested	Result			Detail	S

Rep



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 56794 Seq: 1 Gender: F

Reported: 14/10/1988 Weight:
Hospitalisation: Age: 36Y

Onset Date: 31/07/1988 **DOB**:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Retinal pigmentation			

Medicine Details:

MODECATE (Suspected)		Reason: Unspecifi	ed schizophrenia	_
Injection	100.0 Milligram	Weekly	Intramuscular	
Batch:	Started: 01/01/1979	Stopp	oed:	CONTIN
MELLERIL (Suspected)		Reason: Unspecifi	ed schizophrenia	
Tablet	500.0 Milligram	Daily	Oral	
Batch:	Started: 01/11/1983	Stopp	oed:	
MELLERIL (Suspected)		Reason: Unspecifi	ed schizophrenia	
Tablet	600.0 Milligram	Daily	Oral	
Batch:	Started: 01/11/1984	Stopp	ped: 28/09/1988	

Laboratory Investigations:

Date	Туре	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 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

ase Number:						
Danaria d.		Seq: 1			Gender:	
-	30/08/1988				Weight:	
ospitalisation:					Age:	
Onset Date:				_	DOB:	
	Recovered			С	ausality:	Causality probable
eaction Deta	ils: red Term	Severity	Reno	rt Description		Treatment
Pruritus	<u>ca remi</u>	Ceventy	Тере	T Description		ricatinent
MELLERIL (Suspe		40.0	Reas	•		
Tablet Batch:		10.0 Started: 25/0		Daily	Oral	.
Datcii.		Starteu. 25/0	7771900	Stopped.	27/07/1988)
	nvestigations:					

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 57910
 Seq: 1
 Gender:
 F

 Reported:
 21/12/1988
 Weight:

Hospitalisation: Age: 70Y
Onset Date: 10/12/1988 DOB:

Outcome: Death Causality: Causality possible

Reaction Details:

•	todotion Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Neutropenia	Life threatening		
	Sudden death			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Suspected)			Reason:	Depression	
Oral application	60.0	Milligram	Daily		Oral
Batch:	Started: 24/	10/1988		Stopped:	13/12/1988
MELLERIL (Suspected)			Reason:		
	25.0	Milligram	Daily		
Batch:	Started: 08/	10/1988		Stopped:	
DILTIAZEM HYDROCHLORIDE (Suspected)			Reason:		
	360.0	Milligram	Daily		
Batch:	Started: 01/	08/1988		Stopped:	
THEO-DUR (Suspected)			Reason:		
	600.0	Milligram	Daily		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 4/10/88 18/10 12/12 13/12 leucocytes (4.0-11.0) 14.3 10.1 0.6 0.9 granulocytes (2.5-7.5) 9.1 9 0 0 lymphocyte (1.5-3.5) 0.9 0.6 0.8 monocytes (0.2-0.8) 0.2 0 0.1

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details	:					
Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detail	21/12/1988 10/12/1988 Death	Seq: 1			Gender: Weight: Age: DOB: Causality:	70Y
Medicine Deta						
NITRADISC (Suspe	cted)	50.0	Milligram	Reason: Daily		
Batch:		Started:	www.gram	Dany	Stopped:	
Laboratory Inv	vestigations:					
Additional Info		v accurate but in	ndicates tha	t start occurred	I sometime during the	month.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	58666	Seq: 1			G	ender: M
Reported:	16/01/1989	_			W	eight:
ospitalisation:						Age: 84Y
Onset Date:	25/10/1988					DOB:
Outcome:	Not yet reco	vered			Cau	sality: Causality possible
eaction Detai	ls:					
Preferre	ed Term	Seve	rity	Repo	ort Description	Treatment
Extrapyramidal d	isorder					
Medicine Deta		E (Suspected)	50.0 Milli		son: Daily	
Batch:		Start			Stopped:	
_aboratory In	Type	Range Da	ate Tested	Result		Details
	. , , , ,	- tungo - Di	210 100104	rtooun		2 0140
Additional Inf	ormation:					
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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Det						
Case Numb		Seq: 1			ler: M	
-	ed: 28/02/1989			Weig		
ospitalisatio			Age:			
	ite: 31/01/1989				OB:	
	ne: Recovered			Causali	ity: Causality possible	
eaction De					1	
	ferred Term	Severity	Report Des	cription	Treatment	
Nausea						
omiting						
Medicine D	Details:					
	Details: E HYDROCHLORID		Reason:			
THIORIDAZINI	E HYDROCHLORID	0.0	Reason:	Stonned		
	E HYDROCHLORID		Reason:	Stopped:		
THIORIDAZINI Batch	E HYDROCHLORID	0.0 Started:	Reason:	Stopped:		
Batch	E HYDROCHLORID	0.0 Started:	Reason:		Details	

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 59250	Seq: 1		Gende	er: M
Reported: 28/02/1989		Weight: Age: DOB:		t:
ospitalisation:				e:
Onset Date: 31/01/1989)			_
Outcome: Unknown			Causalit	y: Causality possible
eaction Details:				
Preferred Term	Severity	Report Description		Treatment
Headache				
Vausea				
Medicine Details: THIORIDAZINE HYDROCHLORI		Reason:		
THIORIDAZINE HYDROCHLORI	0.0		d-	
Medicine Details: THIORIDAZINE HYDROCHLORI Batch:		Reason: Stopp	ped:	
THIORIDAZINE HYDROCHLORI	0.0 Started:		ped:	
THIORIDAZINE HYDROCHLORI	0.0 Started:			etails

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 60078 Seq: 1 Gender: M

Reported: 03/05/1989 Weight: 102.00 Hospitalisation: Age: 30Y

Onset Date: 29/03/1989 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	todotion Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Pruritus			
	Rash maculo-papular			

Medicine Details:

RIVOTRIL (Other drug)		Reason:	Generalizd convulsive epilepsy	
Tablet	6.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	CONTIN
DILANTIN (Other drug)		Reason:	Generalizd convulsive epilepsy	
Capsule	400.0 Milligram	Daily	Oral	
Batch:	Started: 01/02/1989		Stopped:	CONTIN
EPILIM (Other drug)		Reason:	Generalizd convulsive epilepsy	
Oral Liquid	3.0 Gram	Daily	Oral	
Batch:	Started:		Stopped:	CONTIN
TEGRETOL (Other drug)		Reason:	Generalizd convulsive epilepsy	
Tablet	800.0 Milligram	Daily	Oral	
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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report	Details:
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Case Number: 60078 Seq: 1 Gender: M

Reported: 03/05/1989 Weight: 102.00 Hospitalisation: Age: 30Y

Onset Date: 29/03/1989 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Medicine Details:

Micaicinic Details.			
VALIUM (Other drug)		Reason: Generalizd co	onvulsive epilepsy
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
MELLERIL (Suspected)		Reason: Hallucinations	s
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 22/03/1989	Stopped:	29/03/1989

Laboratory Investigations:

Additional Information:

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

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Case Number: 60431

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

l Informatio	n:						
,,	ŭ						
		Date Tested	Pasult			De	tails
		started. 01/04/10			оторреи.		
	s			Daily	Stonned:	Oral	
		0.5 14:00			neuroses	Oral	
Details:							
l							
			•		•		
eferred Term	Se	everity	Repo	ort Des	cription		Treatment
	COVCICU				·	ausant	y. Gausanty possible
	covered				C		y: Causality possible
	39						
	on: ate: ne: Not yet re etails: ferred Term Details: uspected) on n:	Details: uspected) on: sylinvestigations:	petails: Details: Severity Details: Suspected) Sign 2.5 Milling 1: Started: 01/04/19 y Investigations: Type Range Date Tested	One: Interestigations: Type Range Date Tested Result Paralls: Not yet recovered Severity Report Report Severity Report Severity Report Report Severity Report Report Severity Repor	on: ate: ne: Not yet recovered etails: Inferred Term Severity Report Des Details: uspected) Reason: n: Started: 01/04/1989 y Investigations: Type Range Date Tested Result	on: ate: ne: Not yet recovered C ptails: Iferred Term Severity Report Description Details: uspected) Reason: Neuroses on 2.5 Millilitre Daily n: Started: 01/04/1989 Stopped:	on: Age ate: DO ne: Not yet recovered Causality etails: Inferred Term Severity Report Description Details: uspected) Reason: Neuroses on 2.5 Millilitre Daily Oral ne: Started: 01/04/1989 Stopped: Y Investigations: Type Range Date Tested Result De



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
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Case Number: 60649 Seq: 1 Gender: F

Reported: 10/05/1989 Weight:
Hospitalisation: Age: 19Y

Onset Date: 27/01/1989 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia			

Medicine Details:

MEGICINE DETAILS.				
THIORIDAZINE HYDROCHLORIDE (Sus	spected)	Reason:		
Oral Liquid	50.0 Milligram	1 time	Oral	
Batch:	Started: 18/01/1989	Stopp	Stopped:	
CARBAMAZEPINE (Suspected)		Reason:		
Tablet	100.0 Milligram	Daily	Oral	
Batch:	Started: 03/01/1989	Stopp	ed: 06/01/1989	

Laboratory Investigations:

<u> </u>	y mroonga				
Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 25/11/88 27/1/89 31/1 2/2 6/2 13/2 21/2 white blood cell count: 7.1 2.6 3.1 3.4 5.3 3.5 4.3

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

	etails:							
Case Num	nber: 60708	Seq:	1				Gende	r: F
Repor	rted: 29/05/198	39					Weight	:
lospitalisat	tion:						Age	e: 25Y
Onset D	Date: 12/05/198	39					DOE	3:
Outco	ome: Recovere	:d				С	ausality	: Causality possible
eaction D	Details:							
Pr	referred Term	Se	everity	Rep	ort De	scription		Treatment
Grand mal c	convulsion						fo to	v diazepam stat, oral panado or headache, dilantin 100mg ds for few days, tofranil dose raded down and ceased.
Medicine								_
TOFRANIL (S					ason:	Depression		
Table		_	250.0 Milli	-	Daily		Oral	
Bato		S	tarted: 09/05/1			Stopped:		
MELLERIL (S	Suspected)				ason:	Depression		
		_	200.0 Milli	-	Daily			••
Bato		S	tarted: 23/04/1			Stopped:		
NOCTEC (Su					ason:	Specific disord		ер
	l application	_	1.0 Gra		Daily		Oral	
Bato	ch:	S	tarted: 23/04/1	989		Stopped:	12/05/19	89
<u> Laborato</u>	ry Investigat				_			
Laborato Date	ry Investigat	Range	Date Tested	Result			Det	ails
			Date Tested	Result			Det	ails
			Date Tested	Result			Det	ails
			Date Tested	Result			Det	ails
			Date Tested	Result			Det	ails
			Date Tested	Result			Det	ails
			Date Tested	Result			Det	ails
Date	Туре	Range	Date Tested	Result			Det	ails
Date		Range	Date Tested	Result			Det	ails
Date	Туре	Range	Date Tested	Result			Det	ails
Date	Туре	Range	Date Tested	Result			Det	ails
Date	Туре	Range	Date Tested	Result			Det	ails

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 61692 Seq: 1 Gender: M

 Reported: 21/07/1989
 Weight: 73.00

 Hospitalisation:
 Age: 35Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	todotion Details.			
	Preferred Term	Severity	Report Description	Treatment
	Abdominal pain			
	Dyspepsia			

Medicine Details:

ALDAZINE (Suspected) Reason: Unspecified schizophrenia

200.0 Milligram Daily

Batch: Started: 01/01/1989 **Stopped:** 28/05/1989

Laboratory Investigations:

Date	Туре	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.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 61702 Reported: 31/07/1989 ospitalisation: Onset Date: Outcome: Recovered	Seq: 1		Weig A D	der: F jht: ge: 61Y OB: lity: Causality probable
Preferred Term	Severity	Report Des		Treatment
kin exfoliation	Seventy	Report Des	сприоп	Haloperidol 5mg nocte.
edicine Details: /ENTOLIN (Other drug)		Reason:		
Inhalation	0.0		Inhala	ation
Batch: IELLERIL (Suspected)	Started:	Reason:	Stopped: Unspecified psychosi	•
Oral application	200.0 Milli		Oral	S
Batch:	Started: 29/05/1		Stopped: 10/07	/1080
aboratory Investigatio Date Type	ns: Range Date Tested	Result		Details
	<u> </u>	<u> </u>		
dditional Information:				
ort Run: 01/06/2007 02:43PM	Database: pusime02	ADRS004		Page 21 of 393



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
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 Case Number:
 61767
 Seq: 1
 Gender: M

 Reported:
 01/08/1989
 Weight:
 85.00

 Hospitalisation:
 Age: 33Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u>teaction Details.</u>			
Preferred Term	Severity	Report Description	Treatment
Dyspepsia			No problems when taking melleril, reaction occurred when aldazine started

Medicine Details:

ALDAZINE (Suspected)

Reason:

300.0 Milligram Daily

Batch: Started: 01/01/1989 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 63260 Seq: 1 Gender: F

Reported: 31/08/1989 Weight: 81.00
Hospitalisation: Hospitalisation prolonged Age: 72

Onset Date: 16/06/1989 **DOB:** 29/11/1916

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous			Topical steroids

Medicine Details:

MELLERIL (Suspected) Reason: Depression

Oral application 25.0 Milligram Daily Oral

Batch: Started: 10/06/1989 **Stopped:** 22/06/1989

Laboratory Investigations:

	<u> </u>				
Date	Туре	Range	Date Tested	Result	Details
	Histology				Skin biopsy, non-specific inflammation. a definite cause has not been identified but a drug eruption is possible.

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report D	etails:
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 Case Number:
 63467
 Seq: 1
 Gender: M

 Reported:
 27/11/1989
 Weight:

Hospitalisation:
Onset Date:
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Euphoric mood			

Medicine Details:

ALDAZINE (Suspected) Reason: Unspecifid affective psychosis

0.0

Batch: Started: 01/06/1989 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 63625 Seq: 1 Gender: M

Reported: 04/12/1989 Weight: 69.00 Hospitalisation: Age: 34

Onset Date: 13/07/1989 **DOB**: 13/12/1954

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Details.			
	Preferred Term	Severity	Report Description	Treatment
	Aggression			
	Hyponatraemia			

Medicine Details:

Medicine Details.				
MELLERIL (Suspected)		Reason:		
Tablet	50.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/1972	Sto	opped:	
TEGRETOL (Suspected)		Reason: Other8	Runspecified epilepsy	
Tablet	800.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/1975	Sto	opped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Electrolytes				27/6/89 8/9/89 20/10/89 sodium 129 mmol/l 135 137 (135-146) chloride 96 mmol/l 102 104 (98-106)

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.

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Case Number: 63636

Reported: 22/11/1989

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M **Weight:** 70.00

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

lospitalisation:					Age: 60		
Onset Date:					DOB: 05/0	4/1929	
Outcome: Not yet rece	overed			Caus	sality : Cau	sality possi	ble
eaction Details:		•					
Preferred Term	Severity		Report De	scription		Treatmen	
Cataract					Melleril on nocte	dose reduce	d to 50 mg
Cataract subcapsular							
Medicine Details: MELLERIL (Suspected)			Reason:	Unspecified psych	nosis		
	300	.0 Milligram	Daily	Chiepodinou poyon			
Batch:	Started:			Stopped:			
CHLORPROMAZINE HYDROCHL	ORIDE (Suspected)		Reason:				
	500	0.0 Milligram	Daily				
Batch:	Started:			Stopped:			
Laboratory Investigation		Fested Re	esult		Details		
1		•	<u>'</u>				
Additional Information	:						
eport Run: 01/06/2007 02:43PM	Database: pusime02	!	ADRS0	04		Page 26	of 393



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 63845
 Seq: 1
 Gender:
 F

 Reported:
 21/12/1989
 Weight:

Hospitalisation: Age: 70Y
Onset Date: 21/11/1989
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
	Bone marrow failure			Observation
	Pancytopenia			

Medicine Details:

CLINORIL (Suspected)		Reason: Other disturbance of sensation	
	300.0 Milligram	Daily	
Batch:	Started: 01/05/1989	Stopped: 28/11/1989	
MOGADON (Suspected)		Reason: Specific disorders of sleep	
	2.5 Milligram	Daily	
Batch:	Started:	Stopped:	
MELLERIL (Suspected)		Reason:	
	25.0 Milligram	Daily	
Batch:	Started:	Stopped:	ļ

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				1 13/12/89 8/12/89 20/12/89 21/12/89 range hb: 9.7 10.2 11.0 11.1 (11.5-16.5) wcc: 1.8 1.7 1.5 1.7 (4.0-11.0) plts: 43 36 43 45 (150-400) 19/12/89 - bone marrow report: active cellular marrow with marked left &
	Misclassified at				Shift in myeloid series.

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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
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Case Number: 64290 Seq: 1 Gender: F

 Reported:
 06/02/1990
 Weight:
 65.00

 Hospitalisation:
 Age:
 80Y

Onset Date: 04/12/1989 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Botans.				
	Preferred Term	Severity	Report Description	Treatment	l
	Hepatic function abnormal				l
	Malaise				l
	Pyrexia			Cessation of all medication.	l

Medicine Details:

PARNATE (Suspected)	•	Reason:	Depression	
Tablet	10.0 Milligram	Daily		Oral
Batch:	Started: 08/11/1989		Stopped:	
PARNATE (Suspected)	·	Reason:	Depression	
Tablet	50.0 Milligram	Daily		Oral
Batch:	Started:		Stopped:	05/12/1989
NOCTEC (Suspected)	·	Reason:	Specific disord	lers of sleep
Capsule	1.0 Dose Unspecifi	ied Daily		Oral
Batch:	Started: 25/10/1989		Stopped:	06/12/1989
MELLERIL (Suspected)	·	Reason:	Otr spec symp	psychopathol nec
Tablet	50.0 Milligram	Daily		Oral
Batch:	Started: 27/10/1989		Stopped:	20/11/1989

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Bili alp ast ggt glucose ld 11/12/89 52.9 umol/l 193 u/l 890 u/l 399 u/l 15.1 umol/l 452 u/l 15/12/89 71.3 umol/l 175 u/l 445 u/l 365 u/l 06/02/90 now normal

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	64290	Seq: 1		Gender	:: F
Reported:	06/02/1990			Weight	: 65.00
Hospitalisation:				Age	: 80Y
Onset Date:	04/12/1989			DOE	3:
Outcome:	Recovered			Causality	: Causality possible
Reaction Detai	ils:				
Medicine Det					
COLOXYL WITH S	ENNA (Suspected)		Reason:	Constipation	
Tablet		2.0 Dose	Unspecified Daily	Oral	
Batch:		Started: 01/11/198	,9	Stopped: 06/12/198	39
ATIVAN (Suspecte	ed)		Reason:	Otr spec symp psychopa	thol nec
Tablet		10.0 Milligr	ram Daily	Oral	
Batch:		Started: 20/11/198	9	Stopped: 06/12/198	39
l abayatayı lu					
Laboratory in	vestigations:				
Additional In	formation:				
Auditional III	omation.				

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	64559	Seq:	1			Gend	ler: F	
	23/02/199	_				Weig	ht:	
spitalisation:						A	ge: 46Y	
Onset Date:	13/02/199	0					OB:	
Outcome:	Recovered	d				Causal	ity: Causality pro	bable
action Deta							•	
	ed Term	Se	everity	Rep	ort Desc	ription	Treatme	ent
ninitis								
edicine Det								
IELLERIL (Suspo Tablet	ected)		75.0 Milli		ason:	Oral		
Batch:		c	75.0 Milli tarted: 13/02/19		Total	Stopped:		
aborato <u>ry lı</u>								
Date	Туре	Range	Date Tested	Result		Г	Details	
dditional In	formatio	. .						
aditional in	ioiiiiatioi	1.						
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rt Run: 01/06/20	07 02:43PM	Database: ρι	usime02		ADRS004		Page 30	of 393



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Repo Hospitalisa Onset I	Date: 22/01/199 ome: Not yet re	90	ı ; 1					С	DC	nt: e: 45\ B:	/ usality p	ossible	
	referred Term	5	Severity		Rep	ort Des	crip	tion			Treati	nent	
Extrapyram Hypertonia Hypokinesia Hypotensio	n												
	malignant synd	rome											
Pyrexia Somnolenc	e									Parace parlode	tamol, he	parin,	
Medicine HALOPERIO	Details:					ason:							
			5.0	Milligram		Daily							
Bat			Started:				S	topped:					
THIORIDAZ	INE HYDROCHLOF	RIDE (Suspecte				ason:							
Bat			50.0 Started:	Milligram		Daily	s	topped:					
CLONAZEP	AM (Suspected)					ason:							
Bat	ch:		2.0 Started:	Milligram		Daily	s	topped:					
Laborato Date	ry Investigat	ions: Range	Date Test	ed F	Result					etails			
	Biochemistry					Creat 24/1/90	ck 59	22/1/90 348	83 *note	1190 ck-mb=2	23/1/90 5 22 u/l, 1.89		00 ck.
Additiona	al Informatio	n:											

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Reported: 27/02/1990 spitalisation: Onset Date: 25/10/1989 Outcome: Recovered action Details: Preferred Term	Seq: 1	Repo	DC	ht: ge: 86Y DB: ity: Causality possible Treatment
Spitalisation: Onset Date: 25/10/1989 Outcome: Recovered action Details: Preferred Term	Severity	Repo	Aç D(Causali	ge: 86Y DB: ity: Causality possible Treatment
Outcome: Recovered action Details: Preferred Term	Severity	Repo	D(Causali	DB: ity: Causality possible Treatment
Outcome: Recovered action Details: Preferred Term	Severity	Repo	Causali	ty: Causality possible Treatment
Action Details: Preferred Term	Severity	Repo		Treatment
Preferred Term	Severity	Repo	rt Description	
	Severity	Repo	rt Description	
ypotension				
				Ceased therapy
edicine Details: CARDIPRIN 100 (Other drug)		Reas	on:	
, σ,	0.0			
Batch:	Started:		Stopped:	
MELLERIL (Suspected)		Reas	on: Unspecified psychosis	i
Tablet	500.0 Mi	illigram	Daily Oral	
Batch:	Started: 24/10/	/1989	Stopped: 25/10/	1989
SERENACE (Suspected)		Reas	on: Unspecified psychosis	3
Tablet	5.0 Mi	illigram	Daily Oral	
Batch:	Started:		Stopped: 25/10/	1989
.aboratory Investigations: Date Type Range	Date Tested	Result		Petails

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
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Case Number: 67336 Seq: 1 Gender: M

Reported: 31/07/1990 Weight: 51.00 Hospitalisation: Age: 82Y

Onset Date: 21/07/1990 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Dotano.			
Preferred Term	Severity	Report Description	Treatment
Rash erythematous			Ceased serenace,started application of topical celestone-m ointment daily and paraffin cream-bd-to rash.

Medicine Details:

SERENACE (Suspected)		Reason: Unspecified psychosis
Oral application	10.0 Milligram	Daily Oral
Batch:	Started: 11/07/1990	Stopped:
SERENACE (Suspected)		Reason: Unspecified psychosis
Oral application	15.0 Milligram	Daily Oral
Batch:	Started: 12/07/1990	Stopped : 24/07/1990
TRYPTANOL (Suspected)		Reason: Incontinence of urine
	30.0 Milligram	Daily
Batch:	Started: 19/03/1990	Stopped : 17/07/1990
MELLERIL (Suspected)		Reason: Disturbance of sleep
	50.0 Milligram	Daily
Batch:	Started: 05/06/1990	Stopped: 11/07/1990

Laboratory Investigations:

<u> </u>	y mroonga				
Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
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Case Number: 67886 Seq: 1 Gender: M

Reported: 18/10/1990 Weight: 115.00 Hospitalisation: Age: 38Y

Onset Date: 17/10/1990 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

 <u> </u>			
Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			

Medicine Details:

McGicilic Details.					
MELLERIL (Suspected)		Reason:	Otr spec symp psychor	pathol nec	
Oral application	500.0 Milligram	Daily	Oral		
Batch:	Started: 09/10/1990		Stopped: 11/10/1	990	
MELLERIL (Suspected)		Reason:	Otr spec symp psychor	pathol nec	
Oral application	200.0 Milligram	Daily	Oral		
Batch:	Started: 12/10/1990		Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

R	Δ	n	^	rt	D	eta	il	le:
	G	u	u		_	CLO		

 Case Number:
 67927
 Seq: 1
 Gender:
 F

 Reported:
 22/10/1990
 Weight:
 80.00

Hospitalisation:
Onset Date: 24/09/1990
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

toaction Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Confusional state			On investigation no medical cause of her confusion were found
Hallucination			

Medicine Details:

FELODIPINE (Other drug)			Reason:	Essential beni	gn hypertension	
	10.0	Milligram	Daily			
Batch:	Started:			Stopped:	CONTIN	
ALLOPURINOL (Suspected)			Reason:			
	300.0	Milligram	Daily			
Batch:	Started:			Stopped:	02/10/1990	
PHENIRAMINE AMINOSALICYLATE (Susp	ected)		Reason:			
	75.0	Milligram	Daily			
Batch:	Started:			Stopped:	24/09/1990	
DICLOFENAC SODIUM (Suspected)			Reason:			
	100.0	Milligram	Daily			
Batch:	Started:			Stopped:	02/10/1990	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Renal function: creatinine=0.12

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:			
Case Number: 67927	Seq: 1	Gender: F	
Reported: 22/10/199	0	Weight: 80.	00
Hospitalisation:		Age : 78	
Onset Date: 24/09/199	0	DOB:	
Outcome: Recovered		Causality: Ca	usality possible
Reaction Details:		·	, ,
Medicine Details:			
THIORIDAZINE HYDROCHLOR	IDE (Suspected)	Reason:	
	30.0 Milligram	Daily	
Batch:	Started:	Stopped : 26/09/1990	
	_		
Laboratory Investigat	ions:		
Additional Information	า:		

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 68549 Seq: 1 Gender: F

Reported: 30/11/1990 Weight: 70.00 Hospitalisation: Age: 70Y

Onset Date: 26/10/1990 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	todotion Botano.				
	Preferred Term	Severity	Report Description	Treatment	
	Hepatitis cholestatic				
	Rash				

Medicine Details:

MIANSERIN HYDROCHLORIDE (Other drug) Reason: Depression

120.0 Milligram Daily

Batch: Started: 01/08/1990 Stopped: CONTIN

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec

20.0 Milligram Daily

Batch: Started: 01/09/1990 Stopped: 04/11/1990

Laboratory Investigations:

Date	Туре	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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

`aca Numb		_						_	_		
	er: 68664	Seq:	1					Gender:	F		
-	ed: 04/12/1990							Weight:			
ospitalisatio								Age:			
	ite: 25/08/1990						_	DOB		-1:4. · · ·	.lale
	ne: Not yet reco	overed					С	ausality:	Caus	ality poss	sible
action De	etails: ferred Term	Cox	(ority)		Donort	Dogori	ntion			Trootmo	o t
lallucination	ierrea rerm	Sev	erity,	Visual and	Report					Treatme	11
			1		,			'			
			10.0	Millian	Reaso		on.				
TEMAZEPAM	(Suspected)	64-		Milligram		s necess					
TEMAZEPAM Batch	(Suspected)	Sta	10.0 f	Milligram	A	s necess	ary Stopped:				
TEMAZEPAM Batch	(Suspected)	Sta	arted:		Reason	s necess	Stopped:				
TEMAZEPAM Batch	(Suspected) : spected)		arted:	Milligram Millilitre	Reason	s necess	Stopped:				
MYLANTA (Su Batch	(Suspected) : spected)		20.0		Reason	n: s necess	Stopped:				
TEMAZEPAM Batch MYLANTA (Su Batch	(Suspected) : spected)		20.0 I		Reason A	n: s necess	Stopped:				
TEMAZEPAM Batch MYLANTA (Su Batch	(Suspected) :: :: :: :: :: :: :: :: :: :: :: :: ::	Sta	20.0 I	Millilitre	Reason A	n: as necess n: as necess n:	Stopped:				
TEMAZEPAM Batch MYLANTA (Su Batch MADOPAR Q Batch	(Suspected) :: :: :: :: :: :: :: :: :: :: :: :: ::	Sta	20.0 arted: 20.0 arted:	Millilitre	Reason A	n: s necess n: eaily	Stopped: ary Stopped:				
TEMAZEPAM Batch MYLANTA (Su Batch MADOPAR Q Batch	(Suspected) : ispected) : (Suspected)	Sta	20.0 farted: 20.0 farted:	Millilitre	Reason Reason ecified D	n: s necess n: eaily	Stopped: ary Stopped:				
TEMAZEPAM Batch MYLANTA (Su Batch MADOPAR Q Batch	(Suspected) : ispected) : (Suspected) : E HYDROCHLORID	Sta Sta DE (Suspected)	20.0 farted: 20.0 farted:	Millilitre Dose Unspe	Reason Reason ecified D	n: s necess n: aily n: aily	Stopped: ary Stopped:				
Batch MYLANTA (Su Batch MADOPAR Q Batch THIORIDAZIN	(Suspected) : ispected) : (Suspected) : E HYDROCHLORID	Sta Sta DE (Suspected) Sta	20.0 arted: 20.0 arted: 2.0 arted: 75.0	Millilitre Dose Unspe	Reason Reason ecified D	n: s necess n: aily n: aily	Stopped: ary Stopped: Stopped:				
Batch MYLANTA (Su Batch MADOPAR Q Batch THIORIDAZIN	(Suspected) : ispected) : (Suspected) : E HYDROCHLORID	Sta Sta Sta Sta Sta Sta Sta Ons:	20.0 arted: 20.0 arted: 2.0 arted: 75.0	Millilitre Dose Unspe	Reason A Reason D Reason D	n: s necess n: aily n: aily	Stopped: ary Stopped: Stopped:	Deta	ils		

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:				
Case Number: 68664 Reported: 04/12/1990 Hospitalisation: Onset Date: 25/08/1990 Outcome: Not yet recovered Reaction Details:	Seq: 1		Gender: Weight: Age: DOB: Causality:	
Madiaina Datailas				
Medicine Details: FAMOTIDINE (Suspected)		Reason:		
1 Ame 1 Bitte (Guspesteu)	40.0 Milligram	Daily		
Batch:	Started:		Stopped:	
Laboratory Investigations:				
Additional Information:				

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 68970
 Seq: 1
 Gender: F

 Reported:
 03/01/1991
 Weight:

Hospitalisation:
Onset Date: 31/05/1990
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Dantrolene, levodopa & bromocriptine

Medicine Details:

RANITIDINE (Other drug)		Re	ason:		
	300.0	Milligram	Daily		
Batch:	Started:			Stopped:	CONTIN
TEMAZEPAM (Other drug)		Re	ason:		
	20.0	Milligram	Daily		
Batch:	Started:			Stopped:	30/05/1990
COLOXYL (Other drug)		Re	ason:		
	2.0	Dose Unspecified	d Daily		
Batch:	Started:			Stopped:	CONTIN
HYDROXYCHLOROQUINE SULPHA	TE (Other drug)	Re	ason:		
	400.0	Milligram	Daily		
Batch:					

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	68970	Seq: 1				Gender:	F
Reported:	03/01/1991					Weight:	
lospitalisation:						Age:	86Y
Onset Date:	31/05/1990					DOB:	
Outcome:	Recovered				Ca	ausality:	Causality possible
eaction Detai	ils:						
Medicine Det				Decer			
FOLIC ACID (Other	r arug)	F 0	Milliarom	Reason:			
D-4-b-			Milligram	Daily	04	00/05/4000	
Batch:	(DBOCHLODIDE (C.,	Started:		Decem	Stopped:	29/05/1990	
I HIORIDAZINE HI	DROCHLORIDE (Su		Milligram	Reason:			
Patch:		Started:	Willigram	Daily	Stopped:	31/05/1000	
Batch:		Starteu.			Stoppeu.	3 1/03/ 1990	
Laboratory Ir	vestigations:						
,	3						
Additional In							
- the date of onse	t is not necessarily	accurate but indi	cates that o	onset occurred	sometime d	uring the r	nonth.
						armig and i	
						army are r	
						armig are r	

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Hospitalisati Onset D	ted: 23/01/199 on: ate: me: Unknown		1		W e	DOB:	13Y
	eferred Term	Sev	erity	Repo	rt Description		Treatment
Dyskinesia							
Weight incre	ased						
Medicine	Dotaile:						
MELLERIL (S				Reas	son:		
			0.0				
Batc	h:	Sta	rted:		Stopped:		
ZASTEN (Sus	spected)			Reas	son:		
		-	0.0				
Batc		Sta	rted:	Reas	Stopped:		
THEO-DUR (S	ouspecteu)		800.0 Milli		Daily		
Batc	h:	Sta	rted:	gram	Stopped:		
INTAL (Suspe				Reas			
			2.0 Dos	e Unspecified	Daily		
Batc	h:	Sta	rted:		Stopped:		
Labaratar	v lovosticot	lanai					_
Date	y Investigat Type		Date Tested	Result		Detai	ils
24.0	. , , , ,	. tuge	24.0 . 00.04	. 1000.11		2010.	
Additiona	l Informatio	n:					

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:			
Case Number: 69227 Reported: 23/01/1991 Hospitalisation: Onset Date: Outcome: Unknown Reaction Details:	Seq: 1	Gender: Weight: Age: DOB: Causality:	13Y
Madiata Batatla			
Medicine Details: PREDNISOLONE (Suspected)		Reason:	
PREDNISOLONE (Suspected)	12.0 Milligram	Alternate days	
Batch:	Started:	Stopped:	
Laboratory Investigations:			
Additional Information:			

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

	70577	Seq: 1			Gender:	M
	: 01/05/1991				Weight:	
spitalisation					Age:	
-	: 19/03/1991				DOB:	
	Unknown			C		Causality possible
action Deta					,	
	red Term	Severity	Repor	t Description		Treatment
riapism						
	4.41.					
ledicine De ALDAZINE (Susp			Reaso	on: Unspecified ps	vchosis	
Tablet	ootouj	350.0		Daily	Oral	
Batch:		Started: 18/0		-	19/03/199 ²	l
	NATE (Suspected)		Reaso			
		500.0 I	Milligram I	Daily		
		Started:		Stopped:		
Batch:						
	nvestigations	:				
		: ange Date Teste	ed Result		Detai	ls

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 70840 Seq: 1 Gender: M

Reported: 15/05/1991 Weight: 63.00 Hospitalisation: Age: 64Y

Onset Date: 23/04/1991 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	toaction Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Neutropenia			
	Thrombocytopenia			

Medicine Details:

Medicine Details.					
MELLERIL (Suspected)		Reason: Otr	spec symp psychor	pathol nec	
Tablet	125.0 Milligram	Daily	Oral		
Batch:	Started: 02/12/1986		Stopped: 23/04/1	991	
CLONAZEPAM (Suspected)		Reason:			
	2.0 Milligram	Daily			
Batch:	Started: 28/02/1991		Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils	2.5-7.5	22/04/1991	1.4	
	Neutrophils	2.5-7.5	26/04/1991	1.4	
	Neutrophils	2.5-7.5	02/05/1991	2.2	
	Neutrophils	2.5-7.5	20/05/1991	2.2	
	Neutrophils	2.5-7.5	29/05/1991	1.9	
	Neutrophils	2.5-7.5	03/07/1991	1.2	
	Platelets	150-400	22/04/1991	90	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 70840
 Seq: 1
 Gender: M

 Reported:
 15/05/1991
 Weight:
 63.00

Hospitalisation:
Onset Date: 23/04/1991
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

		- 0:		
MELLERIL (Suspected)		Reason: Otr spec	symp psychopathol	nec
Tablet	125.0 Milligram	Daily	Oral	
Batch:	Started: 02/12/1986	Stopp	ed: 23/04/1991	
CLONAZEPAM (Suspected)		Reason:		
	2.0 Milligram	Daily		
Batch:	Started: 28/02/1991	Stopp		CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets	150-400	26/04/1991	80	
	Platelets	150-400	02/05/1991	210	
	Platelets	150-400	20/05/1991	ADEQUATE	
	Platelets	150-400	29/05/1991	75	

Additional Information:

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Case Number: 71244

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Weight: Age: 38Y DOB: Causality: Causality possible In Treatment Given an intracavernosa in aramine without effect, take to theatre, had a winter shu inserted and penis drained procedure repeated 23/3/9 procedure repeated 23/3/9 CONTIN Poped: CONTIN
Causality: Causality possible Treatment Given an intracavernosa in aramine without effect. take to theatre, had a winter shu inserted and penis drained procedure repeated 23/3/9 procedure repeated 23/3/9 pped: CONTIN pped: CONTIN pped: CONTIN
Given an intracavernosa in aramine without effect. take to theatre, had a winter shuinserted and penis drained procedure repeated 23/3/9 CONTIN pped: CONTIN pped: CONTIN pped: CONTIN
Given an intracavernosa in aramine without effect. take to theatre, had a winter shu inserted and penis drained. procedure repeated 23/3/9 CONTIN pped: CONTIN pped: CONTIN pped: CONTIN CONTIN CONTIN
Given an intracavernosa in aramine without effect. take to theatre, had a winter shu inserted and penis drained. procedure repeated 23/3/9 CONTIN pped: CONTIN pped: CONTIN pped: CONTIN CONTIN CONTIN
pped: CONTIN pped: CONTIN CONTIN CONTIN CONTIN CONTIN
pped: CONTIN pped: CONTIN pped: CONTIN
pped: CONTIN pped: CONTIN pped: CONTIN
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pped: CONTIN
Details
Details

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report D	Details:
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 Case Number:
 71265
 Seq:
 1
 Gender:
 M

 Reported:
 07/06/1991
 Weight:
 60.00

 Hospitalisation:
 Age:
 35Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	l
Urticaria			Promethazine 30mg daily.	l

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspe	ected)		Reason:	Depression	
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started: 07/	05/1991		Stopped:	
THIORIDAZINE HYDROCHLORIDE (Sus	pected)		Reason:	Depression	
Oral application	100.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
NAPROSYN (Suspected)			Reason:		
	750.0	Milligram	Daily		
Batch:	Started: 05/	06/1991		Stopped:	
AUGMENTIN FORTE (Suspected)			Reason:		
	3.0	Dose Unspe	cified Daily		
Batch:	Started: 05/	06/1991		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report	Details:
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Case Number: 71883 Seq: 1 Gender: M

Reported: 28/06/1991 Weight:

Hospitalisation: Age: 19Y
Onset Date: 20/05/1991
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure		Ejaculatory problems	

Medicine Details:

MODECATE (Suspected) Reason:

Injection 25.0 Milligram Fortnightly Intramuscular

Batch: Started: L TERM Stopped: CONTIN

ALDAZINE (Suspected) Reason: Unspecified schizophrenia

150.0 Milligram Daily

Batch: Started: 16/05/1991 **Stopped:** 20/05/1991

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 71950
 Seq:
 1
 Gender:
 M

 Reported:
 02/07/1991
 Weight:

Hospitalisation: Age: 36Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term Severity		Report Description	Treatment
Dystonia		Dystonic reaction acute	
Erectile dysfunction		Erection failure	
Libido decreased		Loss of libido	
Tardive dyskinesia			

Medicine Details:

MELLERIL (Suspected)		Reason: Unsp	ecified psychosis	
Tablet	300.0 Milligram	Daily	Oral	
Batch:	Started: 01/08/1990	s	topped: 28/02/19	991
MODECATE (Suspected)		Reason: Unsp	ecified psychosis	
	12.5 Milligram	Daily		
Batch:	Started: 01/09/1990	s	topped:	02W
LITHIUM CARBONATE (Suspected)		Reason:		
	12.5 Milligram	Daily		
Batch:	Started: 01/09/1990	S	topped:	02W

Laboratory Investigations:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 72181
 Seq: 1
 Gender:
 F

 Reported:
 07/08/1991
 Weight:

Hospitalisation:
Onset Date: 21/07/1991
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.	dotton Botanoi							
Preferred Term	Severity	Report Description	Treatment					
Dysphagia			Phenergan 20mg, prednisolone 50mg, reducing to 5mg, nilstat oral drops 1ml					
Rash maculo-papular		Rash over face and trunk						
Erythema multiforme								

Medicine Details:

PANADOL (Other drug)	Reason:				
Tablet	500.0 Milligram As	necessary Oral			
Batch:	Started: 05/07/1991	Stopped:			
TRIPRIM (Suspected)	Reason:	Othr diseases of urinary tract			
Tablet	1.0 Dose Unspecified Dai	ily Oral			
Batch:	Started: 12/07/1991	Stopped: 18/07/1991			
ERYC (Suspected)	Reason:	Cellul&absc otr,mult&nos sites			
Capsule	8.0 Dose Unspecified Dai	ily Oral			
Batch:	Started: 18/07/1991	Stopped: 21/07/1991			
MELLERIL (Suspected)	Reason:				
Tablet	1.0 Dose Unspecified Dai	ily Oral			
Batch:	Started: 13/07/1991	Stopped : 21/07/1991			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking salt tablets 600mg bd. no known allergies.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 72435 Seq: 1 Gender: M
Reported: 21/08/1991 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction betails.			
Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Severe		Hamilton's sunscreen spf 15+ applied 3-4 times daily.
Dermatitis bullous		Blistering on back of hands	
Cheilitis		Cracked lips	
Pruritus			

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Su	CHLORPROMAZINE HYDROCHLORIDE (Suspected)			Unspecified schizophren	a
Oral application	600.0	Milligram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	
THIORIDAZINE HYDROCHLORIDE (Suspected)		Reason: Unspec		Unspecified schizophren	a
Tablet	800.0	Milligram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	
CARBAMAZEPINE (Suspected)	Reason:				
Tablet	800.0	Milligram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	
BENZTROPINE MESYLATE (Suspected)	Reason:				
Tablet	2.0	Milligram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient exposed to chlorpromazine approx 18 months without effects described above.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 72526 Seq: 1 Gender: F

Reported: 22/08/1991 Weight: 85.00 Hospitalisation: Age: 53Y

Onset Date: 28/05/1991 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia		Loss of hair	
Fatigue		Tired	
Constipation			
Dry mouth			
Red blood cell sedimentation rate i			
Thirst			
Vertigo			

Medicine Details:

STELAZINE (Other drug)		Reason:		
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started: 01/05/1991	Stopp	ed:	
TRYPTANOL (Other drug)		Reason:		
Tablet	25.0 Milligram	Daily	Oral	
Batch:	Started: 01/05/1991	Stopp	ed:	
MODURETIC (Other drug)		Reason: Unspecifie	d schizophrenia	
	25.0 Milligram	Alternate weeks		
Batch:	Started: 01/01/1985	Stopp	ed:	
MELLERIL (Suspected)		Reason:		
Tablet	250.0 Milligram	Daily	Oral	
Batch:	Started: 01/05/1991	Stopp	ed: 03/06/1991	

Laboratory Investigations:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 72776
 Seq: 1
 Gender:
 F

 Reported:
 11/09/1991
 Weight:
 74.00

 Hospitalisation:
 Age: 39Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

- 100.01.01. = 01001			
Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction	Severe	Sunburn, blistering hands, neck, ankle.	Betamethasone 0.05% cream.
Oedema peripheral		Swelling of hands, ankles	

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (S	suspected)		Reason:	Other atyp for	ns schizophrenia
Oral application	1.2	Gram	Daily		Oral
Batch:	Started:		L TERM	Stopped:	11/09/1991
HALOPERIDOL (Suspected)			Reason:	Other atyp for	ns schizophrenia
Oral application	30.0	Milligram	Daily		Oral
Batch:	Started:		L TERM	Stopped:	11/09/1991
CHLORPROMAZINE HYDROCHLORIDE (S	suspected)		Reason:	Other atyp for	ns schizophrenia
Oral application	800.0	Milligram	Daily		Oral
Batch:	Started: 11	/09/1991		Stopped:	
THIORIDAZINE HYDROCHLORIDE (Suspe	cted)		Reason:		
Oral application	800.0	Milligram	Daily		Oral
Batch:	Started: 11	/09/1991		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had long term exposure to chlorpromazine without severe reaction until now.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 72798
 Seq: 1
 Gender:
 F

 Reported:
 03/09/1991
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Retinal pigmentation			

Medicine Details:

Micalcinic Details.			
LARGACTIL (Suspected)		Reason:	
Oral application	500.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1977	Stopped:	02/11/1988
MELLERIL (Suspected)		Reason:	
Oral application	600.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1978	Stopped:	02/11/1988

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 72799
 Seq: 1
 Gender:
 F

 Reported:
 03/09/1991
 Weight:

Hospitalisation: Age: 39Y
Onset Date: 15/08/1991
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cataract		Eye deterioration.	

Medicine Details:

MODURETIC (Suspected)	F	Reason:	
Injection	100.0 Milligram	Weekly	Intramuscular
Batch:	Started: 01/01/1978	Stopped:	24/04/1989
LARGACTIL (Suspected)	F	Reason:	
Oral application	500.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1977	Stopped:	12/11/1988
MELLERIL (Suspected)	F	Reason:	
Oral application	600.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1978	Stopped:	12/11/1988
SERENACE (Suspected)	F	Reason:	
	60.0 Milligram	Daily	
Batch:	Started: 01/01/1989	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

On 15 aug 91 further eye deterioration noted, bilateral atrophic retinal changes, corneal haze (both corneas), anterior star shaped opacity with sub- ephithelial deposits on surface of both lenses. 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 73409 Seq: 1 Gender: F

 Reported:
 09/10/1991
 Weight:
 42.00

 Hospitalisation:
 Age:
 81Y

Onset Date: 05/06/1991 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Febrile, shivering, agitated	

Medicine Details:

PANADOL (Other drug)		Rea	son:	
Tablet	2.0	Dose Unspecified	As necessary	Oral
Batch:	Started:		Stopped:	
LANOXIN PG (Other drug)		Rea	son:	
Oral application	1.0	Dose Unspecified	Daily	Oral
Batch:	Started:	L TERM	Stopped:	04/06/1991
SENOKOT (Other drug)		Rea	son:	
Oral application	2.0	Dose Unspecified	Alternate days	Oral
Batch:	Started:	L TERM	Stopped:	
SERENACE (Suspected)		Rea	son: Otr spec sym	p psychopathol nec
Injection	2.0	Milligram	1 time	Intramuscular

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Misclassified at				Ck visc to 500's

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

	73409	Seq: 1		Gender:	F
Reported:	09/10/1991			Weight:	42.00
Hospitalisation:				Age:	81Y
Onset Date:	05/06/1991			DOB:	
Outcome:	Recovered			Causality:	Causality possible
Reaction Detai	ls:				
Medicine Det	ails:				
THIORIDAZINE HY	DROCHLORIDE (Susp	pected)	Reason:	Paranoid type schizophren	nia
Tablet		25.0 Milligrar	n Daily	Oral	
Batch:		Started: 04/06/1991		Stopped: 05/06/199	1
Laboratory In	vestigations:				
Laboratory In	vestigations:				
Laboratory In	vestigations:				
Laboratory In	vestigations:				
Laboratory In	vestigations:				
Laboratory In	vestigations:				
Laboratory In	vestigations:				
Laboratory In	vestigations:				
Laboratory In					

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 73656
 Seq: 1
 Gender: M

 Reported:
 11/09/1991
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 06/08/1991
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Jaundice			
Neutropenia			Gentamicin and piperacillin

Medicine Details:

BACTRIM DS (Suspected)	ed) Reason:					
	2.0 Dose Unspe	ecified Daily				
Batch:	Started:		Stopped:		02W	
VOLTAREN (Suspected)		Reason:	Osteoarthritis			
	100.0 Milligram	Daily				
Batch:	Started: 01/01/1988		Stopped:	08/08/1991		
MELLERIL (Suspected)		Reason:				
	10.0 Milligram	Daily				
Batch:	Started: 01/06/1991		Stopped:	08/08/1991		
AMOXYCILLIN SODIUM (Suspected)		Reason:	Pyrexia of unk	nown origin		
	1.5 Gram	Daily				
Batch:	Started: 05/08/1991		Stopped:	08/08/1991		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				Wcc 0.7 neut less 5%

Additional Information:

Mild g.r.f. creat. 0.26 Ihr renal failure. 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Detail	s:						
Hospitalisation: Onset Date:	11/09/1991 Admitted to hospi 06/08/1991 Recovered	Seq: 1			Gender: Weight: Age: DOB: Causality:	94Y	
veaction Detai	113.						
Medicine Det							
PAROVEN (Suspe	cted)	1.0	Rea Dose Unspecified	son: Daily			
Batch:		Started:	· 		ed: 08/08/1991		
Laboratory In	vestigations:						
Additional Inf Mild g.r.f. creat. 0.2 year. the dosage s		the dosage sta	art date is not accu e but indicates that	urate but indicate t start occurred s	es that start oc cometime durin	curred sometime durirng the month.	ng the

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Repo	nber: 74392 orted: 26/11/199 tion: Admitted	1					83Y	
	ome: Recovere	d				DOB: alitv:	Causality possible	
eaction I		-					у розония	
	referred Term	Se	everity	Rep	ort Description		Treatment	
granulocy	rtosis					Ce	ftriaxone iv, fluid placement.	
yrexia						ier	nacement.	
	Details:						_	
LANOXIN (S	Suspectea)		0.0	Rea	ason:			
Bat	tch:	s	Started:		Stopped:			
LASIX (Sus			nuitou.	Rea	ason:			
	,		0.0					
Bat	tch:	S	Started:		Stopped:			
SLOW-K (S	uspected)			Rea	ason:			
			0.0					
	tch:	S	Started:		Stopped:			
ALLOPURI	NOL (Suspected)			Rea	ason:			
			0.0					
Bat	tch:	S	Started:		Stopped:			
aborato	ry Investigat	ions:						
Date	Туре	Range	Date Tested	Result		Detai		
	White blood cells				White cell count of 1.0 x 10, marrow examination showe 14/11/1991 her white cell coneutrophiles.	d mvel	hout any neutrophiles. bone oid maturation arrest. by as 8.4 x 10/9/I with 73%	
Addition	al Informatio	n:			,			

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:			
Case Number: 74392 Reported: 26/11/1991 Hospitalisation: Admitted to Onset Date: Outcome: Recovered Reaction Details:	hospital	Gender: Weight: Age: DOB: Causality:	83Y
Medicine Details:			
MELLERIL (Suspected)	0.0	Reason:	
Batch:	Started:	Stopped:	
Laboratory Investigation	ons:		
Additional Information	:		

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 74599
 Seq: 1
 Gender: M

 Reported:
 04/12/1991
 Weight:

Hospitalisation: Age: 32Y
Onset Date: 01/11/1991
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	toaction Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Pruritus			
	Rash			

Medicine Details:

ROACCUTANE (Suspected)		Reason:	Other acne of	sebaceous glands
Capsule	0.0	Daily		Oral
Batch:	Started: 01/05/1991		Stopped:	28/11/1991
ALDAZINE (Suspected)		Reason:	Unspecified ps	sychosis
Tablet	400.0 Milligram	Daily		Oral
Batch:	Started: 29/10/1991		Stopped:	01/11/1991
RIVOTRIL (Suspected)		Reason:	Specific disord	ders of sleep
Oral application	2.0 Milligram	Daily		Oral
Batch:	Started: 29/10/1991		Stopped:	01/11/1991

Laboratory Investigations:

Date	Туре	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.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Numbe	r: 74688	Seq: 1		Ge	nder: F
Reporte	d: 07/12/1991			We	ight:
ospitalisatio	n:				Age: 38
Onset Dat	e:				DOB : 13/03/1953
	e: Unknown			Caus	ality: Causality possible
action Det					
	erred Term	Severity		ort Description	Treatment
Retinal pigmer	ntation		Pigmented mac	ula lesion.	
Medicine D				son:	
			Milligram	Daily	
Batch:		Started:		Stopped:	
.aboratory	Investigation	DNS: Range Date Test	ted Result		Details
	31				
Additional	Information	:			
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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

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 Details:

Preferred Term	Severity	Report Description	Treatment
Torsade de pointes			

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Su	uspected)	Reason: Unspe	ecified schizophrenia
Oral application	200.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1986	St	opped: 18/12/1991

DOTHIEPIN HYDROCHLORIDE (Suspected) Reason: Depression

150.0 Milligram Daily

Batch: Started: 01/01/1986 Stopped: 18/12/1991

Laboratory Investigations:

Date	Туре	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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:

Case Number: 75017 Seq: 1 Gender: M

Reported: 08/01/1992 Weight: 86.00 Hospitalisation: Age: 19Y

Onset Date: 05/01/1992 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	teaction Betails.			
	Preferred Term	Severity	Report Description	Treatment
	Rash maculo-papular		Rash on arms and legs	Promethazine
	Pruritus			

Medicine Details:

LITHICARB (Other drug)		Reason:		
Tablet	1.5 Gram	Daily	Oral	
Batch:	Started: 25/11/1991	St	opped:	
RIVOTRIL (Other drug)		Reason:		
Tablet	4.0 Milligram	Daily	Oral	
Batch:	Started: 27/11/1991	St	opped:	
ALDAZINE (Suspected)		Reason: Unspe	ecified psychosis	
Tablet	300.0 Milligram	Daily	Oral	
Batch:	Started: 03/01/1992	St	opped: 05/01/1992	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 75117 Seq: 1 Gender: F

Reported: 16/01/1992 Weight: 83.00 Hospitalisation: Age: 56Y

Onset Date: 05/12/1991 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Pruritus			
Rash			Teldane, ciproxin and betnovate.

Medicine Details:

vieuicine Details.			
TRYPTANOL (Other drug)		Reason: Depression	
Tablet	75.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1980	Stopped:	
AGON (Suspected)		Reason: Essential benign hypertensi	ion
	5.0 Milligram	Daily	
Batch:	Started : 15/08/1991	Stopped: 17/12/1991	
MELLERIL (Suspected)		Reason: Depression	
Oral application	75.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1980	Stopped:	

Laboratory Investigations:

Date	Туре	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.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Dana-41	75289	36	eq: 1					Gender:	F
-	29/01/19	92						Weight:	
spitalisation:								Age:	
Onset Date:								DOB:	
Outcome:	Recover	ed					С	ausality:	Causality possible
action Deta	ils:								
Prefer	red Term		Severity	╙	Repo	rt De	scription		Treatment
allucination				<u></u>					
ledicine Det			40.0		Reas	on: Daily			
Batch:			Started:	IVIIII	gram	Daily	Stopped:		CONTIN
POTASSIUM NOS	(Other drug	g)			Reas	on:	2 lale 4-41.		
			1.2	Grai		Daily			
Batch:			Started:			-	Stopped:		CONTIN
MIANSERIN HYDI	ROCHLORIC	DE (Suspected	l)		Reas	on:	Depression		
			20.0	Milli	gram	Daily			
Batch:			Started:				Stopped:	24/01/1992	<u> </u>
THIORIDAZINE H	YDROCHLO	RIDE (Suspec	ted)		Reas	on:	Depression		
			20.0	Milli	gram	Daily			
Batch:			Started:				Stopped:	24/01/1992	
aboratory lı	nvestins	ations:							
	Type	Range	Date Tes	ted	Result			Detai	S
Date				_					

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	75522	Seq:	1			G	ender: M		
Reported:	11/02/1992			Weight:					
ospitalisation:							Age : 89		
Onset Date:	11/06/1991						DOB : 23	/06/1901	
Outcome:	Unknown				Causality: Causality possible				
eaction Detai		•					T		
	ed Term	Sev	erity	Rep	ort Desc	cription		Treatmer	nt
Agitation									
Hallucination									
nsomnia Vlania									
Medicine Deta				Re	ason: [Depression			
TROZAO (Guspect	cuj		20.0 Milli		Daily	7CP1C33I011			
Batch:		Sta	Started: 04/06/1991			Stopped: 11/06/1991			
THIORIDAZINE HY	DROCHLORIDE (Suspected)		Re	ason:	•••			
			25.0 Milli	gram	Daily				
Batch:		Sta	rted: 04/06/19	991		Stopped: 0	9/06/1991		
_aboratory In	vestigations	s:							
			Date Tested	Result			Details		
Additional Inf	ormation:				1				
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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 75674 Seq: 1 Gender: F

Reported: 24/02/1992 Weight: 70.00
Hospitalisation: Age: 26Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

iteaction Details.			
Preferred Term	Severity	Report Description	Treatment
Benign hepatic neoplasm		Hepatic adenoma.	
Blood alkaline phosphatase increas			

Medicine Details:

DEPO-PROVERA (Suspected)		Reason: Irregular menstruation
	50.0 Milligram	Monthly
Batch:	Started: 01/10/1984	Stopped: 28/11/1991
EPILIM (Suspected)		Reason: Other&unspecified epilepsy
	1.2 Gram	Daily
Batch:	Started: 01/01/1981	Stopped: 31/01/1991
TEGRETOL (Suspected)		Reason: Other&unspecified epilepsy
	800.0 Milligram	Daily
Batch:	Started: 01/01/1982	Stopped: 31/01/1991
MELLERIL (Suspected)		Reason:
	60.0 Milligram	Daily
Batch:	Started: 01/01/1987	Stopped: 31/01/1991

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Mass detected on ultra sound abdomen organized therefore urinary tract infect.

Additional Information:

Patient was on depo-provera 150mg every 3 months. 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 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 start occurred sometime

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 75848
 Seq: 1
 Gender:
 F

 Reported:
 05/03/1992
 Weight:

Hospitalisation: Admitted to hospital **Age**: 81

Onset Date: 19/11/1991 **DOB:** 30/12/1909

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Low wwc	
Extrapyramidal disorder		Parkinsonism.	
Dementia			

Medicine Details:

MELLERIL (Suspected)		Reason:	
	30.0 Milligram	Daily	
Batch:	Started:		Stopped:
MELLERIL (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started: 19/11/1991		Stopped: 21/11/1991
AMITRIPTYLINE HYDROCHLORIDE	(Suspected)	Reason:	
	10.0 Milligram	Daily	
Batch:	Started:		Stopped:
CLONAZEPAM (Suspected)		Reason:	
	500.0 Microgram	Daily	
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells		20/11/1991	2.9	
	White blood cells		25/11/1991	4.8	

Additional Information:

See original report for other medication.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 76492 Seq: 1 Gender: F

Reported: 08/04/1992 Weight: 75.00
Hospitalisation: Admitted to hospital Age: 63Y
Onset Date: 13/02/1992 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Fluid restriction

Medicine Details:

THIORIDAZINE HYDROCHLORIDE	(Suspected)		Reason:	Paranoid type schizophrenia	
Tablet	50.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
OXAZEPAM (Suspected)			Reason:	Paranoid type schizophrenia	
Oral application	30.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
TEMAZEPAM (Suspected)			Reason:	Paranoid type schizophrenia	
Capsule	10.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium	137-145	13/02/1992	117	
	Sodium	137-145	14/02/1992	127	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:	Re	po	rt	De	tai	ls:
-----------------	----	----	----	----	-----	-----

Case Number: 76506 Seq: 1 Gender: F

 Reported:
 08/04/1992
 Weight:
 55.00

 Hospitalisation:
 Age:
 49Y

 Onset Date:
 26/03/1992
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Anxiety			
Confusional state			
Nausea			Haloperidol 10mg daily.
Vomiting			

Medicine Details:

PROZAC (Suspected)		Reason:	Depression	
Capsule	20.0 Milligram	Daily		Oral
Batch:	Started: 18/03/1992		Stopped:	21/03/1992
LITHIUM CARBONATE (Suspected)		Reason:	Depression	
	500.0 Milligram	Daily		
Batch:	Started: 15/03/1992		Stopped:	24/03/1992
MELLERIL (Suspected)		Reason:		
	25.0 Milligram	Daily		
Batch:	Started: 13/03/1992		Stopped:	24/03/1992

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 77126 Seq: 1 Gender: F
Reported: 18/05/1992 Weight:

Hospitalisation: Age: 82Y

Onset Date: 03/05/1992 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancytopenia			

Medicine Details:

NEO-CYTAMEN (Suspected)		Reason:		
Injection	0.0		Intravenous	
Batch:	Started:	L TERM	Stopped:	
MELLERIL (Suspected)		Reason:	Unspecified psychosis	
	50.0 Mill	igram Daily		
Batch:	Started: 01/04/1	991	Stopped: 04/05/1992	
CARDIPRIN 100 (Suspected)		Reason:		
	100.0 Mill	igram Daily		
Batch:	Started:	L TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 77236 Seq: 1 Gender: M
Reported: 22/05/1992 Weight:

Reported: 22/05/1992 Weight:
Hospitalisation: Age: 59Y

Onset Date: 16/05/1992 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Severity	Report Description	Treatment
Severe		Treated with promethazine 25 mg tds, hydcortisone 100 mg iv,
		Severe

Medicine Details:

PHENYTOIN SODIUM (Suspected) Reason: Otr prim malig n lymphoid tisu

Oral application 200.0 Milligram Daily Oral

Batch: **Started**: 01/03/1992 **Stopped**: 18/05/1992

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

Oral application 3.0 Dose Unspecified Daily Oral

Batch: Started: 01/04/1992 **Stopped:** 20/05/1992

Laboratory Investigations:

Date	Туре	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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 77348 Seq: 1 Gender: F

 Reported:
 01/06/1992
 Weight:
 50.00

 Hospitalisation:
 Age:
 89Y

 Onset Date:
 28/05/1992
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		On thigh, arms	Promethazine 25 mg tds.

Medicine Details:

CLONAZEPAM (Suspected)		Reason:	
Injection	1.0 Milligram	1 time	Intravenous
Batch:	Started: 26/05/1992	Stopped:	
IMIPRAMINE HYDROCHLORIDE (Susp	pected)	Reason: Incontinence	of urine
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 24/05/1992	Stopped:	28/05/1992
TRIMETHOPRIM (Suspected)		Reason: Othr diseases	s of urinary tract
Oral application	300.0 Milligram	Daily	Oral
Batch:	Started: 26/05/1992	Stopped:	28/05/1992
THIORIDAZINE HYDROCHLORIDE (Su	ispected)	Reason:	
Oral application	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

Case Number: 77348

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Reported: lospitalisation: Onset Date:						A		50.00 89Y
	Not yet recovered							Causality possible
eaction Detai							•	, p
Medicine Deta								
DIGOXIN (Suspect	ed)			Reas		Congestive heart fail	ure	
Tablet			Microgram		Daily	Oral		CONTIN
Batch: COLOXYL WITH SI	ENNA (Suspected)	Started:		Reas	on:	Stopped: Constipation		CONTIN
Tablet	ENNA (Suspecteu)	1.0	Dose Unspec			Oral		
Batch:		Started: 24		,,,,,	Duny	Stopped:		CONTIN
aboratory In	vestigations:							
Additional Inf	ormation:							

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number:77700Seq:1Gender:MReported:19/06/1992Weight:80.00Hospitalisation:Admitted to hospitalAge:65Y

Onset Date: 20/05/1992 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Severity	Report Description	Treatment
		Treated with intragam, prednisolone, platelt transfusion. melleril, prothiaden and serepax ceased.
	Severity	

Medicine Details:

PROTHIADEN (Other drug)		Reason:	Depression	
Oral application	175.0 Milligram	Daily		Oral
Batch:	Started: 27/03/1992		Stopped:	22/05/1992
ALLOPURINOL (Other drug)		Reason:	Gout	
Oral application	100.0 Milligram	Daily		Oral
Batch:	Started:	L TERM	Stopped:	CONTIN
MELLERIL (Suspected)		Reason:	Depression	
Oral application	100.0 Milligram	Daily		Oral
Batch:	Started: 06/04/1992		Stopped:	22/05/1992
SEREPAX (Suspected)		Reason:	Depression	
Tablet	45.0 Milligram	Daily		Oral
Batch:	Started: 27/03/1992		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets		22/05/1992	1	
	Platelets		28/05/1992	165	

Additional Information:

Patient rechallenged with prothiaden 25mg nocte commencing 15/6/92 with no adverse effect.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 78092
 Seq: 1
 Gender: M

 Reported:
 02/07/1992
 Weight:

Hospitalisation: Age: 52Y
Onset Date: 25/06/1992
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression			

Medicine Details:

viedicine Details:					
FLUPHENAZINE DECANOATE (Suspected)			Reason:	Unspecified psychosis	
	100.0	Milligram	Week	ly	
Batch:	Started:	L	TERM	Stopped:	
ARTANE (Suspected)			Reason:	Unspecified psychosis	
Tablet	10.0	Milligram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	
MELLERIL (Suspected)			Reason:	Unspecified psychosis	
Tablet	600.0	Milligram	Daily	Oral	
Batch:	Started:	L	TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred 3 weeks after fluphenazine changed from 2 x 50mg/2ml amps to 1 x 100mg/ml ampoule per week.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 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 Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Life threatening		
Hypokalaemia	Life threatening		

Medicine Details:

viedicine Details:			
THIORIDAZINE HYDROCHLORIDE (Suspected)	Reason: Anxiety neurosis	
Oral application	0.0	Oral	
Batch:	Started:	Stopped:	
DOTHIEPIN HYDROCHLORIDE (Sus	pected)	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	Туре	Range	Date Tested	Result	Details
	Potassium				Serum potasium level - 2.2 mmol/l.

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
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Case Number: 80092 Seq: 1 Gender: F

Reported: 25/03/1992 Weight:
Hospitalisation: Age:
Onset Date: 25/03/1992 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

MELLERIL (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Known reaction to stemetil and maxolon

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 80433
 Seq: 1
 Gender: F

 Reported:
 19/10/1992
 Weight:

Hospitalisation: Age: 54Y
Onset Date: 10/09/1992
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Disturbance in attention			
Extrapyramidal disorder			
Gait disturbance			
Speech disorder			
Thinking abnormal			
Tremor			

Medicine Details:

LITHIUM CARBONATE (Other drug)			Reason:	Unspecifid affe	ective psychosis	
Tablet	1.0	Gram	Daily		Oral	
Batch:	Started:		L TERM	Stopped:	16/09/1992	
OROXINE (Other drug)			Reason:	Myxedema		
Tablet	250.0	Microgran	m Daily		Oral	
Batch:	Started:		L TERM	Stopped:		CONTIN
FLUOXETINE HYDROCHLORIDE (Suspected	d)		Reason:	Depression		
Capsule	20.0	Milligram	Daily		Oral	
Batch:	Started: 20/	04/1992		Stopped:	13/09/1992	
MELLERIL (Suspected)			Reason:	Reactive depre	essive psychosis	i
Oral application	200.0	Milligram	Daily		Oral	
Batch:	Started: 01/	05/1992		Stopped:	13/09/1992	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Ren	ort	Deta	ils:
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Case Number: 80633 Seq: 1 Gender: F
Reported: 28/10/1992 Weight:
Hospitalisation: Age: 84Y

Onset Date: 22/10/1992 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Blothy rash in places	Phenergan 25mg 6 hourly
Pruritus		Itching over body, face and limbs	
Periorbital oedema			
Pyrexia			

Medicine Details:

AMOXYCILLIN TRIHYDRATE (Sus	spected)	Reason:	Other diseases of lung	
	0.0			
Batch:	Started:		Stopped: 17/10/1992	
TAGAMET (Suspected)		Reason:	Peptic ulcer nos w/o ment perf	
Tablet	800.0 Milligram	Daily	Oral	
Batch:	Started: 17/10/1992		Stopped: 26/10/1992	
MELLERIL (Suspected)		Reason:	Otr spec symp psychopathol nec	
Tablet	30.0 Milligram	Daily	Oral	
Batch:	Started: 17/10/1992		Stopped: 18/10/1992	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 80656 Seq: 1 Gender: M

Reported: 20/10/1992 Weight: 69.00 Hospitalisation: Age: 67Y

Onset Date: 31/05/1992 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.	caction betains.									
Preferred Term	Severity	Report Description	Treatment							
Delirium										
Hallucination			Melleril ceased, madopar dose reduced							

Medicine Details:

MELLERIL (Suspected) Reason:

Oral application 50.0 Milligram As necessary Oral

Batch: Started: Stopped: 07/05/1992

MADOPAR (Suspected) Reason: Paralysis agitans

6.0 Dose Unspecified Daily

Batch: Started: 01/12/1990 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	oa	rt	De	tai	ls:
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Case Number: 81490 Seq: 1 Gender: F

 Reported: 13/12/1992
 Weight: 53.00

 Hospitalisation:
 Age: 35Y

 Onset Date: 30/06/1992
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	todotion Botans.			
	Preferred Term	Severity	Report Description	Treatment
	Hypertonia		Stiffness	
	Extrapyramidal disorder			

Medicine Details:

HALDOL DECANOATE (Suspected)	i	Reason:	
Injection	50.0 Milligram	3 times	Intramuscular
Batch:	Started: 16/06/1992	Stopped:	30/06/1992
MODECATE (Suspected)	F	Reason: Unspecified so	chizophrenia
Injection	50.0 Milligram	Weekly	Intramuscular
Batch:	Started: 27/05/1992	Stopped:	16/06/1992
MELLERIL (Suspected)	F	Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 29/06/1992	Stopped:	30/06/1992
KEMADRIN (Suspected)	F	Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 25/06/1992	Stopped:	05/07/1992

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 81749 Seq: 1 Gender: F

 Reported: 23/12/1992
 Weight: 73.00

 Hospitalisation:
 Age: 65Y

Onset Date: 13/12/1992 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

i toaction Dotaile			
Preferred Term	Severity	Report Description	Treatment
Purpura			
Vasculitis			

Medicine Details:

AURORIX (Suspected)		Reason:	Depression	
Tablet	450.0 Milligram	Daily		Oral
Batch:	Started: 08/12/1992		Stopped:	12/12/1992
MELLERIL (Suspected)		Reason:	Depression	
Tablet	75.0 Milligram	Daily		Oral
Batch:	Started: 09/12/1992		Stopped:	12/12/1992
METFORMIN HYDROCHLORIDE (Suspected)	Reason:	Diabetes melli	tus
Oral application	500.0 Milligram	Daily		Oral
Batch:	Started:	L TERM	Stopped:	
DESIPRAMINE HYDROCHLORIDE (Suspect	ed)	Reason:	Depression	
Tablet	750.0 Milligram	Daily		Oral
Batch:				

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haematology				Skin biospy: leukocytoclastic vasculitis in keeping with drug reactions.

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 83130
 Seq: 1
 Gender:
 F

 Reported:
 10/03/1993
 Weight:

Hospitalisation: Age: 78Y
Onset Date: 25/05/1992
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Anaemia			40 packed cells and 40 ffp tx.
Gastric ulcer haemorrhage			
Melaena			
Prothrombin level decreased			

Medicine Details:

CAPTOPRIL (Other drug)		Reason:	Congestive heart failure	
Oral application	25.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	
DOXEPIN HYDROCHLORIDE (Other drug)		Reason:		
Oral application	10.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	
FELDENE (Suspected)		Reason:	Otr&unsp vertebrogen pain synd	
	0.0			
Batch:	Started: 01/03/1992		Stopped:	1W
WARFARIN SODIUM (Suspected)		Reason:	Otr&nos disord of heart rhythm	
Tablet	4.0 Milligram	Daily	Oral	
Batch:	Started: 01/01/1988		Stopped: 25/02/1992	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin				Hb - 5.4
	International	2.0 - 4.0	25/05/1992	11.3	
	International	2.0 - 4.0	26/05/1992	2.4	
	International	2.0 - 4.0	26/05/1992	2.8	
	International	2.0 - 4.0	27/05/1992	2.2	
	International	2.0 - 4.0	28/05/1992	1.6	

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.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai	10/03/1993 25/05/1992 Unknown	Seq: 1				Gender: Weight: Age: DOB: ausality:		
Medicine Deta	ails: DROCHLORIDE (Sus	pacted)		Reason:				7
Oral application			0 Milligram	Daily		Oral		
Batch:	ation	Started:	o wiiiigiaiii	Daily	Stopped:			
Laboratory In	vestigations:							
Additional Inf the dosage start do necessarily accura		ut indicates th start occurred	at start occurr I sometime du	red sometime or	during the y 1.	ear. the do	osage start date is not	

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 83207
 Seq: 1
 Gender:
 F

 Reported:
 16/03/1993
 Weight:

Hospitalisation: Age: 69

Onset Date: DOB: 26/07/1923

Outcome: Recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Amoxycillin, metronidazole, clavulenic acid, metronidazole.

Medicine Details:

Medicine Details.				
DILTIAZEM HYDROCHLORIDE (Other drug)			Reason:	
	180.0	Milligram	Daily	
Batch:	Started:			Stopped:
CAPTOPRIL (Other drug)			Reason:	
	200.0	Milligram	Daily	
Batch:	Started:			Stopped:
GLIBENCLAMIDE (Other drug)			Reason:	
	5.0	Milligram	Daily	
Batch:	Started:			Stopped:
PHENOXYMETHYLPENICILLIN (Other drug)			Reason:	
Oral application	500.0	Milligram	Daily	Oral
Batch:	Started:			Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	0 - 60 U/L	18/12/1992	35	
	ALT = SGPT	0 - 60 U/L	10/02/1993	86	
	ALT = SGPT	0 - 60 U/L	12/02/1993	89	
	ALT = SGPT	0 - 60 U/L	01/03/1993	16	
	ALT = SGPT	0 - 60 U/L	15/02/1993	44	
	AST = SGOT	0 - 50 U/L	18/12/1992	23	
	AST = SGOT	0 - 50 U/L	10/02/1992	49	

Additional Information:

Abnormal Ifts accompanied urinary tract infection.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 83207 Gender: F Seq: 1 Reported: 16/03/1993 Weight:

Hospitalisation: Age: 69

Onset Date: DOB: 26/07/1923

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Batch:

MELLERIL (Suspected)	r	Reason:
	0.0	
Batch:	Started:	Stopped:

Stopped:

SURGAM (Suspected)

Reason:

0.0

Batch: Started:

ROHYPNOL (Suspected) Reason:

0.0

Stopped: ZOCOR (Suspected) Reason: Othr&unspec metabolic diseases

Tablet 20.0 Milligram Daily Oral

Started:

Batch: Started: 05/01/1993 Stopped: 11/02/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	AST = SGOT	0 - 50 U/L	15/02/1993	15	
	AST = SGOT	0 - 50 U/L	01/03/1993	16	
	AST = SGOT	0 - 50 U/L	12/02/1993	81	
	Bilirubin	0 - 21 UMOL/L	18/12/1992	13	
	Bilirubin	0 - 21 UMOL/L	10/02/1993	24	
	Bilirubin	0 - 21 UMOL/L	12/02/1993	16	
	Bilirubin	0 - 21 UMOL/L	15/02/1993	8	

Additional Information:

Abnormal Ifts accompanied urinary tract infection.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 83207 Seq: 1 Gender: F
Reported: 16/03/1993 Weight:

Hospitalisation: Age: 69

Onset Date: **DOB**: 26/07/1923

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

DILTIAZEM HYDROCHLORIDE (Other drug)			Reason:	
	180.0	Milligram	Daily	
Batch:	Started:			Stopped:
CAPTOPRIL (Other drug)			Reason:	
	200.0	Milligram	Daily	
Batch:	Started:			Stopped:
GLIBENCLAMIDE (Other drug)			Reason:	
	5.0	Milligram	Daily	
Batch:	Started:			Stopped:
PHENOXYMETHYLPENICILLIN (Other drug)			Reason:	Stopped:
111		Milligram	Reason: Daily	Stopped: Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	0 - 21 UMOL/L	01/03/1993	9	
	GGT = SGGT =	0 - 40 U/L	18/12/1992	94	
	GGT = SGGT =	0 - 40 U/L	10/02/1993	174	
	GGT = SGGT =	0 - 40 U/L	12/02/1993	243	
	GGT = SGGT =	0 - 40 U/L	15/02/1993	195	
	GGT = SGGT =	0 - 40 U/L	01/03/1993	75	
	SAP = ALP	0 - 120 U/L	18/12/1992	86	

Additional Information:

Abnormal Ifts accompanied urinary tract infection.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report D	etails	; :								
ospitalisa Onset	orted: ´ation: Date:	83207 16/03/199 Recovere		: 1			C			
eaction			u				O	ausanty.	Causanty	possible
					Pos	eon:				
				0.0	Rea	son:				
MELLERIL	(Suspect		s	0.0	Rea	son:	Stopped:			
MELLERIL Ba	(Suspect	ted)	s	0.0 Started:		son:	Stopped:			
Medicine MELLERIL Ba SURGAM (S	(Suspect	ted)	s				Stopped:			
MELLERIL Ba SURGAM ((Suspect	ted)		Started:			Stopped:			
MELLERIL Ba SURGAM (9 Ba	(Suspectons) Suspectons tch:	ted)		Started: 0.0	Rea					
MELLERIL Ba SURGAM ((Suspectons) Suspectons tch:	ted)		Started: 0.0	Rea	son:				
MELLERIL Ba SURGAM (S Ba ROHYPNO	(Suspectons) Suspectons tch:	ted)	s	0.0 Started:	Rea	son:				
MELLERIL Ba SURGAM (S Ba ROHYPNO	(Suspecters) tch: tch: tch: L (Suspecters)	ed)	s	0.0 Started: 0.0	Rea Rea	son:	Stopped:	netabolic di	seases	
MELLERIL Ba SURGAM (Ba ROHYPNO	(Suspecters) tch: tch: tch: L (Suspecters)	ed)	s	0.0 Started: 0.0	Rea Rea Rea	son:	Stopped:	metabolic di	seases	
MELLERIL Ba SURGAM (S Ba ROHYPNOI Ba ZOCOR (Su	(Suspected tch: L (Suspected tch: uspected	ed)	s	0.0 Started: 0.0 Started:	Rea Rea Rea	son:	Stopped: Stopped: Othr&unspec r			
Ba SURGAM (S Ba ROHYPNOI Ba ZOCOR (Su Tab	(Suspected tch: L (Suspected tch: uspected blet tch:	ed)	s s	0.0 Started: 0.0 Started: 20.0 Milli	Rea Rea Rea	son:	Stopped: Stopped: Othr&unspec r	Oral		
Ba SURGAM (S Ba ROHYPNOI Ba ZOCOR (Su Tab Ba	tch: Suspected tch: L (Suspe tch: uspected plet tch:	ed) ected)	s s ions:	0.0 Started: 0.0 Started: 20.0 Milli Started: 05/01/19	Rea Rea Rea gram 993	son:	Stopped: Stopped: Othr&unspec r	Oral 11/02/1993	3	
MELLERIL Ba SURGAM (S Ba ROHYPNOI Ba ZOCOR (Su Tab	tch: Suspected tch: uspected blet tch:	ed) ected) /estigat	s s ions: Range	0.0 Started: 0.0 Started: 20.0 Milli Started: 05/01/19	Rea Rea gram 993	son:	Stopped: Stopped: Othr&unspec r	Oral	3	
Ba SURGAM (S Ba ROHYPNOI Ba ZOCOR (Su Tat Ba	tch: Suspected tch: L (Suspe tch: uspected plet tch:	ed) cted) /estigat Type ALP	s ions: Range 0 - 120 U/L	0.0 Started: 0.0 Started: 20.0 Milli Started: 05/01/19 Date Tested 10/02/1993	Rea Rea gram 993 Result 155	son:	Stopped: Stopped: Othr&unspec r	Oral 11/02/1993	3	
Ba SURGAM (S Ba ROHYPNOI Ba ZOCOR (Su Tab Ba	tch: Suspected tch: L (Suspe tch: uspected plet tch: SAP = /	rected) /estigat Type ALP ALP	sions: Range 0 - 120 U/L 0 - 120 U/L	0.0 Started: 0.0 Started: 20.0 Milli Started: 05/01/19 Date Tested 10/02/1993 12/02/1993	Rea Rea gram 993 Result 155 233	son:	Stopped: Stopped: Othr&unspec r	Oral 11/02/1993	3	
Ba SURGAM (S Ba ROHYPNOI Ba ZOCOR (Su Tab Ba	tch: Suspected tch: L (Suspe tch: uspected plet tch:	red) Petigat Type ALP ALP ALP	s ions: Range 0 - 120 U/L	0.0 Started: 0.0 Started: 20.0 Milli Started: 05/01/19 Date Tested 10/02/1993	Rea Rea gram 993 Result 155	son:	Stopped: Stopped: Othr&unspec r	Oral 11/02/1993	3	

Additional Information:

Abnormal Ifts accompanied urinary tract infection.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report De	etails:							
Case Num	ber : 83240	Seq:	: 1				Gender:	F
Repor	ted: 12/03	1993					Weight:	80.00
lospitalisat	ion:						Age:	66Y
Onset D	ate: 29/05	1992					DOB:	
Outco	me: Recov	vered				Ca	ausality:	Causality possible
eaction D	etails:							
Pr	eferred Terr	n Se	everity	Repo	ort Desc	ription		Treatment
Aggression								
Confusional	state							
Urinary rete	ntion							
Medicine DI-GESIC (O				Rea	son:			
			0.0					
Bato	:h:	S	Started:			Stopped:		
DOLOBID (O	ther drug)			Rea	son:			
			0.0					
Bato	:h:	S	Started:			Stopped:		
DIAZEPAM (Other drug)			Rea	son:			
Table	et		10.0 Mill	igram	Daily		Oral	
Bato	:h:	S	Started:			Stopped:	30/05/1992	2
SLOW-K (Ot	her drug)			Rea	son:			
Table	et		3.0 Dos	se Unspecified	Daily		Oral	
Bato	:h:	S	Started:			Stopped:		
<u>Laborato</u> i	rv Investi	gations:						
Date	Type	Range	Date Tested	Result			Detai	ls
	• •							
		•		•				

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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 83240 Seq: 1 Gender: F

Reported: 12/03/1993 Weight: 80.00 Hospitalisation: Age: 66Y

Onset Date: 29/05/1992 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

CHLOTRIDE (Other drug)		Reason:	
Tablet	500.0 Milligram	Alternate days	Oral
Batch:	Started:	Stoppe	d:
BENZTROPINE MESYLATE (Suspected)		Reason: Paralysis a	gitans
Tablet	3.0 Dose Unspe	ecified Daily	Oral
Batch:	Started: 22/05/1992	Stoppe	d: 29/05/1992
MELLERIL (Suspected)		Reason: Depression	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1991	Stoppe	d: 30/05/1992
TRYPTANOL (Suspected)		Reason: Depression	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1991	Stoppe	d: 30/03/1992

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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 83925 Gender: F Seq: 1

Weight: 48.00 Reported: 15/04/1993 **Hospitalisation:** Age: 53Y

Onset Date: 07/04/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Dizziness			Fluids, rest.	
	Syncope				İ

Medicine Details:

SUDAFED (Suspected)		Reason:	
	2.0 Dose Unspec	cified Total	
Batch:	Started: 07/04/1993	Stopped:	
MELLERIL (Suspected)		Reason:	
	50.0 Milligram	As necessary	
Batch:	Started:	Stopped:	
MOCLOBEMIDE (Suspected)		Reason: Depression	

600.0 Milligram Daily

Started: Batch: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has mitral valve disease (?rheumatic origin) difficult antidepressant choice.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:	Re	po	rt	De	tai	ls:
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Case Number: 83978 Seq: 1 Gender: F

Reported: 31/03/1993 Weight: 58.00 Hospitalisation: Age: 28Y

Onset Date: 23/02/1993 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction			Calamine applied.
Rash maculo-papular			

Medicine Details:

PROTHIADEN (Other drug)		Reason:	Depression	
Capsule	150.0 Milligram	Daily		Oral
Batch:	Started: 12/02/1993		Stopped:	
AMITRIPTYLINE HYDROCHLORIDE	(Other drug)	Reason:	Depression	
Oral application	150.0 Milligram	Daily		Oral
Batch:	Started: 22/01/1993		Stopped:	11/02/1993
MELLERIL (Suspected)		Reason:	Depression	
Tablet	75.0 Milligram	Daily		Oral
Batch:	Started: 15/02/1993		Stopped:	24/02/1993

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Rei	port	Detai	ls:
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Case Number: 84160 Seq: 1 Gender: F

Reported: 16/04/1993 Weight: 63.00 Hospitalisation: Age: 19Y

Onset Date: 10/06/1992 **DOB**:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			

Medicine Details:

MIANSERIN HYDROCHLORIDE (Other	er drug)	Reason:	Depression	
Tablet	100.0 Milligram	Daily	Oral	
Batch:	Started: 04/06/1992		Stopped:	
TETRACYCLINE (Other drug)		Reason:	Other acne of sebaceous glands	
	750.0 Milligram	Daily		
Batch:	Started: 01/06/1992		Stopped:	
THIORIDAZINE HYDROCHLORIDE (S	suspected)	Reason:	Depression	
Tablet	50.0 Milligram	Daily	Oral	
Batch:	Started: 09/06/1992		Stopped: 11/06/1992	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 84194 Seq: 1 Gender: M

Reported: 26/04/1993 Weight: 79.00 Hospitalisation: Age: 66Y

Onset Date: 25/04/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Severe		

Medicine Details:

ENALAPRIL MALEATE (Other drug)		Reason: Essential benign hypertension
	20.0 Milligram	Daily
Batch:	Started: 01/03/1993	Stopped:
ATENOLOL (Other drug)		Reason: Essential benign hypertension
	100.0 Milligram	Daily
Batch:	Started: 01/01/1992	Stopped:
WARFARIN SODIUM (Other drug)		Reason: Phleb&thrombophleb lowr extrem
	2.5 Milligram	Daily
Batch:	Started: 01/01/1993	Stopped:
MOCLOBEMIDE (Suspected)		Reason: Depression
	150.0 Milligram	3 times
Batch:	Started: 25/04/1993	Stopped : 26/04/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient previously hypertensive-bp 180/120, with three doses of moclobemide 150mg-bp 90/70. when moclobemide ceased, rapid increase to 150/90 in 8 hours. 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

 Report Details:

 Case Number:
 84194
 Seq: 1
 Gender: M

 Reported:
 26/04/1993
 Weight:
 79.00

 Hospitalisation:
 Age: 66Y

Onset Date: 25/04/1993 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

MELLERIL (Suspected) Reason: Otr spec symp psychopathol nec

75.0 Milligram Daily

Batch: Started: 24/04/1993 **Stopped:** 26/04/1993

Laboratory Investigations:

Additional Information:

Patient previously hypertensive-bp 180/120, with three doses of moclobemide 150mg-bp 90/70. when moclobemide ceased, rapid increase to 150/90 in 8 hours. 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 84390 Seq: 1 Gender: M

Reported: 05/05/1993 Weight: 82.00 Hospitalisation: Age: 71Y

Onset Date: 19/04/1993 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia	,		
Coma			
Dysphagia			
Leukocytosis			
Neuroleptic malignant syndrome			Dobutamine inf 25mg per hour.
Tardive dyskinesia			

Medicine Details:

			<u> </u>		
PEXID (Other drug)		Reason:	Chron isch heart dis r	no hyper	
	300.0 Milligram	Daily			
Batch:	Started: 01/01/1992		Stopped:	CONTIN	
CARDIZEM (Other drug)		Reason:	Chron isch heart dis r	no hyper	
	270.0 Milligram	Daily			
Batch:	Started: 01/01/1991		Stopped:	CONTIN	
AMITRIPTYLINE HYDROCHLORID	E (Other drug)	Reason:			
	75.0 Milligram	Daily			
Batch:	Started: 01/01/1992		Stopped: 19/04	/1993	
RENITEC (Other drug)		Reason:	Congestive heart failu	ıre	
	2.5 Milligram	Daily			
Batch:	Started: 01/01/1992		Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine	50-120 U/L	19/04/1993	12,474	Ck was predominantly of skeletal muscle origin (98%).
	Creatine	50-120 U/L	22/04/1993	177	Ck was predominantly of skeletal muscle origin (98%).
	Electrocardiograph				Ecg revealed bradycardia but no p waves.
	LDH	U/L	22/04/1993	177	
	White blood cells		19/04/1993	13.0	

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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 84390 Seq: 1 Gender: M

 Reported:
 05/05/1993
 Weight:
 82.00

 Hospitalisation:
 Age:
 71Y

Onset Date: 19/04/1993 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

SOLPRIN (Other drug)		Reason:	Chron isch heart dis no hyper	
	150.0 Milligram	Daily		
Batch:	Started: 01/01/1991		Stopped:	CONTIN
HALDOL DECANOATE (Suspected)		Reason:	Manic-depression psycho,ma	nic
	10.0 Milligram	Daily		
Batch:	Started: 15/04/1993		Stopped: 19/04/1993	
MELLERIL (Suspected)		Reason:	Manic-depression psycho,ma	nic
	150.0 Milligram	Daily		
Batch:	Started: 19/04/1993		Stopped: 19/04/1993	
VALIUM (Suspected)		Reason:	Manic-depression psycho,ma	nic
	15.0 Milligram	Daily		
Batch:	Started: 19/04/1993		Stopped: 19/04/1993	

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. 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 84675
 Seq: 1
 Gender: M

 Reported:
 24/05/1993
 Weight:

Reported: 24/05/1993 Weight:
Hospitalisation: Age: 34Y

Onset Date: 31/07/1992 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment	
Ejaculation failure				

Medicine Details:

Batch:	Started: 01/07/1992		Stopped:	
	100.0 Milligram	Daily		
MELLERIL (Suspected)		Reason:	Unspecified schizophrenia	

TEGRETOL (Suspected) Reason: Unspecified schizophrenia

300.0 Milligram Daily

Batch: Started: 01/07/1992 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

When patient omitted medication for 1 week ejaculation resumed. - 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report	Details:
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Case Number: 84854 Seq: 1 Gender: F
Reported: 27/05/1993 Weight:

Hospitalisation: Age: 84Y
Onset Date: 08/08/1992
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			

Medicine Details:

LANOXIN (Other drug)		F	Reason:	Congestive he	art failure
Tablet	250.0	Microgram	Daily		Oral
Batch:	Started:			Stopped:	
LOSEC (Other drug)		F	Reason:	Peptic ulcer no	os w/o ment perf
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started: Stopped:				
FERRO-GRADUMET (Other drug)		F	Reason:		
Tablet	1.0	Dose Unspecifi	ed Daily		Oral
Batch:	Started:			Stopped:	
MELLERIL (Suspected)		F	Reason:	Other paranoid	d states
Tablet	25.0	Milligram	Daily		Oral
Batch:	Started: 05/08/1992			Stopped:	08/08/1992

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	84854	Seq: 1				Gender:	F	
Reported:	27/05/1993					Weight:		
ospitalisation:						Age:	84Y	
Onset Date:	08/08/1992					DOB:		
Outcome:	Recovered				C	ausality:	Causality poss	ible
action Deta	ils:							
<u>ledicine Det</u>								
TOFRANIL (Suspe	ected)			Reason:	Incontinence o			
Tablet			Milligram	Daily		Oral		
Batch:		Started:				08/08/1992		
NDERAL (Suspec	cted)			Reason:	Chron isch hea		per	
Tablet		80.0	Milligram	Daily		Oral		
Batch:		Started:			Stopped:	08/08/1992		
ala a wata wa Iw		_						
aboratory ir	nvestigations	:						
dditional In	formation:							
	07 02:44DM Dat			VDDCU			Daga 101	~ 4 20

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 85477
 Seq: 1
 Gender:
 F

 Reported:
 24/06/1993
 Weight:

Hospitalisation: Age: 61Y
Onset Date: 20/06/1993
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

,	icaciion Details.							
	Preferred Term	Severity	Report Description	Treatment				
	Duodenal ulcer							
	Dyspepsia							
	Haematemesis							
	Oesophagitis ulcerative							

Medicine Details:

PROZAC (Other drug)		Reason:	Depression	
Tablet	20.0 Milligram	Daily		Oral
Batch:	Started: 20/05/1993		Stopped:	04/06/1993
MELLERIL (Suspected)		Reason:	Anxiety neuro	sis
Tablet	10.0 Milligram	Daily		Oral
Batch:	Started: 20/05/1993		Stopped:	04/06/1993
LEXOTAN (Suspected)		Reason:	Anxiety neuro	sis
Tablet	3.0 Milligram	Daily		Oral
Batch:	Started: 01/01/1992		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Gastroscopy - oesophageal and duodenal ulcer.

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 85860
 Seq: 1
 Gender: M

 Reported:
 06/07/1993
 Weight:

Hospitalisation: Age: 23Y
Onset Date: 04/05/1993
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

	Preferred Term	Severity	Report Description	Treatment
D;	ystonia	Severe		8mg im cogentin.

Medicine Details:

LARGACTIL (Suspected)		Reason: Manic-depression psycho,manic	
Oral application	50.0 Milligram	1 time Oral	
Batch:	Started: 03/05/1993	Stopped:	
SERENACE (Suspected)		Reason: Manic-depression psycho,manic	
Injection	10.0 Milligram	1 time Intramuscular	
Batch:	Started: 03/05/1993	Stopped:	
SERENACE (Suspected)		Reason: Manic-depression psycho,manic	
Injection	5.0 Milligram	1 time Intramuscular	
Batch:	Started: 04/05/1993	Stopped:	
MELLERIL (Suspected)		Reason: Manic-depression psycho,manic	
Oral application	150.0 Milligram	Daily Oral	
Batch:	Started: 03/05/1993	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 86985 Seq: 1 Gender: F

 Reported: 23/08/1993
 Weight: 60.00

 Hospitalisation:
 Age: 55Y

Onset Date: 15/07/1993 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Pruritus			
Rash maculo-papular			

Medicine Details:

Medicine Details.				
SURMONTIL (Suspected)		Reason:	Depression	
Oral application	150.0 Milligram	Daily		Oral
Batch:	Started: 01/07/1993		Stopped:	22/07/1993
MELLERIL (Suspected)		Reason:	Otr spec symp	psychopathol nec
Oral Liquid	50.0 Milligram	Daily		Oral
Batch:	Started: 13/07/1993		Stopped:	15/07/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 02:44PM Database: pusime02 ADRS004 Page 107 of 393



Report Details:

Case Number: 87105

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

ospitalisation: Onset Date:	: 27/08/199 :	,,						Weight	t:		
Outcome:			Age: 83Y								
	•		DOB:								
action Deta	Not yet re	covered					Ca	ausality	y: Caus	sality poss	ible
		1									
	red Term	S	everity		Repo	ort De	scription			Treatmer	nt
ardive dyskines	sia										
remor											
ledicine Det MELLERIL (Suspo					Rea	son:	Anxiety neuros	ie			
MELLERIL (Susp	ectea)		50.0	Milli		son: Daily	Anxiety neuros	IS			
Batch:		;	Started:		gram	Dany	Stopped:	19/08/19	93		
CARDIZEM (Suspected)					Rea	son:	Chron isch hea				
, -1	,		120.0	Milli		Daily			••		
Batch:		;	Started:				Stopped:				
MODURETIC (Sus	spected)				Rea	son:					
			1.0	Dos	e Unspecified	Daily					
Batch:		;	Started:				Stopped:				
SANDOCAL 1000	(Suspected)					son:					
				Dos	e Unspecified	Daily					
Batch:			Started:		L TERM		Stopped:				
aboratory lı	nvestigat	ions:									
Date	Туре	Range	Date Tes	ed	Result			Det	tails		

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 87515
 Seq:
 1
 Gender:
 M

 Reported:
 07/09/1993
 Weight:

Hospitalisation: Age: 33Y
Onset Date: 13/08/1993
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	toaotion Dotailoi			
	Preferred Term	Severity	Report Description	Treatment
	Lymphopenia			
	Neutropenia			

Medicine Details:

BACTRIM DS (Suspected)		Reason:		
Tablet	8.0 Dose Unspec	cified Daily		Oral
Batch:	Started: 02/08/1993		Stopped:	13/08/1993
THIORIDAZINE HYDROCHLORIDE (Susp	ected)	Reason:	Unspecified so	chizophrenia
Oral application	100.0 Milligram	Daily		Oral
Batch:	Started: 04/08/1993		Stopped:	13/08/1993
FLUCONAZOLE (Suspected)		Reason:	Moniliasis	
Capsule	100.0 Milligram	Daily		Oral
Batch:	Started: 03/01/1993		Stopped:	
NILSTAT (Suspected)		Reason:	Moniliasis	
Solution	4.0 Millilitre	Daily		Oral
Batch:	Started: 06/08/1993		Stopped:	19/08/1993

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Lymphocytes	1.5 - 4.0	05/08/1993	0.7	
	Lymphocytes	1.5 - 4.0	13/08/1993	0.3	
	Lymphocytes	1.5 - 4.0	20/08/1993	0.3	
	Neutrophils	2 - 7.5	05/08/1993	3.2	
	Neutrophils	2 - 7.5	13/08/1993	1.2	
	Neutrophils	2 - 7.5	20/08/1993	1.6	
	White blood cells	4 - 11	05/08/1993	4.4	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Rep	ort	Deta	ils:
-----	-----	------	------

 Case Number:
 87515
 Seq: 1
 Gender: M

 Reported:
 07/09/1993
 Weight:

Hospitalisation: Age: 33Y
Onset Date: 13/08/1993
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

BACTRIM DS (Suspected)		Reason:		
Tablet	8.0 Dose Unspec	cified Daily		Oral
Batch:	Started: 02/08/1993		Stopped:	13/08/1993
THIORIDAZINE HYDROCHLORIDE (Sus	pected)	Reason:	Unspecified so	chizophrenia
Oral application	100.0 Milligram	Daily		Oral
Batch:	Started: 04/08/1993		Stopped:	13/08/1993
FLUCONAZOLE (Suspected)		Reason:	Moniliasis	
Capsule	100.0 Milligram	Daily		Oral
Batch:	Started: 03/01/1993		Stopped:	
NILSTAT (Suspected)		Reason:	Moniliasis	
Solution	4.0 Millilitre	Daily		Oral
Batch:	Started: 06/08/1993		Stopped:	19/08/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	White blood cells	4 - 11	13/08/1993	1.7	
	White blood cells	4 - 11	20/08/1993	2.2	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:				
Case Number: 90021	Seq: 1			nder: F
Reported: 23/12/19	193			ght:
ospitalisation: Onset Date: 27/07/19	003			Age: 33 DOB: 22/02/1960
Outcome: Not yet r				ality: Causality possible
eaction Details:	COVERCU		Caus	anty. Causanty possible
Preferred Term	Severity	Report De	scription	Treatment
Dystonia		·		Intravenous rehydration
Medicine Details: HALOPERIDOL (Suspected)		Reason:		
TIALOF LINDOL (Guspecteu)	26.0 Mil			
Batch:	Started: 23/07/1	_	Stopped:	
THIORIDAZINE HYDROCHLO		Reason:		
	50.0 Mil	ligram Total		
Batch:	Started:		Stopped:	
	50.0 Mil	ligram Total	Stopped:	
				Detaile
Laboratory Investiga Date Type	ations: Range Date Tested	Result		Details
		Result		Details

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 90349 Seq: 1 Gender: M

Reported: 04/01/1994 Weight: 76.00
Hospitalisation: Age: 58Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

i todotion Botans.	caction betails.							
Preferred Term	Severity	Report Description	Treatment					
Somnolence								
Visual disturbance								

Medicine Details:

Micalonic Betails.			
MELLERIL (Suspected)		Reason: Anxiety neurosis	
	25.0 Milligram	As necessary	
Batch:	Started: 01/05/1993	Stopped:	
PROZAC (Suspected)		Reason: Depression	
Tablet	40.0 Milligram	Daily Oral	
Batch:	Started: 30/11/1993	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Day of reaction patient took melleril 25mg midi and nocte, prozac 20, 2 mane and 1 nocte. next morning vision blue for approx 3 hours. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 90864 Seq: 1 Gender: F

Reported: 02/02/1994 Weight: 60.00 Hospitalisation: Age: 42Y

Onset Date: 27/01/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal			
Syncope			
Ventricular tachycardia			

Medicine Details:

PRIADEL (Suspected)		Reason: Unspecifid affective psychosis	
Tablet	800.0 Milligram	Weekly Oral	
Batch:	Started:	Stopped:	
MELLERIL (Suspected)		Reason: Anxiety neurosis	
Tablet	300.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1993	Stopped:	
RIVOTRIL (Suspected)		Reason: Anxiety neurosis	
Tablet	2.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
INDERAL (Suspected)		Reason: Anxiety neurosis	
Tablet	40.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Long qt

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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:				
Case Number: 90864	Seq: 1			Gender: F
Reported: 02/02/1994	-			Weight: 60.00
Hospitalisation:				Age: 42Y
Onset Date: 27/01/1994				DOB:
Outcome: Recovered				Causality: Causality possible
Reaction Details:				
Madiaina Dataila				
Medicine Details: MICROGYNON 30 ED (Suspected)		Reaso	on.	
Pill	1.0			Oral
Batch:	Started:	L TERM	,	Stopped:
DUPHALAC (Suspected)		Reaso	on:	

Daily

Oral

Stopped:

40.0 Millilitre

Started: 01/10/1993

Laboratory Investigations:

Oral Liquid

Batch:

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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 91519 Gender: M Seq: 1

Weight: Reported: 10/03/1994 **Hospitalisation: Age:** 63

Onset Date: 26/11/1993 **DOB:** 14/04/1930

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Paraesthesia		Tingling mouth and lips.	
	Dystonia			Cogentin.

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Si	uspected)	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	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:							
Case Number: 91523 Reported: 10/03/1994	Seq: 1				Gender: ∪ Weight:		
Hospitalisation:				_	je:		
Onset Date: 24/11/1993					DB:		
Outcome: Recovered				Causali	ty: Causal	ity possible	
Reaction Details:		_					
Preferred Term	Severity		Report De	scription	Tı	reatment	
Photosensitivity reaction							
Madiaina Dataila.							
Medicine Details: DANAZOL (Other drug)			Reason:	Otr intostno 2 poritono	ım degaço		
Capsule	600.0	Milligram	Daily	Otr intestne&peritone Oral	iiii usedse		
Batch:	Started:	wiiiigram	Daily	Stopped:			
Daton.	Jiai ieu.			Gloppeu.			

SALAZOPYRIN (Other drug) Reason: Otr intestne&peritoneum dsease

25.0 Milligram

Tablet 4.0 Gram Daily Oral Batch: Started: Stopped:

Started:

ZANTAC (Other drug) Reason: Otr intestne&peritoneum dsease

Tablet 300.0 Milligram Daily Oral Batch: Started: Stopped:

Laboratory Investigations:

Oral application

Batch:

Date	Туре	Range	Date Tested	Result	Details

Daily

Oral

Stopped:

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Reported: 10/03/1994 Dispitalisation: Onset Date: 24/11/1993 Outcome: Recovered Paction Details:			Gender: U Weight: Age: DOB: Causality: Causality possible				
ledicine Deta	ails: 'DROCHLORIDE (St	uspected)	Reason:	Pneumonia,ur	specified		
Oral applic		300.0 Milligram	Daily		Oral		
Batch:		Started: 10/11/1993	·	Stopped:	24/11/1993		
MELLERIL (Suspe	cted)		Reason:				
		25.0 Milligram	Daily				
Batch:		Started:		Stopped:	24/11/1993		
aboratory In	vestigations:						

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 92422 Seq: 1 Gender: F

Reported: 26/04/1994 Weight: 45.00 Hospitalisation: Age: 20Y

Onset Date: 25/06/1993 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Severity	Report Description	Treatment
		Therapy changed to stelazine.
	Severity	

Medicine Details:

<u> Wiedicine Details:</u>				
AMITRIPTYLINE HYDROCHLORIDE (Oti	her drug)	Reason: Unspe	cified schizophrenia	
Tablet	50.0 Milligram	Daily	Oral	
Batch:	Started:	Ste	opped:	
FLUPHENAZINE NOS (Other drug)		Reason:		
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started:	Ste	opped:	
THIORIDAZINE HYDROCHLORIDE (Sus	pected)	Reason: Unspe	cified schizophrenia	
Oral application	500.0 Milligram	Daily	Oral	
Batch:	Started: 03/09/1992	Ste	opped: 02/07/1993	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Prolactin	35 - 520 MIU/L	25/06/1993	3247	
	Prolactin	35 - 520 MIU/L	12/07/1993	2009	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 92868 Seq: 1 Gender: F

Reported: 09/05/1994 Weight: 51.00 Hospitalisation: Age: 26Y

Onset Date: 13/04/1994 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis			

Medicine Details:

AMOXYCILLIN TRIHYDRATE (Suspected) Reason: Bronchitis, unqualified

1.5 Gram

Batch: Started: 09/04/1994 Stopped: 14/04/1994

PROZAC (Suspected) Reason: Depression

 Tablet
 40.0
 Milligram
 Daily
 Oral

 Batch:
 Started: 28/12/1993
 Stopped: 14/04/1994

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Specific disorders of sleep

100.0 Milligram Daily

Batch: Started: 28/12/1993 **Stopped:** 14/04/1994

TRIPHASIL (Suspected) Reason: Contraception

1.0 Dose Unspecified Daily

Batch: Started: 18/02/1994 **Stopped:** 14/04/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Alt 4615, ast 4555, amylase 81, alh phos 44, ggt 71.

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:

Case Number: 93029 Seq: 1 Gender: M

Reported: 17/05/1994 Weight:

Hospitalisation: Age: 49
Onset Date: 06/07/1993 DOB: 14/

Onset Date: 06/07/1993 DOB: 14/01/1944
Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			Propranolol.

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Specific disorders of sleep

25.0 Milligram 1 time

Batch: Started: 06/07/1993 Stopped:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Specific disorders of sleep

100.0 Milligram 1 time

Batch: Started: 05/07/1993 Stopped:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Specific disorders of sleep

75.0 Milligram Total

Batch: Started: 05/07/1993 **Stopped:** 06/07/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 93238 Seq: 1 Gender: F

Reported: 30/05/1994 Weight: 42.00 Hospitalisation: Age: 14Y

Onset Date: 31/01/1994 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Accommodation disorder			

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason:

Oral application 175.0 Milligram Daily Oral

Batch: Started: 01/12/1993 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Sequelae: wears glasses. - 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:	Re	po	rt	De	tai	ls:
-----------------	----	----	----	----	-----	-----

Case Number: 93757 Seq: 1 Gender: M

Reported: 17/06/1994 Weight:
Hospitalisation: Age: 39Y

Onset Date: 05/08/1993 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Spasms in back of legs and jaws.	Cogentin 2 mg im.

Medicine Details:

MELLERIL (Suspected) Reason: Unspecifid affective psychosis

Oral application 275.0 Milligram Total Oral

Batch: Started: 04/08/1993 Stopped: 05/08/1993

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 94784 Seq: 1 Gender: F

Reported: 02/08/1994 Weight:
Hospitalisation: Age: 69Y

Onset Date: 23/07/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	todotion Dotails.				
	Preferred Term	Severity	Report Description	Treatment	
	Hypotension				
	Syncope				

Medicine Details:

TEGRETOL (Other drug)		Reason:		
Oral application	800.0 Milligram	Daily	Oral	
Batch:	Started: 24/03/1994	Sto	pped:	
EUHYPNOS (Other drug)		Reason: Specific	c disorders of sleep	
Capsule	20.0 Milligram	Daily	Oral	
Batch:	Started: 16/05/1994	Sto	pped:	
SERENACE (Other drug)		Reason: Unspec	cified psychosis	
Oral application	15.0 Milligram	Daily	Oral	
Batch:	Started: 11/07/1994	Sto	pped:	
COGENTIN (Other drug)		Reason:		
Tablet	1.0 Milligram	Daily	Oral	
Batch:	Started: 11/07/1994	Sto	pped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient previously had a similar collapse on a combination of moclobemide 300mg bd and pericyazine 5mg bd and carbamazepine 400mg bd.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:				
Case Number: 9478	34 Seq: 1		Gender:	F
Reported: 02/08	8/1994		Weight:	
Hospitalisation:			Age:	69Y
Onset Date: 23/0	7/1994		DOB:	
Outcome: Reco			Causality:	Causality probable
Reaction Details:			-	• •
Medicine Details:				
ALDAZINE (Suspected)		Reason: Ur	nspecified psychosis	
Tablet	50.0 Milli	gram 1 time	Oral	
Batch:	Started: 22/07/19	994	Stopped:	
				_
Laboratory Invest	igations:			
Additional Inform	ation:			
Patient previously had a	similar collapse on a combination	of moclobemide 300m	ng bd and pericyazine	5mg bd and
carbamazepine 400mg b	od.			

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 9 Reported: 1 ospitalisation: Onset Date: 0 Outcome: N	1/08/1994	Seq: 1					С	Gender: Weight: Age: DOB: ausality:	77Y
action Details				<u> </u>					
Preferred Confusional state	Term	Severit	ty		Repoi	t De	scription		Treatmen
ledicine Detai					Reas		Otr spec symp	novohonoth	nol non
Tablet	eu)		25 N	Milligram		Daily	Oli spec symp	Oral	ioi riec
Batch:		Started		wiiiigram		Daily	Stopped:	05/07/1994	1
OGENTIN (Suspect	ted)	Otal to			Reas	on:	оторрош	00/01/100	
Tablet	,		2.0	Milligram		Daily		Oral	
		Started		ŭ			Stopped:	05/07/1994	1
Batch:									
_aborato <u>r</u> y Inv		Ta v							
_aboratory Inv	estigations: ype Rang	e Date	e Tes	ted R	Result			Detail	ls

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 95194
 Seq: 1
 Gender: U

 Reported:
 19/08/1994
 Weight:

Hospitalisation: Age:
Onset Date: 02/05/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased			

Medicine Details:

ZOLOFT (Interaction)		Reason:	Depression	
	50.0 Milligram	Daily		
Batch:	Started: 01/03/1994		Stopped:	02/05/1994
LITHIUM CARBONATE (Interaction)		Reason:	Depression	
	1.0 Gram	Daily		
Batch:	Started: 01/01/1993		Stopped:	02/05/1994
MELLERIL (Interaction)		Reason:	Depression	
	30.0 Milligram	Daily		
Batch:	Started: 01/01/1990		Stopped:	02/05/1994
SERC (Interaction)		Reason:	Meniere's dise	ease
	3.0 Dose Unspe	cified Daily		
Batch:	Started: 01/01/1993		Stopped:	02/05/1994

Laboratory Investigations:

Date	Туре	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 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:					
Case Number: 95194 Reported: 19/08/1994 Hospitalisation:	Seq: 1			Gender: Weight: Age:	U
Onset Date: 02/05/1994				DOB:	
Outcome: Not yet recovered	l			Causality:	Causality possible
Reaction Details:					
Medicine Details: TEGRETOL (Other drug)			Reason:	Other&unspecified epilepsy	
Batch:	400.0 Started:	Milligram	Daily L TERM	Stopped:	CONTIN
RIVOTRIL (Other drug)	Starteu.		Reason:	Other&unspecified epilepsy	
(**************************************	4.0	Milligram			
Batch:	Started:		L TERM	Stopped:	CONTIN
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 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Deta	ails:				
Case Numbe	r: 95936	Seq: 1		Ger	nder: M
Reporte	d: 15/09/1994			Wei	ght:
lospitalisatio					Age: 40
Onset Dat					OOB: 04/03/1954
	e: Recovered			Causa	ality: Causality possible
eaction Det					
	erred Term	Severity	Report	Description	Treatment
Anxiety					
Biood creatine Hyperhidrosis	phosphokinase i	ncr			
Pyrexia					
Medicine D THIORIDAZINE Batch:	etails: HYDROCHLORIDE	(Suspected) 25.0 Milli Started: 04/09/19	_	n: aily Stopped:	
Date		Range Date Tested	Result		Details
Cre	eatine	13/08/1994	2313		
Cro	eatine	14/08/1994	1414		
Additional	nformation:				

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls	:
----	----	----	----	-----	----	---

Case Number: 96047 Seq: 1 Gender: M

Reported: 26/09/1994 Weight: 57.00 Hospitalisation: Age: 85Y

Onset Date: 25/07/1994 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

•	todotion Botans.			
	Preferred Term	Severity	Report Description	Treatment
	Coma		Unrousable from sleep	
	Hypertonia			

Medicine Details:

LANOXIN PG (Other drug)		Reason: Congestive heart failure	
Oral application	62.0 Microgram	Daily Oral	
Batch:	Started:	Stopped:	
TAGAMET (Other drug)		Reason:	
Tablet	400.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
DISPRIN (Other drug)		Reason: Chron isch heart dis no hyper	
Oral application	150.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
MELLERIL (Suspected)		Reason: Otr spec symp psychopathol nec	
Oral application	25.0 Milligram	Daily Oral	
Batch:	Started: 25/07/1994	Stopped: 10/08/1994	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 96641
 Seq: 1
 Gender: M

 Reported:
 24/10/1994
 Weight: 75.00

Hospitalisation: Age: 69Y
Onset Date: 12/10/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

touction Dotailor			
Preferred Term	Severity	Report Description	Treatment
Herpes zoster			
Neutropenia			Morphine and acyclovir
Thrombocytopenia			

Medicine Details:

FLUOROURACIL (Suspected)		Reason:	Other malig n	no spec of site	
Oral application	1.9 Gram	Daily		Oral	
Batch:	Started: 26/09/1994		Stopped:	29/09/1994	
CISPLATIN (Suspected)		Reason:	Other malig n	no spec of site	
Oral application	190.0 Milligram	Daily		Oral	
Batch:	Started: 26/09/1994		Stopped:	26/09/1994	
ORUDIS (Suspected)		Reason:	Osteoarthritis		
Capsule	25.0 Milligram	Daily		Oral	
Batch:	Started:		Stopped:		CONTIN
MELLERIL (Suspected)		Reason:			
Tablet	50.0 Milligram	Daily		Oral	
Batch:	Started: 01/01/1994		Stopped:		CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Neutrophils				12/10/94 neutrophils diff==32%
	Platelets	(150-400)	12/10/1994	130	
	White blood cells	(4.0-11.0)	12/10/1994	0.9	

Additional Information:

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

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Reported: 24/10/1994				
14 11 41			Weight:	75.00
ospitalisation:			Age:	69Y
Onset Date: 12/10/1994			DOB:	
Outcome: Not yet recovered	ed	C	ausality:	Causality possible
eaction Details:			-	
Andinina Datalla				
Medicine Details: PANADEINE FORTE (Suspected)	Reas	son: Pain		
Tablet	12.0 Dose Unspecified		Oral	
		-		
Batch:	Started: 27/09/1994	Stopped:	17/10/1994	
aboratory Investigations	:			
aboratory Investigations.	:			
.aboratory Investigations	:			
aboratory Investigations.	:			
aboratory Investigations.	:			
aboratory Investigations.	:			
aboratory Investigations	:			
aboratory Investigations	:			
	:			
Additional Information:				
Additional Information:		metime during the	year.	
Additional Information:		metime during the	year.	
Additional Information:		metime during the	year.	
Laboratory Investigations Additional Information: he dosage start date is not accurate		metime during the	year.	

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 96675 Seq: 1 Gender: F

Reported: 27/10/1994 Weight:
Hospitalisation: Age: 32Y

Onset Date: 12/05/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia			

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other dr	rug)	Reason:	Depression
Capsule	20.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:
THYROXINE SODIUM (Other drug)		Reason:	Myxedema
Tablet	100.0 Microgram	Daily	Oral
Batch:	Started:		Stopped:
DIAZEPAM (Other drug)		Reason:	Otr spec symp psychopathol nec
Oral application	30.0 Milligram	Daily	Oral
Batch:	Started: 07/05/1994		Stopped:
MELLERIL (Suspected)		Reason:	Unspecified schizophrenia
Oral application	250.0 Milligram	Daily	Oral
Batch:	Started: 01/05/1994		Stopped: 12/05/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Similar experience with clorpromazine.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 96714 Seq: 1 Gender: F
Reported: 26/10/1994 Weight:

Hospitalisation: Age: 78Y
Onset Date: 10/10/1994
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Fluid restriction for 12 days

Medicine Details:

TEMAZEPAM (Other drug)		Reas	son:	Disturbance of	fsleep
Capsule	1.0	Dose Unspecified	As ne	cessary	Oral
Batch:	Started:			Stopped:	
THYROXINE SODIUM (Other drug)		Reas	son:	Myxedema	
	50.0	Microgram	Daily		
Batch:	Started:			Stopped:	
FERRO-GRADUMET (Other drug)		Reas	son:		
Tablet	1.0	Dose Unspecified	Daily		Oral
Batch:	Started:			Stopped:	
METAMUCIL (Other drug)		Reas	son:	Constipation	
Oral application	2.0	Dose Unspecified	Daily		Oral
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum osmolality	(280-305)	10/10/1994	248	
	Sodium	(136-145)	10/10/1994	120	
	Sodium	(136-145)	11/10/1994	123	
	Sodium	(136-145)	14/10/1994	133	

Additional Information:

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Report Details:

Case Number: 96714

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Age: 787 DOB: DOB	Reported: 26/10/1994					Weight:	
Outcome: Unknown eaction Details: Medicine Details:	lospitalisation:					Age:	78Y
Medicine Details: ASCORBIC ACID (Other drug)	Onset Date: 10/10/1994					DOB:	
Medicine Details: ASCORBIC ACID (Other drug) Reason: Oral application 250.0 Milligram Daily Oral Batch: Started: Stopped: COLOXYL WITH SENNA (Other drug) Reason: Constipation Tablet 2.0 Dose Unspecified Daily Oral Batch: Started: Stopped: MELLERIL (Suspected) Reason: Unspecified schizophrenia Tablet 50.0 Milligram As necessary Oral Batch: Started: Stopped: 10/10/1994 COGENTIN (Suspected) Reason: Tablet 50.0 Microgram As necessary Oral Batch: 50.0 Microgram As necessary Oral	Outcome: Unknown				C	ausality:	Causality possible
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Batch: Stopped: COLOXYL WITH SENNA (Other drug) Reason: Constipation Tablet 2.0 Dose Unspecified Daily Oral Batch: Stopped: MELLERIL (Suspected) Reason: Unspecified schizophrenia Tablet 50.0 Milligram As necessary Oral Batch: Started: Stopped: 10/10/1994 COGENTIN (Suspected) Reason: Colspan="4">Reason: Tablet 500.0 Microgram As necessary Oral Batch: Started: Stopped: 10/10/1994				Reason:			
Batch: Stopped: COLOXYL WITH SENNA (Other drug) Reason: Constipation Tablet 2.0 Dose Unspecified Daily Oral Batch: Stopped: MELLERIL (Suspected) Reason: Unspecified schizophrenia Tablet 50.0 Milligram As necessary Oral Batch: Started: Stopped: 10/10/1994 COGENTIN (Suspected) Reason: Stopped: 10/10/1994 Tablet 500.0 Microgram As necessary Oral Batch: Started: Stopped: 10/10/1994	· · · · · · · · · · · · · · · · · · ·	250.0	Milligram			Oral	
Tablet 2.0 Dose Unspecified Daily Oral Batch: Started: Stopped: MELLERIL (Suspected) Reason: Unspecified schizophrenia Tablet 50.0 Milligram As necessary Oral Batch: Started: Stopped: 10/10/1994 COGENTIN (Suspected) Feason: Reason: Oral Tablet 500.0 Microgram As necessary Oral Batch: Started: Stopped: 10/10/1994					Stopped:		
Batch: Started: Stopped: MELLERIL (Suspected) Reason: Unspecified schizophrenia Tablet 50.0 Milligram As necessary Oral Batch: Stopped: 10/10/1994 COGENTIN (Suspected) Tablet 500.0 Microgram As necessary Oral Batch: Started: Stopped: 10/10/1994	COLOXYL WITH SENNA (Other drug)			Reason:	Constipation		
MELLERIL (Suspected) Reason: Unspecified schizophrenia Tablet 50.0 Milligram As necessary Oral Batch: Started: Stopped: 10/10/1994 COGENTIN (Suspected) Reason: Tablet 500.0 Microgram As necessary Oral Batch: Started: Stopped: 10/10/1994	Tablet	2.0	Dose Unspeci	fied Daily		Oral	
Tablet 50.0 Milligram As necessary Oral Batch: Started: Stopped: 10/10/1994 COGENTIN (Suspected) Reason: Tablet 500.0 Microgram As necessary Oral Batch: Started: Stopped: 10/10/1994	Batch:	Started:			Stopped:		
Batch: Started: Stopped: 10/10/1994 COGENTIN (Suspected) Reason: Tablet 500.0 Microgram As necessary Oral Batch: Started: Stopped: 10/10/1994	MELLERIL (Suspected)			Reason:		chizophrenia	
Batch: Started: Stopped: 10/10/1994 COGENTIN (Suspected) Tablet 500.0 Microgram As necessary Oral Batch: Started: Stopped: 10/10/1994		50.0	Milligram	As ne			
COGENTIN (Suspected)Tablet500.0MicrogramAs necessaryOralBatch:Started:Stopped:10/10/1994			· ·			10/10/1994	,
Tablet 500.0 Microgram As necessary Oral Batch: Started: Stopped: 10/10/1994	COGENTIN (Suspected)			Reason:			
Batch: Started: Stopped: 10/10/1994		500.0	Microgram	As ne	cessary	Oral	
	Batch:		ŭ				,
_aboratory Investigations:							
	_aboratory Investigations:						
	Additional Information:						
Additional Information:	Additional information.						
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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	96714	Seq: 1			Gender:	F
Reported:	26/10/1994				Weight:	
Hospitalisation:					Age:	78Y
Onset Date:	10/10/1994				DOB:	
Outcome:	Unknown				Causality:	Causality possible
Reaction Detai	ils:					
Medicine Det						
SALBUTAMOL (St	uspected)			Reason: Dyspne		
Inhalation			Milligram	As necessary	Inhalation	
Batch:		Started:			oped: 10/10/199	4
MAXOLON (Suspe	ected)				and vomiting	
Tablet			Milligram	As necessary	Oral	
Batch:		Started:		Stop	oped: 10/10/199	4
Laboratory In	vestigations:					
Laboratory in	ivestigations.					
Additional Inf	formation:					

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 96751 Seq: 1 Gender: F

Reported: 31/10/1994 Weight: 55.00
Hospitalisation: Age: 73Y

Onset Date: 20/10/1994 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano:							
	Preferred Term	Severity	Report Description	Treatment			
	Pruritus						
	Rash maculo-papular						

Medicine Details:

SINEMET (Other drug)	Rea	Reason: Paralysis agitans
Tablet	4.0 Dose Unspecified	ed Daily Oral
Batch:	Started: 01/01/1988	Stopped:
NORMISON (Other drug)	Rea	Reason: Specific disorders of sleep
	20.0 Milligram	Daily
Batch:	Started: 01/01/1990	Stopped:
PROTHIADEN (Other drug)	Rea	Reason:
	75.0 Milligram	Daily
Batch:	Started:	Stopped:
MELLERIL (Suspected)	Rea	Reason:
Oral application	20.0 Milligram	Daily Oral
Batch:	Started: 17/08/1994	Stopped: 20/10/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Quinalone yellow is in melleril. patient also became itchy after 1st dose of temaze instead of normison and has also had a reaction to coumadin 5mg & 1mg tablets, but not to the 2mg coumadin tablets. 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 96914 Seq: 1 Gender: M

Reported: 03/11/1994 Weight: 63.00 Hospitalisation: Age: 40Y

Onset Date: 28/10/1994 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

0.00.00							
Preferred Term	Severity	Report Description	Treatment				
Confusional state							
Hyponatraemia			Fluid restriction.				
Somnolence							

Medicine Details:

PAROXETINE HYDROCHLORIE	DE (Suspected)	Reason:	Depression	
Tablet	20.0 Milligram	Daily		Oral
Batch:	Started: 27/10/1994		Stopped:	28/10/1994
THIORIDAZINE HYDROCHLOR	IDE (Suspected)	Reason:		
Tablet	100.0 Milligram	Daily		Oral
Batch:	Started: 27/10/1994		Stopped:	28/10/1994
PROPRANOLOL HYDROCHLO	Reason:			
Tablet	60.0 Milligram	Daily		Oral
Batch:	Started: 27/10/1994		Stopped:	28/10/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium		26/10/1994	137	
	Sodium		28/10/1994	107	

Additional Information:

Took overdose of thioridazine and propranolol on the 25/10/94.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details	:	
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 Case Number:
 97237
 Seq: 1
 Gender:
 F

 Reported:
 21/11/1994
 Weight:

Hospitalisation: Age: 93

Onset Date: 30/08/1994 DOB: 07/05/1901

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano:							
	Preferred Term	Severity	Report Description	Treatment			
	Confusional state						
	Extrapyramidal disorder						

Medicine Details:

LEVODOPA-CARBIDOPA (Suspected)		Reason:	Paralysis agita	ns
Oral application	1.0 Dose	e Unspecified Daily		Oral
Batch:	Started: 30/08/19	994	Stopped:	02/09/1994
THEO-DUR (Suspected)		Reason:	Otr respiratory	systm diseases
Oral application	400.0 Millio	gram Daily		Oral
Batch:	Started:		Stopped:	01/09/1994
MELLERIL (Suspected)		Reason:		
Oral application	50.0 Millio	gram Daily		Oral
Batch:	Started:		Stopped:	02/09/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 97272 Seq: 1 Gender: F

Reported: 23/11/1994 Weight: 65.00 Hospitalisation: Age: 85Y

Onset Date: 29/10/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Nouvelon Botano.							
	Preferred Term	Severity	Report Description	Treatment			
	Oedema						
	Renal impairment						
	Right ventricular failure						

Medicine Details:

KSR (Other drug)		Reason:	
	4.0 Dose Unspe	cified Daily	
Batch:	Started:	Stopped:	
VOLTAREN (Suspected)		Reason: Gout	
Tablet	100.0 Milligram	Daily Oral	
Batch:	Started: 04/10/1994	Stopped: 30/10/1994	
UREX (Suspected)		Reason: Congestive heart failure	
	80.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZANTAC (Suspected)		Reason:	
	150.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Chloride		31/10/1994	108	
	Chloride		03/11/1994	107	
	Creatinine		29/10/1994	0.35	
	Creatinine		31/10/1994	0.34	
	Creatinine		03/11/1994	0.25	
	Potassium		31/10/1994	5.4	
	Potassium		03/11/1994	3.2	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 97272 Seq: 1 Gender: F

 Reported: 23/11/1994
 Weight: 65.00

 Hospitalisation:
 Age: 85Y

Onset Date: 29/10/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

CARTIA (Suspected)			Reason:		
	100.0	Milligram	Daily		
Batch:	Started:			Stopped:	
ALODORM (Suspected)			Reason:		
	5.0	Milligram	Daily		
Batch:	Started:			Stopped:	
QUINIDINE BISULPHATE (Suspected)			Reason:		
	300.0	Milligram	Daily		
Batch:	Started:			Stopped:	31/10/1994
ALDAZINE (Suspected)			Reason:		
	25.0	Milligram	Daily		
Batch:	Started:			Stopped:	31/10/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium		31/10/1994	143	
	Sodium		03/11/1994	145	
	Urea		31/10/1994	27.3	
	Urea		03/11/1994	21.3	
	bicarbonate		31/10/1994	22	
	bicarbonate		03/11/1994	28	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 97467 Seq: 1 Gender: F

 Reported: 01/12/1994
 Weight: 55.00

 Hospitalisation:
 Age: 65Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

١,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Coordination abnormal			
	Visual disturbance			

Medicine Details:

MELLERIL (Suspected) Reason: Depression

Tablet 150.0 Milligram Daily Oral

Batch: Started: 01/01/1990 **Stopped:** 31/01/1992

Laboratory Investigations:

Date	Туре	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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 97867 Seq: 1 Gender: M
Reported: 14/12/1994 Weight:
Hospitalisation: Age: 35Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

ACICLOVIR (Suspected)		Reason:	Unspecified vi	ral encephalitis
Injection	3.0 Gram	Daily		Intravenous
Batch:	Started: 10/11/1994		Stopped:	14/11/1994
THIORIDAZINE HYDROCHLORIDE (Suspec	ted)	Reason:		
	225.0 Milligram	Daily		
Batch:	Started: 16/11/1994		Stopped:	22/11/1994
PHENYTOIN SODIUM (Suspected)		Reason:		
Injection	400.0 Milligram	Daily		Intravenous
Batch:	Started: 10/11/1994		Stopped:	16/11/1994
SUCRALFATE (Suspected)		Reason:		
Tablet	4.0 Gram	Daily		Oral
Batch:	Started: 10/11/1994		Stopped:	14/11/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	<30 U/L	14/11/1994	27	
	ALT = SGPT	<30 U/L	18/11/1994	198	
	ALT = SGPT	<30 U/L	28/11/1994	238	
	Bilirubin	<18 UMOL/L	14/11/1994	11	
	Bilirubin	<18 UMOL/L	18/11/1994	36	
	Bilirubin	<18 UMOL/L	28/11/1994	16	
	GGT = SGGT =	<35 U/L	14/11/1994	58	

Additional Information:

See original report for other medication.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 97867
 Seq: 1
 Gender: M

 Reported:
 14/12/1994
 Weight:

Hospitalisation:
Onset Date:

DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

CEFTRIAXONE (Suspected) Reason:

 Injection
 2.0 Gram
 Daily
 Intravenous

 Batch:
 Started: 10/11/1994
 Stopped: 15/11/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	GGT = SGGT =	<35 U/L	18/11/1994	396	
	GGT = SGGT =	<35 U/L	28/11/1994	162	
	SAP = ALP	30-100 U/L	14/11/1994	78	
	SAP = ALP	30-100 U/L	18/11/1994	158	
	SAP = ALP	30-100 U/L	28/11/1994	138	

Additional Information:

See original report for other medication.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 99527 Seq: 1 Gender: F

Reported: 10/03/1995 Weight: 82.00 Hospitalisation: Age: 38Y

Onset Date: 04/03/1995 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphagia			Im cogentin 2mg

Medicine Details:

TEMAZE (Other drug)		Reason:	Specific disord	ders of sleep	
Capsule	20.0 Milligran	n As ne	ecessary	Oral	
Batch:	Started: 27/02/1995		Stopped:		CONTIN
SINEQUAN (Other drug)		Reason:	Depression		
Oral application	100.0 Milligran	n Daily		Oral	
Batch:	Started:	L TERM	Stopped:		
LITHIUM CARBONATE (Other drug)		Reason:			
Tablet	500.0 Milligran	n Daily		Oral	
Batch:	Started: 01/01/1994		Stopped:	27/02/1995	12M
PROZAC (Suspected)		Reason:	Depression		
Capsule	20.0 Milligran	n Daily		Oral	
Batch:	Started: 02/03/1995		Stopped:	05/03/1995	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	99527	Seq: 1			Gender:	F
Reported:	10/03/1995				Weight:	82.00
Hospitalisation:					Age:	38Y
Onset Date:	04/03/1995				DOB:	
Outcome:	Recovered			С	ausality:	Causality possible
Reaction Detai					-	• •
Medicine Deta	ails:					
MELLERIL (Suspe			Reason:	Unspecified ps	ychosis	
Oral applica	ation	300.0 Milligram	Daily		Oral	
Batch:		Started: 01/03/1995		Stopped:	05/03/1995	5
Laboratory In	vestigations:					
_	_					
Additional Inf						
tne dosage start da	ate is not accurate b	ut indicates that start occurr	ed sometim	ne during the y	ear.	

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:					
Case Number: 99680	Seq: 1	Gender: M			
Reported: 20/03/1995		Weight:			

Hospitalisation: Age: 61Y
Onset Date: 01/03/1995
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Confusional state			
Dyskinesia			
Tremor			

Medicine Details:

BENZTROPINE MESYLATE (Other drug)		Reason:	
Oral application	1.0 Milligram	As necessary Oral	
Batch:	Started: 09/02/1995	Stopped:	CONTIN
CLONAZEPAM (Other drug)		Reason: Specific disorders of sleep)
	0.0	As necessary	
Batch:	Started: 09/02/1995	Stopped:	CONTIN
TEMAZEPAM (Other drug)		Reason: Anxiety neurosis	
	0.0	As necessary	
Batch:	Started: 09/02/1995	Stopped:	CONTIN
RANITIDINE (Other drug)		Reason: Other diseases of esopha	gus
Tablet	300.0 Milligram	Daily Oral	
Batch:	Started: 30/01/1995	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	99680	Seq: 1		Gender:	M
Reported:	20/03/1995			Weight:	
Hospitalisation:				Age:	61Y
Onset Date:	01/03/1995			DOB:	
Outcome:	Recovered			Causality:	Causality possible
Reaction Detai	ls:				
Medicine Deta			Reason:	Depression	
LITHIUWI CARBON.	ATE (Suspected)	750.0 Milligram	Daily	Depression	
Batch:		Started: 21/02/1995	Dally	Stopped: 02/03/1995	
	DROCHLORIDE (Sus		Reason:	Unspecified psychosis	,
THIORIDAZINE III	DICOCITEORIDE (Sus	300.0 Milligram	Daily	Orispecified psychosis	
Batch:		Started: 28/02/1995	Daily	Stopped : 02/03/1995	
	ROCHLORIDE (Susp		Reason:	Depression	,
OZIKITO KZINIZ TITIS		50.0 Milligram	Daily	Doproccion	
Batch:		Started: 10/02/1995	24,	Stopped: 02/03/1995	5
Laboratory In	vestigations:				
Additional Inf	ormation:				
Additional IIII	ormation.				

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Reported: 28/03/1995	Reported: 28/03/1995		er: 99853	Seq: 1				Gender:	M
Onset Date: 07/03/1995 DOB: Outcome: Unknown Causality: Causality possection Details: Preferred Term Severity Report Description Treatme roleptic malignant syndrome dicine Details: SOXIN (Other drug) Reason: Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: LLERIL (Suspected) Reason: 75.0 Milligram Daily	Onset Date: 07/03/1995 Outcome: Unknown Causality: Causality possible ction Details: Preferred Term Severity Report Description Treatment roleptic malignant syndrome dicine Details: SOXIN (Other drug) Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: LLERIL (Suspected) Reason: 75.0 Milligram Daily Batch: Started: 17/01/1995 Stopped: 01/03/1995			-				Weight:	
Outcome: Unknown Causality: Causality possection Details: Preferred Term Severity Report Description Treatme uroleptic malignant syndrome Glicine Details: GOXIN (Other drug) Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily	Outcome: Unknown Causality: Causality possible ction Details: Preferred Term Severity Report Description Treatment uroleptic malignant syndrome dicine Details: GOXIN (Other drug) Reason: Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily Batch: Started: 17/01/1995 Stopped: 01/03/1995	_						_	
Ction Details: Preferred Term Severity Report Description Treatme uroleptic malignant syndrome Colicine Details: GOXIN (Other drug) Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily	Preferred Term Severity Report Description Treatment uroleptic malignant syndrome Continuous								
Preferred Term Severity Report Description Treatme uroleptic malignant syndrome Pedicine Details: GOXIN (Other drug) Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily	Preferred Term Severity Report Description Treatment uroleptic malignant syndrome Redicine Details: GOXIN (Other drug) Reason: Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily Batch: Started: 17/01/1995 Stopped: 01/03/1995						Ca	ausality:	Causality possible
uroleptic malignant syndrome edicine Details: IGOXIN (Other drug) Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily	edicine Details: GOXIN (Other drug) Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily Batch: Started: 17/01/1995 Stopped: 01/03/1995			0		D I D			Torontoronal
edicine Details: IGOXIN (Other drug) Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) 75.0 Milligram Daily	edicine Details: IGOXIN (Other drug) Reason: Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily Batch: Started: 17/01/1995 Stopped: 01/03/1995				 	Report Desc	cription		Treatment
GOXIN (Other drug) Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) 75.0 Milligram Daily	Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily Batch: Started: 17/01/1995 Stopped: 01/03/1995	ловерист	alignant syndroni	=					
Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily	Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily Batch: Started: 17/01/1995 Stopped: 01/03/1995								
Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily	Tablet 250.0 Microgram Daily Oral Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily Batch: Started: 17/01/1995 Stopped: 01/03/1995					Reason:			
Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily	Batch: Started: Stopped: ELLERIL (Suspected) Reason: 75.0 Milligram Daily Batch: Started: 17/01/1995 Stopped: 01/03/1995			250.0) Microgram			Oral	
ELLERIL (Suspected) Reason: 75.0 Milligram Daily	Reason: 75.0 Milligram Daily Batch: Started: 17/01/1995 Stopped: 01/03/1995 boratory Investigations:		:		0 -	,			
	Batch: Started: 17/01/1995 Stopped: 01/03/1995 boratory Investigations:	ELLERIL (Su	spected)			Reason:			
Batch: Started: 17/01/1995 Stopped: 01/03/1995	boratory Investigations:			75.0) Milligram	Daily			
		Batch	!	Started: 1	7/01/1995		Stopped:	01/03/1995	j
Aboratory Investigations: Date Type Range Date Tested Result Details									

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	port	Deta	ails:
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 Case Number:
 99985
 Seq: 1
 Gender:
 F

 Reported:
 03/04/1995
 Weight:

Hospitalisation: Age: 55

Onset Date: 31/05/1994 **DOB**: 05/08/1938

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Details.			
	Preferred Term	Severity	Report Description	Treatment
	Myalgia			
	Pollakiuria			

Medicine Details:

PREMARIN (Other drug)	Reason:				
	1.2 Milligram	Daily			
Batch:	Started:	Stopped:			
PROVERA (Other drug)		Reason:			
	5.0 Milligram	Daily			
Batch:	Started:	Stopped:			
MELLERIL (Suspected)		Reason: Depression			
Oral application	10.0 Milligram	As necessary	Oral		
Batch:	Started: 17/05/1994	Stopped:	10/07/1994		
PROZAC (Suspected)		Reason: Depression			
	20.0 Milligram	Daily			
Batch:	Started: 17/05/1994	Stopped:	28/08/1994		

Laboratory Investigations:

Date	Туре	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.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Hospitalisati Onset Da	ate: ne: Unknown	Seq: 1			Gender: F Weight: Age: DOB: Causality: Causality possible				
	ferred Term	Seve	erity	Repo	rt Descript	ion	7	reatment	
Urinary reten	tion		,	·					
Medicine I									
MELLERIL (S	uspected)		0.0	Reas	son:				
Batch	••	Star	0.0		9	opped:			
AROPAX (Sus		Star	teu.	Reas	Reason:				
7.1.101.7.11 (0.1.1	,		40.0 Millig		Daily				
Batch	n:	Star		-		opped:			
	y Investigat		 T	D					
Date	Туре	Range D	ate Tested	Result			Details		
Additional	l Informatio	n:							

Report Run: 01/06/2007 02:44PM Database: pusime02 ADRS004 Page 151 of 393



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Ren	ort	Deta	ils:
-----	-----	------	------

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 Details:

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	Туре	Range	Date Tested	Result	Details

Additional Information:

Allergic to penicillin

Report Run: 01/06/2007 02:44PM Database: pusime02 ADRS004 Page 152 of 393



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:						
Case Number: 10 Reported: 00 Hospitalisation: Onset Date: Outcome: R Reaction Details	8/05/1995 ecovered	Seq: 1			Gender: Weight: Age: DOB: Causality:	70.00 57Y
Medicine Detai				Reason:	Specific disorders of sleep	
Batch:		Started	10.0 Milligram	Daily	Stopped:	
Laboratory Inve	estigations:					
Additional Info	rmation:					

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Ren	ort	Deta	ils:
-----	-----	------	------

Case Number: 100714 Seq: 1 Gender: F

 Reported:
 08/05/1995
 Weight:
 56.00

 Hospitalisation:
 Age:
 21Y

 Onset Date:
 01/03/1995
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

AROPAX (Suspected)		Reason:	Depression	
Tablet	10.0 Milligram	Daily		Oral
Batch:	Started: 13/01/1995		Stopped:	
AROPAX (Suspected)		Reason:	Depression	
Tablet	20.0 Milligram	Daily		Oral
Batch:	Started: 01/03/1995		Stopped:	05/04/1995
COGENTIN (Suspected)		Reason:		
Tablet	2.0 Milligram	Daily		Oral
Batch:	Started: 16/08/1994		Stopped:	
LITHIUM CARBONATE (Suspected)		Reason:		
Tablet	1.0 Gram	Daily		Oral
Batch:	Started: 20/09/1994		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 02:44PM Database: pusime02 ADRS004 Page 154 of 393



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	100714	Seq: 1		Gender:	F
Reported:	08/05/1995			Weight:	56.00
Hospitalisation:				Age:	21Y
Onset Date:	01/03/1995			DOB:	
Outcome:	Not yet recovered	d		Causality:	Causality possible
Reaction Detai	ils:				
Medicine Det	ails:				
PIMOZIDE (Suspe			Reason:		
Tablet		4.0 Milligram	Daily	Oral	
Batch:		Started: 20/10/1994		Stopped:	
THIORIDAZINE HY	DROCHLORIDE (Sus	pected)	Reason:		
Tablet		200.0 Milligram	Daily	Oral	
Batch:		Started: 07/12/1992		Stopped:	
Laboratory In	vestigations:				
Additional Inf	formation:				
anart Dun : 01/06/20/	07 02:44PM Datah	nace: nucime02	VDB6004		Dogg 455 of 202

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 100894 Seq: 1 Gender: M
Reported: 19/05/1995 Weight:

Hospitalisation: Age: 83Y
Onset Date: 15/03/1995
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Hyperthyroidism			

Medicine Details:

CORDARONE X 200 (Suspected)		Reason: Otr&nos disord of heart rhythm	
Tablet	200.0 Milligram	Daily Oral	
Batch:	Started: 01/03/1993	Stopped: 16/05/1995	
MELLERIL (Suspected)		Reason: Otr ecz&der due otr&unsp cause	
Oral application	40.0 Milligram	Daily Oral	
Batch:	Started: 01/03/1993	Stopped:	
LASIX (Suspected)		Reason: Congestive heart failure	
Oral application	40.0 Milligram	Daily Oral	
Batch:	Started: 01/03/1993	Stopped:	
TRITACE (Suspected)		Reason: Congestive heart failure	
Capsule	2.5 Milligram	Daily Oral	
Batch:	Started: 01/03/1993	Stopped:	

Laboratory Investigations:

	<u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
	Thyroid		15/03/1995	< 0.01	
	Thyroxine		15/03/1995	>77	
	Tri-iodo thyronine		15/03/1995	12	

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 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Detail	s:				
Case Number:	100894	Seq: 1		Gender:	М
Reported:	19/05/1995			Weight:	
ospitalisation:				Age:	
Onset Date:				DOB:	
	Not yet recovered			Causality:	Causality possible
eaction Detai	ils:				
Madiaina Dat	oilo:				
Medicine Det			Reason:	Specific disorders of sleep	
TEMAZEPAM (Sus	spected)	10.0 Milligram	Reason:	Specific disorders of sleep Oral)
	spected)	10.0 Milligram Started: 01/03/1993	Reason: Daily	Oral)
TEMAZEPAM (Sus Oral applic	spected))
TEMAZEPAM (Sus Oral applic	spected)			Oral	
TEMAZEPAM (Sus Oral applic	spected)			Oral)
TEMAZEPAM (Sus Oral applic	spected)			Oral)
TEMAZEPAM (Sus Oral applic	spected)			Oral	
TEMAZEPAM (Sus Oral applic	spected)			Oral	
TEMAZEPAM (Sus Oral applic	spected)			Oral	
TEMAZEPAM (Sus Oral applic	spected)			Oral	
TEMAZEPAM (Sus Oral applic	spected)			Oral	
TEMAZEPAM (Sus Oral applic Batch:	spected) ation			Oral	
TEMAZEPAM (Sus Oral applic Batch:	spected)			Oral	
TEMAZEPAM (Sus Oral applic Batch:	spected) ation			Oral	
TEMAZEPAM (Sus Oral applic Batch:	spected) ation			Oral	

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 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 100982
 Seq: 1
 Gender: M

 Reported:
 19/05/1995
 Weight:

Hospitalisation: Age: 36

Onset Date: 22/03/1994 **DOB**: 19/02/1958

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension		Bp 180/110	
Blood creatine phosphokinase incr			
Hypertonia			
Hypokalaemia			
Hyponatraemia			Diazepam, bromocriptine and propranolol.
Leukocytosis			
Neuroleptic malignant syndrome			

Medicine Details:

COLOXYL (Other drug)	Reason:
----------------------	---------

Tablet 2.0 Dose Unspecified Daily Oral

Batch: Started: Stopped:

IMIPRAMINE HYDROCHLORIDE (Other drug) Reason:

200.0 Milligram Daily

Batch: Started: Stopped:

MODECATE (Suspected) Reason:

Injection 1.0 Dose Unspecified Monthly Intravenous

Batch: Started: Stopped:

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:

10.0 Milligram Daily

Batch: Started: 14/03/1994 **Stopped:** 18/03/1994

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		21/03/1994	1480	
	Creatine		22/03/1994	6100	
	Creatine		24/03/1994	1480	
	Creatine		26/03/1994	250	
	Creatine		23/03/1994	3530	
	Creatine		30/03/1994	140	
	Potassium		21/03/1994	3.4	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 100982
 Seq: 1
 Gender: M

 Reported:
 19/05/1995
 Weight:

Reported: 19/05/1995 Weight:
Hospitalisation: Age: 36

Onset Date: 22/03/1994 **DOB**: 19/02/1958

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

I HIORIDAZINE HTDROCHLORIDE (Suspected)		Reason:	
	100.0 Milligram	Daily	
Batch: Sta	arted: 18/03/1994		Stopped:

ORPHENADRINE NOS (Suspected) Reason:

400.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Potassium		22/03/1994	3.0	
	Potassium		23/03/1994	4.0	
	Potassium		30/03/1994	4.3	
	Potassium		26/03/1994	4.7	
	Potassium		24/03/1994	3.5	
	Sodium		21/03/1994	121	
	Sodium		22/03/1994	125	

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Reported:		Seq:					Gender:	IVI
	: 19/05/199	5				,	Weight:	
lospitalisation:							Age:	36
Onset Date:	: 22/03/1994	4					DOB:	19/02/1958
Outcome:	Recovered	t				Ca	ausality:	Causality possible
eaction Deta	ils:							
Medicine Det	tails:							
COLOXYL (Other	drug)			R	eason:			
Tablet			2.0	Dose Unspecifie	d Daily		Oral	
		0						
Batch:		5	tarted:			Stopped:		
Batch:	ROCHLORIDE		tarted:	R	eason:	Stopped:		
	ROCHLORIDE			R Milligram	eason: Daily	Stopped:		
	ROCHLORIDE	(Other drug)				Stopped:		
IMIPRAMINE HYD		(Other drug)	200.0	Milligram				
IMIPRAMINE HYD		(Other drug)	200.0	Milligram	Daily eason:	Stopped:	Intravenous	s
Batch:		E (Other drug) S	200.0	Milligram R	Daily eason:	Stopped:	Intravenous	s
Batch: MODECATE (Sus Injection	pected)	E (Other drug) S S	200.0 tarted: 1.0 tarted:	Milligram R Dose Unspecifie	Daily eason:	Stopped:	Intravenous	S
Batch: MODECATE (Sus Injection Batch:	pected)	E (Other drug) S S	200.0 tarted: 1.0 tarted:	Milligram R Dose Unspecifie	Daily eason: d Monthly	Stopped:	Intravenous	s
Batch: MODECATE (Sus Injection Batch:	pected)	E (Other drug) S S LORIDE (Suspe	200.0 tarted: 1.0 tarted:	Milligram R Dose Unspecifie R Milligram	Daily eason: d Monthly eason:	Stopped:		
Batch: MODECATE (Sus Injection Batch: TRIFLUOPERAZII Batch:	pected) NE HYDROCHI	Since (Other drug) Since (Suspe	200.0 tarted: 1.0 tarted: ected) 10.0	Milligram R Dose Unspecifie R Milligram	Daily eason: d Monthly eason:	Stopped:		
Batch: MODECATE (Sus Injection Batch: TRIFLUOPERAZII Batch:	pected) NE HYDROCH	S (Other drug) S (S) LORIDE (Suspe	200.0 tarted: 1.0 tarted: ected) 10.0 tarted: 14/0	Milligram R Dose Unspecifie R Milligram 03/1994	Daily eason: d Monthly eason:	Stopped:	18/03/1994	1
Batch: MODECATE (Sus Injection Batch: TRIFLUOPERAZII Batch: Laboratory II Date	pected) NE HYDROCH Ovestigati Type	Since (Other drug) Since (Suspe	200.0 tarted: 1.0 tarted: ected) 10.0 tarted: 14/0	R Dose Unspecifie R Milligram 03/1994	Daily eason: d Monthly eason:	Stopped:		1
Batch: MODECATE (Sus Injection Batch: TRIFLUOPERAZII Batch: Laboratory II Date Sodia	pected) NE HYDROCH nvestigati Type um	S (Other drug) S (S) LORIDE (Suspe	200.0 tarted: 1.0 tarted: ected) 10.0 tarted: 14/0 Date Test	Milligram R Dose Unspecifie R Milligram 03/1994 ed Result 94 130	Daily eason: d Monthly eason:	Stopped:	18/03/1994	1
Batch: MODECATE (Sus Injection Batch: TRIFLUOPERAZII Batch: Laboratory II Date	nvestigati Type um um	S (Other drug) S (S) LORIDE (Suspe	200.0 tarted: 1.0 tarted: ected) 10.0 tarted: 14/0	R Dose Unspecifie R Milligram 03/1994 ed Result 04 130 04 131	Daily eason: d Monthly eason:	Stopped:	18/03/1994	1

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	100982	Seq: 1				Gender:	M
Reported:	19/05/1995					Weight:	
Hospitalisation:						Age:	36
Onset Date:							19/02/1958
Outcome:	Recovered					Causality:	Causality possible
Reaction Detail	ls:						
Medicine Deta	aile.						
	DROCHLORIDE (Sus	pected)			Reason:		
			0.0	Milligram	Daily		
Batch:		Started:				Stopped:	
ORPHENADRINE N	IOS (Suspected)				Reason:		
		40	0.0	Milligram	Daily		
Batch:		Started:	:			Stopped:	
Laboratory In	vestigations:						
	. congunono						
Additional Inf	ormotic						
Additional Int	ormation:						

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 101218 Seq: 1 Gender: F

 Reported:
 26/05/1995
 Weight:
 79.00

 Hospitalisation:
 Age:
 63Y

 Onset Date:
 31/03/1995
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypothyroidism	Severe		Thyroxine

Medicine Details:

LITHICARB (Suspected)		Reason:	Depression		
	500.0 Milligram	Daily			
Batch:	Started: 02/09/1994		Stopped:	26/04/1995	
AROPAX (Suspected)		Reason:	Depression		
Tablet	20.0 Milligram	Daily		Oral	
Batch:	Started: 06/01/1995		Stopped:		CONTIN
TOLVON (Suspected)		Reason:	Depression		
	20.0 Milligram	Daily			
Batch:	Started: 01/01/1993		Stopped:		CONTIN
MELLERIL (Suspected)		Reason:			
	25.0 Milligram	Daily			
Batch:	Started: 01/01/1993		Stopped:	28/04/1995	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Very high thyroid autoantibodies - tsh 100, t4 2.4.

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report De	etails	s:							
Case Num	ber:	101576	Seq	;: 1				Gender:	F
Reported: 16/06/1995								Weight:	
Hospitalisation:								Age:	29Y
Onset D	ate:	08/06/199	95					DOB:	
Outco	me:	Not yet re	covered				С	ausality:	Causality possible
eaction D	etai	ls:							
Pr	eferre	ed Term	S	everity	Rep	ort De	scription		Treatment
Agitation									
Confusional	state)							
Medicine PROZAC (Su					Rea	son:	Depression		
Oral	applica	ation		20.0 Mil	ligram	Daily		Oral	
Bato			5	Started: 08/06/1	1995		Stopped:	09/06/1995	5
MELLERIL (S	Suspe	cted)			Rea	son:			
Table	et			75.0 Mil	ligram	Daily		Oral	
Bato	:h:			Started: 08/06/1	1995		Stopped:		CONTIN
Laborato Date				Data Testad	Pasult			Detai	le.
Date		Туре	Range	Date Tested	Result			Detai	15
Additiona	ıl Inf	ormatio	n:						

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

	ber. 101620	Seq.	· I			ier. IVI
Repor	ted: 29/06/199	5			Weig	ht: 57.00
ospitalisat	ion:				A	ge: 72Y
Onset D	ate:					OB:
Outco	me: Recovered	d			Causal	ity: Causality possible
eaction D	etails:					
	eferred Term	Se	everity	Repo	ort Description	Treatment
- - - - - - - - - - - - - - - - - - -				·		
Medicine THIORIDAZII	Details: NE HYDROCHLOR	IDE (Suspected	I) 0.0	Rea	son:	
Bato	·h·	S	tarted:		Stopped:	
ahorato	ry Investigat	ions:				
Date	Type	Range	Date Tested	Result		Petails
Additiona	ıl Informatio	n:				
port Run: 01/	06/2007 02:44PM	Database: n	usime02	Δ	DRS004	Page 164 of 303

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number	102138	Seq:	1		Ge	nder: M
	: 13/07/1995	-				ight: 19.00
lospitalisation						Age: 3Y
Onset Date						DOB:
	Recovered					ality: Causality possible
eaction Deta						, , , , , , , , , , , , , , , , , , ,
	red Term	Se	everity	Rep	ort Description	Treatment
Drug ineffective						
Medicine De THIORIDAZINE H		E (Suspected	l) 50.0 Milli		son:	
Batch:		S	tarted:	•	Stopped:	
Laboratory I	nvostigatio	ane:				
Date Date	Type	Range	Date Tested	Result		Details
	,,				_	_
Additional Ir						
port Run: 01/06/2	007 02:44PM	Database: pu	usime02	A	DRS004	Page 165 of 393



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

eport De	tails:								
ase Numb	oer: 103156	Seq:	1				Gender:	M	
Report	ted: 30/08/199	5					Weight:		
pitalisati							Age:	86Y	
-	ate: 15/06/199)5					DOB:		
	ne: Recovere					C		Causality proba	ahle
		u				•	adodnity.	Oddodnity proble	ADIC
ction D	eferred Term	So	verity	Dor	ort Desc	crintion		Treatmen	+
exia	sierreu reini	36	venty	110	JUIT DESC	приоп		Heatmen	
	Details:								
	IE HYDROCHLOR	IDE (Suspected			ason:				
Oral a	application		20.0 Mill		Daily		Oral		
Batcl	h:	St	tarted: 09/06/1	1995		Stopped:	16/06/1995	5	
aborato <u>r</u>	y Investiga <u>t</u>								
Date	Туре	Range	Date Tested	Result			Detai	ls	
Additiona	I Informatio	n:							
ort Run : 01/0)6/2007 02:44PN	/ Database: pu	ısime02		ADRS004			Page 166	of 30

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 103445 Seq: 1 Gender: M

Reported: 11/09/1995 Weight:

Hospitalisation: Age: 36Y
Onset Date: 08/08/1995
DOB:

Outcome: Recovered Causality: Causality certain

Reaction Details:

•	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Aggression			
	Dysarthria			

Medicine Details:

MELLERIL (Suspected) Reason: Unspecified psychosis

600.0 Milligram Daily

Batch: Started: 08/08/1995 **Stopped:** 10/08/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Within one hour of taking melleril patient develops same reaction.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 103783
 Seq: 1
 Gender: M

 Reported:
 03/10/1995
 Weight:

Hospitalisation: Age: 44Y
Onset Date: 04/09/1995
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Asthenia			
Coordination abnormal			
Hepatitis			

Medicine Details:

Medicine Details.			
PEPCIDINE (Other drug)		Reason:	
Tablet	40.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
TEGRETOL (Suspected)		Reason: Other&unspecified	epilepsy
Tablet	400.0 Milligram	Daily Oral	
Batch:	Started: 06/05/1995	Stopped: 04/0	9/1995
MELLERIL (Suspected)		Reason:	
Tablet	60.0 Milligram	Daily Oral	
Batch:	Started: 04/09/1995	Stopped:	
NICOTINIC ACID (Suspected)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started:	Stopped: 04/0	9/1995

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT		05/09/1995	1140	
	AST = SGOT		05/09/1995	774	
	Bilirubin		05/09/1995	23	
	SAP = ALP		05/09/1995	208	
	Serum drug level		04/09/1995	34	Tegretel

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Reported: 13/11/1995	Reported: 13/11/1995					
spitalisation: Age: 82Y Onset Date: 24/07/1995 Outcome: Recovered Causality: Causality possible action Details: Preferred Term Severity Report Description Treatment thostatic hypotension Reason: 1.0 Dose Unspecified 1 time Batch: Started: 21/07/1995 Stopped: ELLERIL (Suspected) Reason: Depression 3.0.0 Milligram Daily Batch: Started: 11/07/1995 Stopped: 24/07/1995 EFLEX (Suspected) Reason: Otrânos infecăparasit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995	Age: 82Y DOB: Onset Date: 24/07/1995 Outcome: Recovered Causality: Causality possible action Details: Preferred Term Severity Report Description Treatment thostatic hypotension Reason: 1.0 Dose Unspecified 1 time Batch: Started: 21/07/1995 Reason: Depression 30.0 Milligram Batch: Started: 11/07/1995 Reason: Ottranos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 24/07/1995 Reason: Ottranos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995	ase Number: 104565	Seq: 1			
Onset Date: 24/07/1995 Outcome: Recovered Recovered Causality: Causality possible action Details: Preferred Term Severity Report Description Treatment thostatic hypotension Reason: 1.0 Dose Unspecified 1 time 1 time	Onset Date: 24/07/1995 Outcome: Recovered Recovered Causality: Causality possible action Details: Preferred Term Severity Report Description Treatment thostatic hypotension Bedicine Details: 1.0 Dose Unspecified 1 time Batch: Started: 21/07/1995 Stopped: 24/07/1995 Batch: Started: 11/07/1995 Reason: Otrânos infec¶sit diseases 1.0 Gram Deltails: Started: 21/07/1995 Stopped: 26/07/1995 Batch: Started: 21/07/1995 Stopped: 26/07/1995 Batch: Started: 21/07/1995 Stopped: 26/07/1995 Batch: Started: 21/07/1995 Stopped: 26/07/1995				_	
Outcome: Recovered section Details: Preferred Term Severity Report Description Treatment thostatic hypotension Padicine Details: Reason: 1.0 Dose Unspecified 1 time Batch: Started: 21/07/1995 Stopped: ELLERIL (Suspected) Reason: Depression 30.0 Milligram Daily Batch: Started: 11/07/1995 Stopped: 24/07/1995 EFLEX (Suspected) Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995	Outcome: Recovered section Details: Preferred Term Severity Report Description Treatment thostatic hypotension Padicine Details: Reason: 1.0 Dose Unspecified 1 time Batch: Started: 21/07/1995 Stopped: ELLERIL (Suspected) Reason: Depression 30.0 Milligram Daily Batch: Started: 11/07/1995 Stopped: 24/07/1995 EFLEX (Suspected) Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995	_			_	
Preferred Term Severity Report Description Treatment thostatic hypotension Bedicine Details: I-GESIC (Other drug) Reason: 1.0 Dose Unspecified 1 time Batch: Started: 21/07/1995 Stopped: IELLERIL (Suspected) Reason: Depression 30.0 Milligram Daily Batch: Started: 11/07/1995 Stopped: 24/07/1995 EFLEX (Suspected) Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995	Preferred Term Severity Report Description Treatment thostatic hypotension Bedicine Details: I-GESIC (Other drug) Reason: 1.0 Dose Unspecified 1 time Batch: Started: 21/07/1995 Stopped: IELLERIL (Suspected) Reason: Depression 30.0 Milligram Daily Batch: Started: 11/07/1995 Stopped: 24/07/1995 EFLEX (Suspected) Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995					
Preferred Term Severity Report Description Treatment thostatic hypotension Pedicine Details: Preferred Term Severity Report Description Treatment Reason: 1.0 Dose Unspecified 1 time Batch: Started: 21/07/1995 Stopped: Reason: Depression 30.0 Milligram Daily Batch: Started: 11/07/1995 Stopped: 24/07/1995 REFLEX (Suspected) Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995 Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995	Preferred Term Severity Report Description Treatment thostatic hypotension Reason:				Causality	: Causality possible
edicine Details: Reason: 1.0 Dose Unspecified 1 time Batch: Started: 21/07/1995 Stopped: Reason: Depression 30.0 Milligram Daily Batch: Started: 11/07/1995 Stopped: 24/07/1995 EFLEX (Suspected) Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995 EFLEX (Suspected) Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995	edicine Details: Reason: 1.0 Dose Unspecified 1 time Batch: Started: 21/07/1995 Stopped: Reason: Depression 30.0 Milligram Daily Batch: Started: 11/07/1995 Stopped: 24/07/1995 EFFLEX (Suspected) Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995		Soverity	Panart Da	oorintion	Trootmont
Reason:	Reason:		Seventy	Кероп Бе	Scription	Healment
Reason:	1.0 Dose Unspecified 1 time	anostatio riypotemoleri				
1.0 Dose Unspecified 1 time	1.0 Dose Unspecified 1 time					
1.0 Dose Unspecified 1 time	1.0 Dose Unspecified 1 time					
Reason:	1.0 Dose Unspecified 1 time					
1.0 Dose Unspecified 1 time	1.0 Dose Unspecified 1 time					
Reason:	Reason:					
1.0 Dose Unspecified 1 time	Reason:					
1.0 Dose Unspecified 1 time	1.0 Dose Unspecified 1 time					
1.0 Dose Unspecified 1 time	1.0 Dose Unspecified 1 time					
Batch: Started: 21/07/1995 Stopped:	Batch: Started: 21/07/1995 Stopped:	I-GESIC (Other drug)				
Reason: Depression 30.0 Milligram Daily Batch: Started: 11/07/1995 Stopped: 24/07/1995 Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995 Reason: Otr&nos infec¶sit diseases 26/07/1995 Stopped: 26/07/1995	Reason: Depression 30.0 Milligram Daily Batch: Started: 11/07/1995 Stopped: 24/07/1995 Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995 Stopped: 26/07/1995	Detale				
Batch: Started: 11/07/1995 Stopped: 24/07/1995 Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995 Stopped: 26/07/1995	Batch: Started: 11/07/1995 Stopped: 24/07/1995 Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995 Stopped: 26/07/1995	Batch:	Started: 21/07/			
Batch: Started: 11/07/1995 Stopped: 24/07/1995 KEFLEX (Suspected) Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995 aboratory Investigations:	Batch: Started: 11/07/1995 Stopped: 24/07/1995 KEFLEX (Suspected) Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995 aboratory Investigations:	AELLEBII (Supported)			Deniession	
Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995 aboratory Investigations:	Reason: Otr&nos infec¶sit diseases 1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995 aboratory Investigations:	MELLERIL (Suspected)	30.0 Mi		.,	
1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995 aboratory Investigations:	1.0 Gram Daily Batch: Started: 21/07/1995 Stopped: 26/07/1995 aboratory Investigations:			illigram Daily		15
aboratory Investigations:	aboratory Investigations:	Batch:		illigram Daily /1995	Stopped: 24/07/199	
aboratory Investigations:	aboratory Investigations:	Batch:	Started : 11/07/	illigram Daily /1995 Reason:	Stopped: 24/07/199	
		Batch: (EFLEX (Suspected)	Started: 11/07/	illigram Daily /1995 Reason: ram Daily	Stopped: 24/07/199 Otr&nos infec¶sit dis	eases
		Batch: (EFLEX (Suspected)	Started: 11/07/	illigram Daily /1995 Reason: ram Daily	Stopped: 24/07/199 Otr&nos infec¶sit dis	eases
		Batch: KEFLEX (Suspected)	Started: 11/07/	illigram Daily /1995 Reason: ram Daily	Stopped: 24/07/199 Otr&nos infec¶sit dis	eases
		Batch: KEFLEX (Suspected)	Started: 11/07/	illigram Daily /1995 Reason: ram Daily	Stopped: 24/07/199 Otr&nos infec¶sit dis	eases
Date Type Natige Date rester Result Details	Date Type Native Date rester Result Details	Batch: KEFLEX (Suspected) Batch:	Started: 11/07/ 1.0 Gr Started: 21/07/	illigram Daily /1995 Reason: ram Daily	Stopped: 24/07/199 Otr&nos infec¶sit dis	eases
		Batch: KEFLEX (Suspected) Batch: aboratory Investigations	Started: 11/07/ 1.0 Gr Started: 21/07/	illigram Daily /1995 Reason: ram Daily /1995	Stopped: 24/07/199 Otr&nos infec¶sit dis Stopped: 26/07/199	eases 5
		Batch: KEFLEX (Suspected) Batch: aboratory Investigations	Started: 11/07/ 1.0 Gr Started: 21/07/	illigram Daily /1995 Reason: ram Daily /1995	Stopped: 24/07/199 Otr&nos infec¶sit dis Stopped: 26/07/199	eases 5
Date Type Range Date Tested Result Details	Date Type Range Date Tested Result Details	KEFLEX (Suspected)	Started: 11/07/	illigram Daily /1995 Reason: ram Daily	Stopped: 24/07/199 Otr&nos infec¶sit dis	eases
		Batch: KEFLEX (Suspected) Batch: aboratory Investigations	Started: 11/07/ 1.0 Gr Started: 21/07/	illigram Daily /1995 Reason: ram Daily /1995	Stopped: 24/07/199 Otr&nos infec¶sit dis Stopped: 26/07/199	eases 5
		Batch: KEFLEX (Suspected) Batch: aboratory Investigations	Started: 11/07/ 1.0 Gr Started: 21/07/	illigram Daily /1995 Reason: ram Daily /1995	Stopped: 24/07/199 Otr&nos infec¶sit dis Stopped: 26/07/199	eases 5
		Batch: KEFLEX (Suspected) Batch: aboratory Investigations	Started: 11/07/ 1.0 Gr Started: 21/07/	illigram Daily /1995 Reason: ram Daily /1995	Stopped: 24/07/199 Otr&nos infec¶sit dis Stopped: 26/07/199	eases 5
		Batch: KEFLEX (Suspected) Batch: aboratory Investigations	Started: 11/07/ 1.0 Gr Started: 21/07/	illigram Daily /1995 Reason: ram Daily /1995	Stopped: 24/07/199 Otr&nos infec¶sit dis Stopped: 26/07/199	eases 5
		Batch: KEFLEX (Suspected) Batch: aboratory Investigations	Started: 11/07/ 1.0 Gr Started: 21/07/	illigram Daily /1995 Reason: ram Daily /1995	Stopped: 24/07/199 Otr&nos infec¶sit dis Stopped: 26/07/199	eases 5
		Batch: KEFLEX (Suspected) Batch: aboratory Investigations Date Type R	Started: 11/07/ 1.0 Gr Started: 21/07/	illigram Daily /1995 Reason: ram Daily /1995	Stopped: 24/07/199 Otr&nos infec¶sit dis Stopped: 26/07/199	eases 5
dditional Information:	dditional Information:	Batch: KEFLEX (Suspected) Batch: aboratory Investigations Date Type R	Started: 11/07/ 1.0 Gr Started: 21/07/	illigram Daily /1995 Reason: ram Daily /1995	Stopped: 24/07/199 Otr&nos infec¶sit dis Stopped: 26/07/199	eases 5
dditional Information:	additional Information:	Batch: KEFLEX (Suspected) Batch: aboratory Investigations Date Type R	Started: 11/07/ 1.0 Gr Started: 21/07/	illigram Daily /1995 Reason: ram Daily /1995	Stopped: 24/07/199 Otr&nos infec¶sit dis Stopped: 26/07/199	eases 5

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 105196 Seq: 1 Gender: F

Reported: 07/12/1995 Weight:
Hospitalisation: Age: 70Y

Onset Date: 31/01/1995 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	toaction Botano.				
	Preferred Term	Severity	Report Description	Treatment	
	Dyskinesia				
	Hypertonia				

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Nervousness

Oral application 150.0 Milligram Daily Oral

Batch: Started: L TERM Stopped: 28/01/1995

Laboratory Investigations:

Date	Туре	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.

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Case Number: 105769

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

ospitalisation: Onset Date: Outcome: Unknown eaction Details: Preferred Term peech disorder eatatonia				Age: 36Y
Outcome: Unknown action Details: Preferred Term peech disorder				
Preferred Term Deech disorder				DOB:
Preferred Term peech disorder			Cau	sality: Causality possible
peech disorder	т т			1
	Severity	-	ort Description	Treatment
atatonia		Mutism		
				Bromocriptine and further unilateral ect treatments
eukocytosis				urillateral ect treatments
ledicine Details: TRIFLUOPERAZINE HYDROCHLORIDE	E (Suspected)	Rea	ason:	
Batch:	Started:		Stopped:	
THIORIDAZINE HYDROCHLORIDE (Sus		Rea	ason:	
`		Milligram	Daily	
Batch:	Started:	· ·	Stopped:	
	I Date Tark	ed Result		
aboratory Investigations: Date Type Ran	nge Date Teste	i Nesuit		Details



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 106060 Seq: 1 Gender: M

 Reported:
 25/01/1996
 Weight:
 70.00

 Hospitalisation:
 Age:
 66Y

 Onset Date:
 01/06/1995
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			

Medicine Details:

wealtine Details:			
HALDOL DECANOATE (Other drug)		Reason:	
	0.0		
Batch:	Started: 01/04/1995	Stopped:	
MIXTARD (NORDISK) (Other drug)		Reason: Diabetes mellitus	
	32.0 Unit	Daily	
Batch:	Started: 01/01/1993	Stopped:	CONTIN
MELLERIL (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 106923
 Seq: 1
 Gender:
 F

 Reported:
 06/03/1996
 Weight:

Hospitalisation: Age: 32

Onset Date: 11/10/1995 **DOB:** 04/02/1963

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia			

Medicine Details:

vieulcine Details.	(O (N		_		
CLOMIPRAMINE HYDROCHLORIDE	(Suspected)		Reason:		
	200.0	Milligram	Daily		
Batch:	Started:			Stopped:	
THIORIDAZINE HYDROCHLORIDE (Suspected)		Reason:		
	100.0	Milligram	Daily		
Batch:	Started:			Stopped:	
CLONAZEPAM (Suspected)			Reason:		
	2.0	Gram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	(70-320)	11/10/1995	1681	
	Prolactin	(70-320)	23/11/1995	1989	
	Prolactin	(70-320)	14/12/1995	1027	

Additional Information:

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Case Number: 106973

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Reported: 07/03/1996			Wei	ght:
lospitalisation:				Age: 20
Onset Date:			1	DOB : 24/05/1975
Outcome: Unknown			Causa	ality: Causality probable
eaction Details:				
Preferred Term	Severity	Report	Description	Treatment
Dizziness				
Drug ineffective				
Dry mouth				
Orthostatic hypotension				
Somnolence				
Medicine Details: MELLERIL (Suspected)		Reaso	n:	
	450.0 Milli		aily	
Batch:	Started:	•	Stopped:	
Laboratory Investigation	ns:	D#		Dataila
Date Type	Range Date Tested	Result		Details
Additional Information:	,			
eport Run: 01/06/2007 02:45PM	Database: pusime02	ADI	RS004	Page 174 of 393



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Rei	po	rt	De	tai	ls:

Case Number: 107271 Seq: 1 Gender: M

Reported: 25/03/1996 Weight: 55.00 Hospitalisation: Age: 76Y

Onset Date: 25/01/1996 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness			

Medicine Details:

SERENACE (Other drug)		Reason:	Depression	
Oral application	500.0 Microgram	Daily		Oral
Batch:	Started: 08/01/1996		Stopped:	22/01/1996
SOLPRIN (Other drug)		Reason:	Acute myocard	l infarc,no hypert
Oral application	150.0 Milligram	Daily		Oral
Batch:	Started:		Stopped:	
ALDAZINE (Suspected)		Reason:	Depression	
Tablet	30.0 Milligram	Daily		Oral
Batch:	Started: 04/01/1996		Stopped:	08/01/1996
PERTOFRAN (Suspected)		Reason:	Depression	
	75.0 Milligram	Daily		
Batch:	Started: 05/01/1996		Stopped:	16/01/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Medicine Details: MELLERIL (Suspected)	Report Details:				
Onset Date: 02/05/1996 DOB: Ontcome: Recovered Causality: Causality possible Paction Details: Preferred Term Severity Report Description Treatment Pyrexia aggression Confusional state Said disturbance Hyperhidrosis Pypertonia Reason: Batch: Started: 12/04/1996 Stopped: 28/04/1996 MELLERIL (Suspected) Reason: 30.0 Milligram Daily Batch: Started: 12/04/1996 Stopped: 16/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 12/04/1996 Stopped: 19/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 12/04/1996 Stopped: 19/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 Stopped: 19/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 Stopped: 19/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 Stopped: 19/04/1996	Case Number: 108445	Seq: 1			Gender: M
Onset Date: 02/05/1996 Outcome: Recovered Causality: Causality possible Particle Recovered Severity Report Description Treatment Pyrexia Preferred Term Severity Report Description Treatment Pyrexia Regorts Description Treatment Pyrexia Regorts Description Treatment Pyrexia Regorts Description Treatment Pyrexia Regorts Description Treatment Pyrexia Report Description Treatment Pyrexia Regorts Description Treatment Pyrexia Regorts Description Reason:	Reported: 14/05/1	996			Weight:
Outcome: Recovered Section Details: Preferred Term Severity Report Description Treatment Pyrexia Regression Confusional state Gait disturbance Hyperhidrosis Hypertonia Reason: Batch: Started: 12/04/1996 Stopped: 28/04/1996 MELLERIL (Suspected) Reason: MELLERIL (Suspected) Reason: Started: 12/04/1996 Stopped: 28/04/1996 MELLERIL (Suspected) Reason: 30.0 Milligram Daily Batch: Started: 12/04/1996 Stopped: 16/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 12/04/1996 Stopped: 16/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 Stopped: 19/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 Stopped: 19/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 Stopped: 19/04/1996	ospitalisation:				Age: 72Y
Preferred Term Severity Report Description Treatment Pyrexia Preferred Term Severity Report Description Treatment Pyrexia Preferred Term Temerature up to 38 Preferred	Onset Date: 02/05/1	996			DOB:
Preferred Term Severity Report Description Treatment Pyrexia ggression Confusional state Calit disturbance Report Description Treatment Temerature up to 38 Description Treatment Temerature up to 38 Description Treatment Temerature up to 38 Description Treatment T	Outcome: Recove	red		С	ausality: Causality possible
Aggression Confusional state Aggression Confusional state Gait disturbance Alyperhidrosis Alypertonia Medicine Details: MELLERIL (Suspected) Batch: Started: 12/04/1996 MELLERIL (Suspected) Reason: 30.0 Milligram Daily Batch: Started: 12/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 12/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 12/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: MELLERIL (Suspected) MELLERIL (Suspec	eaction Details:				
Acticine Details: Melleril (Suspected) Mel	Preferred Term	Severity	Repo	t Description	Treatment
Acticine Details: Melleril (Suspected) Batch: Started: 12/04/1996 Melleril (Suspected) Reason: 30.0 Milligram Batch: Started: 12/04/1996 Melleril (Suspected) Reason: 30.0 Milligram Daily Batch: Started: 12/04/1996 Melleril (Suspected) Reason: 30.0 Milligram Daily Batch: Started: 12/04/1996 Melleril (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 Melleril (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 Stopped: 19/04/1996	'yrexia		Temerature up to	38	
Addicine Details: Medicine Details: MELLERIL (Suspected) Batch: Started: 12/04/1996 Melligram Daily Batch: Started: 16/04/1996 Melligram Daily Batch: Melligram Daily					
Medicine Details: MELLERIL (Suspected) Batch: Started: 12/04/1996 MELLERIL (Suspected) Reason: 30.0 Milligram Batch: Started: 12/04/1996 MELLERIL (Suspected) Reason: 30.0 Milligram Batch: Started: 12/04/1996 MELLERIL (Suspected) Reason: 30.0 Milligram Daily Batch: Started: 12/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: MELLERIL (Suspected)					
Medicine Details: MeLLERIL (Suspected) Reason:					
Medicine Details: MELLERIL (Suspected) Reason: 10.0 Milligram As necessary Batch: Started: 12/04/1996 Stopped: 28/04/1996 MELLERIL (Suspected) Reason: 30.0 Milligram Daily Batch: Started: 12/04/1996 Stopped: 16/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 Stopped: 19/04/1996 -aboratory Investigations: Daily					
Reason:	lypertonia				lv fluids for hydration, valium
Started: 12/04/1996 Stopped: 28/04/1996			Reas	on:	
Reason:		10.0	Milligram	As necessary	
30.0 Milligram Daily Batch: Started: 12/04/1996 Stopped: 16/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 Stopped: 19/04/1996 Aboratory Investigations: Started: 16/04/1996 Stopped: 19/04/1996 Aboratory Investigations: Started: 16/04/1996 Stopped: 19/04/1996 Aboratory Investigations: Started: 16/04/1996 Stopped: 19/04/1996 Stopped: 19/04/1996 Aboratory Investigations: Started: 16/04/1996 Stopped: 19/04/1996 Stopped: 19	Batch:	Started: 12/0	04/1996	Stopped:	28/04/1996
Batch: Started: 12/04/1996 Stopped: 16/04/1996 MELLERIL (Suspected) Reason: 20.0 Milligram Daily Batch: Started: 16/04/1996 Stopped: 19/04/1996 .aboratory Investigations: Started: 16/04/1996	MELLERIL (Suspected)		Reas	on:	
MELLERIL (Suspected) 20.0 Milligram Daily Batch: Started: 16/04/1996 Stopped: 19/04/1996 Aboratory Investigations:			_	-	
Batch: Started: 16/04/1996 Stopped: 19/04/1996		Started: 12/0			16/04/1996
Batch: Started: 16/04/1996 Stopped: 19/04/1996 _aboratory Investigations:	MELLERIL (Suspected)				
aboratory Investigations:			_	-	
	Batch:	Started: 16/0	04/1996	Stopped:	19/04/1996
Date Type Range Date Tested Result Details					
	Date Type	Range Date Test	ed Result		Details
	Additional Informati	ion:			
Additional Information:					

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Do	etails:
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 Case Number:
 108630
 Seq: 1
 Gender: M

 Reported:
 22/05/1996
 Weight:

Hospitalisation: Age: 85Y
Onset Date: 22/08/1995
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Agitation			
Confusional state			
Delirium			

Medicine Details:

TEMAZEPAM (Other drug)		Rea	son:		
	10.0	Milligram	As ne	cessary	
Batch:	Started:			Stopped:	CONTIN
LANOXIN PG (Other drug)		Rea	son:	Chron isch heart dis no hyper	
Tablet	2.0	Dose Unspecified	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN
LASIX (Other drug)		Rea	son:	Angina pectoris w/o hyperten	
Oral application	80.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN
SLOW-K (Other drug)		Rea	son:	Congestive heart failure	
Tablet	1.0	Dose Unspecified	Daily	Oral	
Batch:	Started:			Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has alzheimer's disease.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Hospitalisation: Onset Date:	22/05/1996 22/08/1995 Recovered	Seq: 1		Gender: Weight: Age: DOB: Causality:	
Medicine Deta	aile				
MORPHINE NOS (S			Reason:		
		0.0			
Batch:		Started:		Stopped:	
TOFRANIL (Suspe	cted)		Reason:		
		0.0			
Batch:		Started:		Stopped:	
MELLERIL (Suspe	cted)		Reason:		
		0.0			
Batch:		Started:		Stopped:	
Laboratory In	vestigations:				
Additional Inf Patient has alzhein					

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 109141 Seq: 1 Gender: F
Reported: 14/06/1996 Weight:
Hospitalisation: Admitted to hospital Age: 79Y

Onset Date: 30/05/1996 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

caction Details.			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Hypertonia			
Leukocytosis			
Neuroleptic malignant syndrome			Dantrolene
Pyrexia			

Medicine Details:

MADOPAR M (Suspected)		Reason:	Paralysis agitans
	0.0		
Batch:	Started:		Stopped:
MELLERIL (Suspected)		Reason:	Unspecified psychosis
	75.0 Milligram	Daily	
Batch:	Started: 01/01/1994		Stopped:
SELEGILINE HYDROCHLORIDE (Suspected	d)	Reason:	Paralysis agitans
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1994		Stopped:
BROMOCRIPTINE MESYLATE (Suspected)		Reason:	Paralysis agitans
	7.5 Milligram	Daily	
Batch:	Started: 01/01/1994		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		30/05/1996	3000	

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.

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Case Number: 109212

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

	16				Wei	ght:		
spitalisation:		Age: 77 DOB: 15/12/1918						
Onset Date: 17/05/199	6							
Outcome: Not yet re	covered				Causa	llity: Causality possible		
action Details:	<u> </u>	1				<u> </u>		
Preferred Term	Se	Severity		Report Descripti		Treatment		
ktrapyramidal disorder								
ait disturbance								
ledicine Details:								
NORMISON (Other drug)			Rea	son:				
		1.0 Dos	e Unspecified	Daily				
Batch:	S	started:			Stopped:			
HIORIDAZINE HYDROCHLOR	IDE (Suspected	d)	Rea	son:				
		50.0 Milli	gram	Daily				
Batch:	S	started:			Stopped:			
VARFARIN SODIUM (Suspecte	ed)		Rea	son:				
		1.0 Dos	se Unspecified	Daily				
Batch:	S	tarted:			Stopped:			
RUSEMIDE (Suspected)				son:				
ROOLMIDE (Guspecteu)		40.0 Milli	gram	Daily				
				,				
Batch:	s	tarted:			Stopped:			
Batch:					Stopped:			
			Result		Stopped:	Details		

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:		Seq: 1			Gender:	F
Reported:	17/06/1996				Weight:	
Hospitalisation:					Age:	
Onset Date:	17/05/1996					15/12/1918
Outcome:	Not yet recovered	I			Causality:	Causality possible
Reaction Detai	ls:					
Madiales D.C.	-:					
Medicine Deta				Reason:		
KANTIDINE (Susp	ecteu)	300.0	Milligram	Daily		
Batch:		Started:	wiiiigraiii	Daily	Stopped:	
OXAZEPAM (Susp	ected)	Started.		Reason:	эторреи.	
OXAZEI AM (OUSP	ecteu,	30.0	Milligram	Daily		
Batch:		Started:	wiiiigiaiii	Dany	Stopped:	
	SODIUM (Suspected			Reason:	сторрош.	
	(5.5.5)		Gram	Daily		
Batch:		Started:		,	Stopped: 08/05/1996	3
Laboratory In	vestigations:					
Additional Inf	ormation:					

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

06/1996 06/1996 overed erm nokinase incr	Severity		Repo	ort Desc	Caus	eight: Age: 81\ DOB: cality: Car	y usality probable Treatment
erm nokinase incr	Severity		Rep	ort Desc	Caus	DOB:	usality probable
erm nokinase incr	Severity		Repo	ort Desc	Caus		
erm nokinase incr syndrome	Severity		Repo	ort Desc		ality: Cau	
nokinase incr	Severity		Repo	ort Desc	ription		Treatment
nokinase incr	Severity		Repo	ort Desc	ription		Treatment
syndrome							
3)		0 Mill	Rea Iligram	son: Daily	Stonned:		
(Other drug)	Starteu.		Poo	0001	Stopped.		
Other drug)	5	O Mill					
		U IVIIII	lligraffi	Dally	Stonnod:		
	Starteu.		Pos	eon:	Stoppeu.		
	125	O Mic					
		O IVIIC	crogram	Daily	Stopped:		
1	Otartea.		Roa	eon.	оторреа.		
	50	O Mill					
		O IVIIII	iligraili	Daily	Stonned:		
	Otartea.				оторреа.		
tigations:				_			
Rang	e Date T	ested	Result			Details	
	(Other drug) tigations:	5. Started: 125. Started: 50. Started: tigations:	(Other drug) 5.0 Mil Started: 125.0 Mil Started:) 50.0 Mil Started:	(Other drug) 5.0 Milligram Started: Rea 125.0 Microgram Started: Nea 125.0 Microgram Started: Started: Started: Tea	(Other drug) 5.0 Milligram Daily Started: Reason: 125.0 Microgram Daily Started: Reason: 125.0 Milligram Daily Started: Started: Reason: April 125.0 Milligram Daily Started: Started:	(Other drug) 5.0 Milligram Daily Started: Stopped: Reason: 125.0 Microgram Daily Started: Stopped: Reason: 125.0 Milligram Daily Started: Stopped: Reason: 50.0 Milligram Daily Started: Stopped:	(Other drug) 5.0 Milligram Daily Started: Stopped: Reason: 125.0 Microgram Daily Started: Stopped: Reason: 50.0 Milligram Daily Started: Stopped: Stopped: Stopped: **Tigations:**

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details	:				
Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Details	19/06/1996 08/06/1996 Recovered	Seq: 1		Gender: Weight: Age: DOB: Causality:	
Medicine Deta			Reason:		
MEEEERIE (Ouspect	ieu,	0.0	rteason.		
Batch:		Started:		Stopped:	1Y
Laboratory Inv	voctigations:				
Laboratory inv	restigations.				
Additional Info	ormation:				
Additional Info	ormation:				
Additional Info	ormation:				

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 109363
 Seq: 1
 Gender:
 F

 Reported:
 19/06/1996
 Weight:

Hospitalisation: Age: 93Y
Onset Date: 01/02/1996
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Jaundice			

Medicine Details:

LASIX (Other drug)		Rea	son:	Congestive heart failure	
Oral application	80.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	
LANOXIN PG (Other drug)		Rea	son:	Congestive heart failure	
Tablet	2.0	Dose Unspecified	Daily	Oral	
Batch:	Started:			Stopped:	
ASPIRIN (Other drug)		Rea	son:	Chron isch heart dis no hyper	
	0.5	Dose Unspecified	Daily		
Batch:	Started:			Stopped:	
MONOTARD HM (Other drug)		Rea	son:	Diabetes mellitus	
Injection	44.0	Unit	Daily	Subcutaneous	
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT	(5-30)	05/02/1996	560	
	ALT = SGPT	(5-30)	12/02/1996	84	
	AST = SGOT	(10-30)	05/02/1996	234	
	AST = SGOT	(10-30)	12/02/1996	18	
	Bilirubin	(<20)	05/02/1996	75	
	Bilirubin	(<20)	12/02/1996	15	
	GGT = SGGT =	(< 30)	05/02/1996	252	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Rep	ort	Deta	ils:
-----	-----	------	------

 Case Number:
 109363
 Seq: 1
 Gender:
 F

 Reported:
 19/06/1996
 Weight:

Hospitalisation:
Onset Date: 01/02/1996
Age: 93Y
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

EUHYPNOS (Other drug)		Reason: Specific disorders of sleep
Capsule	10.0 Milligram	Daily Oral
Batch:	Started: 29/12/1995	Stopped:
LARGACTIL (Suspected)		Reason: Unspecified psychosis
Tablet	25.0 Milligram	As necessary Oral
Batch:	Started: 01/02/1996	Stopped: 05/02/1996
MELLERIL (Suspected)		Reason: Unspecified psychosis
Tablet	10.0 Milligram	Daily Oral
Batch:	Started: 23/01/1996	Stopped: 01/02/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =	(< 30)	12/02/1996	149	
	SAP = ALP	(30-90)	05/02/1996	348	
	SAP = ALP	(30-90)	12/02/1996	255	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 109630 Seq: 1 Gender: F

 Reported:
 02/07/1996
 Weight:
 50.00

 Hospitalisation:
 Age:
 86Y

Onset Date: 23/06/1996 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion betails.							
Preferred Term	Severity	Report Description	Treatment				
Extrapyramidal disorder							
Hypertonia							

Medicine Details:

<u>viedicine Details:</u>			
BISALAX (Other drug)		Reason:	
	1.0 Dose Unspe	ecified As necessary	
Batch:	Started:	Stopped:	
FOLIC ACID (Other drug)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	
MELLERIL (Suspected)		Reason: Explosive personality disorder	
Tablet	100.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1994	Stopped: 26/06/1996	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 109821
 Seq: 1
 Gender: M

 Reported:
 08/07/1996
 Weight:

Hospitalisation: Admitted to hospital Age: 93Y
Onset Date: 07/02/1996
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		90/50	
Confusional state		Increased confusion	
Blood creatine phosphokinase incr Extrapyramidal disorder Hyponatraemia Malaise			
Neuroleptic malignant syndrome			lv fluids, haemaccel
Shock			
Somnolence			

Medicine Details:

	Rea	son:	Alkalosis	
4.0	Dose Unspecified	Daily		Oral
Started:	L TERM		Stopped:	13/02/1996
	Rea	son:		
10.0	Milligram	Daily		Oral
Started: 01	/11/1995		Stopped:	07/02/1996
	Started:	4.0 Dose Unspecified Started: L TERM	Started: L TERM Reason: 10.0 Milligram Daily	4.0 Dose Unspecified Daily Started: L TERM Stopped: Reason: 10.0 Milligram Daily

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Serum osmolality		07/02/1996	DECREASED	

Additional Information:

History: previous admission 10/95 for chronic hyponatraemia, hypokalaemia, hypokalaemia, renal tubular dysfunction. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 110135 Seq: 1 Gender: F

Reported: 22/07/1996 Weight:
Hospitalisation: Age: 67Y

Onset Date: 30/04/1996 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			

Medicine Details:

MELLERIL (Suspected) Reason:

50.0 Milligram Daily

Batch: **Started**: 01/01/1993 **Stopped**: 12/07/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Caca Niumi	440704	800								
	ber : 110791	•	j: 1				nder:	F		
	ted: 13/08/199	96					eight:			
ospitalisati							Age:	76Y		
Onset D	ate: 13/06/199	96					DOB:			
Outco	me: Unknown					Caus	ality:	Caus	ality po	ssible
eaction D										
	eferred Term	S	everity	Repo	ort Description	on			Treatm	
Hyponatraer	nia						Fluc	drocor	tisone 0	.1mg dail
/ledicine	Details:									
/ledicine VENTOLIN (C				Rea	son:					
VENTOLIN (C	Other drug)		0.0	Rea						
VENTOLIN (C	Other drug) :h:	•	0.0 Started:		Sto	opped:				
VENTOLIN (C	Other drug) :h:	•	Started:	Rea Rea	Sto	ppped:				
VENTOLIN (C Batc	Other drug) h: Other drug)		Started: 0.0		Sto					
VENTOLIN (C Batc ATROVENT (Other drug) h: Other drug) h:		Started:	Rea	Sto son:	opped:				
VENTOLIN (C Batc	Other drug) h: Other drug) h:		0.0 Started:		Sto son:					
Batc ATROVENT (Batc SENOKOT (C	Other drug) ch: Other drug) ch: Other drug)	\$	0.0 Started: 0.0	Rea	Sto son: Sto son:	opped:				
Batc ATROVENT (Batc SENOKOT (C	Other drug) ch: Other drug) ch: Other drug)	\$	0.0 Started:	Rea Rea	Sto son: Sto son:					
Batc Batc SENOKOT (C	Other drug) ch: Other drug) ch: Other drug)	\$	0.0 Started: 0.0 Started:	Rea Rea Rea	Sto	opped:				
Batc ATROVENT (Batc SENOKOT (C Batc THIAMINE (C	Other drug) ch: Other drug) ch: Other drug) ch: Other drug)	<u> </u>	0.0 Started: 0.0	Rea Rea Rea	Sto	opped:				
Batc ATROVENT (Batc SENOKOT (C Batc THIAMINE (C)	Other drug) ch: Other drug) ch: Other drug) ch: Other drug) ch:	; ;	0.0 Started: 0.0 Started: 100.0 Milli	Rea Rea Rea	Sto	opped:				
Batc SENOKOT (C Batc THIAMINE (O	Other drug) ch: Other drug) ch: Other drug) ch: Other drug) ch: Other drug)	sions:	0.0 Started: 0.0 Started: 100.0 Milli Started:	Rea Rea Rea gram	Sto	opped:				
Batc SENOKOT (C Batc THIAMINE (O Batc	Other drug) ch: Other drug) ch: Other drug) ch: Other drug) ch: Type	; ;	0.0 Started: 0.0 Started: 100.0 Milli Started: Date Tested	Rea Rea gram	Sto	opped:	Details	S		
Batc SENOKOT (C Batc THIAMINE (C) Batc TDate	Other drug) ch: Other drug) ch: Other drug) ch: Other drug) ch: Other drug)	sions:	0.0 Started: 0.0 Started: 100.0 Milli Started:	Rea Rea Rea gram	Storeson: Storeson: Storeson: Daily	opped:	Details	s		

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	110791	Seq: 1				Gender:	F	
Reported:	13/08/1996					Weight:		
Hospitalisation:						Age:		
Onset Date:						DOB:		
Outcome:					С	ausality:	Causality possible	
Reaction Detail	ls:							
Madiaina Data	ile.							
Medicine Deta	ROCHLORIDE (Susp	ected)		Reason:				1
OERTIME III DI	CONTECUENCE (Gusp		.0	ittustii.				
Batch:			06/06/1996		Stopped:	13/06/1996		
MELLERIL (Suspec	eted)		-	Reason:				1
, .	-	20	.0 Milligram	Daily				
Batch:		Started:	-	•	Stopped:	10/06/1996	v 1	
								_
I also sets.	45 45							
Laboratory In	vestigations:							
Additional Info	ormation:							

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Case Number: 111355

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

ospitalisation: Onset Date:							Weig	ht:		
Onset Date:							A	ge : 85\	′	
	24/08/1996							OB:		
	Not yet recov	ered					Causal	ity: Ca	usality poss	ible
action Detail			., 1							
Preferre	a Term		everity		Керс	ort De	scription		Treatmer	nt
mphopenia		Requi Speci Cons	ired ialist ultation							
eutropenia										
edicine Deta					Rea	son:				
	.		0.0							
Batch:		s	started: 15/08	8/1996			Stopped:			
ANOXIN (Other dr	·ug)				Rea	son:	Otr&nos disord of hea	art rhythm		
			1.0	Dose Un	specified	Daily				
Batch:		S	started:		L TERM		Stopped:			
VARFARIN SODIU	M (Other drug)				Rea	son:	Otr&nos disord of hea	art rhythm		
			1.0 N	Milligram	1	Daily				
Batch:		S	tarted:		L TERM		Stopped:			
ANITIDINE (Other	drug)				Rea		Gastritis&duodenitis			
		_		Milligram		Daily				
Batch:		S	started:		L TERM		Stopped:			
boratory In			 		1					
Date	Туре	Range	Date Teste	a F	Result		L	Details		



Case Number: 111355

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Reported: 03/09/1996			weign	:
ospitalisation:			Age	e: 85Y
Onset Date: 24/08/1996			DOE	3:
Outcome: Not yet recovered	ł		Causality	: Causality possible
action Details:				
Medicine Details:				
UREX (Other drug)		Reason:	Congestive heart failure	
	20.0 Millig	gram Daily		
Batch:	Started:	L TERM	Stopped:	
LOPRESOR (Other drug)		Reason:		
	50.0 Millig	gram Daily		
Batch:	Started:	L TERM	Stopped:	
ACTRAPID HM (Suspected)		Reason:		
	0.0			
Batch:	Started: 15/08/199	96	Stopped:	
NEO-MERCAZOLE (Suspected)		Reason:	Thyrotoxicosis w/o ment	goiter
Tablet	30.0 Millig	gram Daily		
Batch:	Started: 19/08/199		Stopped: 26/08/19	96
aboratory Investigations:				
Additional Information:				

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Case Number: 111355

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Onset Date: 24/08/1996 Outcome: Not yet recovered action Details:			С	Age: DOB: ausality:	85Y Causality possible
Outcome: Not yet recovered			c		Causality possible
			C	ausality:	Causality possible
action Details:					
adiaina Dataila.					
edicine Details: DIAMICRON (Suspected)		Reason:	Diabetes melli	tus	
	30.0 Milligran			ius	
Batch: Started		L TERM		23/08/1996	
ELLERIL (Suspected)	•	Reason:	эторрец.	23/00/1990	
	IOO Milliaran				
	l0.0 Milligran			04/00/4000	
Batch: Started	:	L TERM	Stopped:	24/08/1996	
ILSTAT (Suspected)	4.0 14:11:11	Reason:		0 1	
Oral application	4.0 Millilitre	Daily		Oral	
Batch: Started	: 15/08/1996		Stopped:		

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 111523
 Seq: 1
 Gender:
 F

 Reported:
 09/09/1996
 Weight:

Hospitalisation: Age: 79Y

Onset Date: 22/08/1996 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal		Generalised t wave inversion.	
Delirium			
Extrapyramidal disorder			

Medicine Details:

ALDAZINE (Suspected)		Reason:	Unspecified psychosis	
Tablet	35.0 Milligram	Daily	Oral	
Batch:	Started: 20/08/1996		Stopped : 20/08/1996	
DISPRIN (Suspected)		Reason:	Chron isch heart dis no hype	er
Tablet	150.0 Milligram	Daily	Oral	
Batch:	Started: 20/08/1996		Stopped:	CONTIN
IMDUR (Suspected)		Reason:	Chron isch heart dis no hype	er
Tablet	60.0 Milligram	Daily	Oral	
Batch:	Started: 20/08/1996		Stopped:	CONTIN
ZANTAC (Suspected)		Reason:	Diaph hern of abd cav w/o o	bst
Tablet	300.0 Milligram	Daily	Oral	
Batch:	Started: 20/08/1996		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Electrocardiograph				Generalised t wave inversion found on ecg.

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 111805
 Seq: 1
 Gender: M

 Reported:
 24/09/1996
 Weight:
 73.00

Hospitalisation:
Onset Date:

DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

eaction betails.								
Preferred Term	Severity	Report Description	Treatment					
Deep vein thrombosis								
Dyspnoea								
Pulmonary embolism								
Respiratory disorder								

Medicine Details:

Micalcinic Details.				
MELLERIL (Suspected)		Reason:	Unspecified psychosis	
	300.0 Milligra	am Daily		
Batch:	Started:		Stopped:	2M
AROPAX (Suspected)		Reason:	Depression	
	20.0 Milligra	am Daily		
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Doppler studies confirmed a proximal dvt extending to the inferior vena cava and requiring a caval filter.
	Protein				Further investigation on blood taken before anticoagulation revealed a protein deficiency (39% normal) which his brother and father also have to a lesser degree.

Additional Information:

Melleril was increased from 75mg to 300mg rather abruptly.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Reported: espitalisation:		Seq:	. 1			Gene	der: F
spitalisation:	: 08/10/199	96				Weig	ıht:
	1 1					Α	ge: 79
Onset Date:	: 12/08/199	96				D	OB : 24/08/1916
Outcome:	Unknown					Causa	lity: Causality possible
action Deta	ıils:						
Prefer	red Term	Se	everity	Repo	ort Desc	cription	Treatment
enal impairme	nt			Progressive rena	al impair	ment from lasix	
elirium							
rthostatic hypo	otension						
omnolence							
ledicine De	tails:						
PROTAPHANE (C	Other drug)			Rea	son:		
Injection			0.0			Subci	utaneous
Batch:		S	tarted:			Stopped:	
SLOW-K (Other d	lrug)			Rea	son:		
Tablet		3.0		Dose Unspecified Daily Oral			
Batch:		s	started:	Stopped:			
YLOPRIM (Other	r drug)			Rea	son:		
Tablet			200.0 M	Milligram	Daily	Oral	
Batch:		S	tarted:			Stopped:	
_ASIX (Suspected	d)			Rea	son:		
Oral appli	cation		80.0 Milligram		Daily	Oral	
		S	Started:			Stopped:	
Batch:							
Batch:	nvootiast	ionoi					
	nvestigat _{Type}	tions:	Date Teste	d Result			Details

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Case Number: 112134

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Reported:	08/10/1996					Weight:		
ospitalisation:						Age:	79	
Onset Date:	12/08/1996					_	24/08/1916	
Outcome:	Unknown				С	ausality:	Causality poss	ible
eaction Detai	ls:							
Medicine Det								
CARDIZEM CD (Su	ispected)			Reason:				
Capsule		240.0	Milligram	Daily		Oral		
Batch:		Started:			Stopped:	12/08/1996		
MELLERIL (Suspe	cted)			Reason:				
Oral applic	ation	100.0	Milligram	Daily		Oral		
Batch:		Started:			Stopped:	12/08/1996		
Laboratory In	vestigation	s:						
A - - :4: 4								
Additional Inf	ormation:							
eport Run : 01/06/200	07 02:45PM D)atahase: nusime02		ADRS004			Page 107	of 303

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	oa	rt	De	tai	ls:
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Case Number: 112344 Seq: 1 Gender: M

Reported: 17/10/1996 Weight: 90.00 Hospitalisation: Age: 43Y

Onset Date: 27/08/1996 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Erectile dysfunction			Melleril ceased then one week later paroxetine ceased & fluoxetine substituted
	Libido decreased			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) Reason: Depression

20.0 Milligram Daily

Batch: Started: 18/08/1996 **Stopped:** 19/09/1996

MELLERIL (Suspected) Reason: Depression

25.0 Milligram Daily

Batch: Started: 18/08/1996 **Stopped:** 11/09/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Ren	ort	Deta	ils:
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 Case Number:
 112499
 Seq: 1
 Gender: F

 Reported:
 23/10/1996
 Weight:

Hospitalisation: Age: 82Y
Onset Date: 05/06/1996
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Rash on knees, thighs, chest.	

Medicine Details:

DIAZEPAM (Suspected)		Reason:	
	2.5 Milligram	As necessary	
Batch:	Started:	Stopped:	
STAPHYLEX (Suspected)		Reason: Unspecified osteomyelitis	
Capsule	2.0 Gram	Daily Oral	
Batch:	Started: 17/05/1996	Stopped: 07/06/1996	
CIPROXIN (Suspected)		Reason: Unspecified osteomyelitis	
Tablet	1.0 Gram	Daily Oral	
Batch:	Started: 17/05/1996	Stopped: 07/06/1996	
HEPARIN SODIUM (Suspected)		Reason: Phleb&thrombophleb lowr e	extrem
Injection	10.0 Thousand In	ternal Daily Subcutaneo	us
Batch:	Started: 16/04/1996	Stopped: 06/06/1996	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: Reported:	112499 23/10/1996	Seq: 1		Gender: Weight:	F
lospitalisation:				Age:	82Y
Onset Date:	05/06/1996			DOB:	
Outcome:	Not yet recovered	i		Causality:	Causality possible
eaction Detai	ils:				
Medicine Deta	aile				
ZANTAC (Suspect			Reason:		
Tablet	,	300.0 Milligram	Daily	Oral	
Batch:		Started: 16/04/1996	,	Stopped:	
	DROCHLORIDE (Sus		Reason:		
Oral applic		30.0 Milligram	Daily	Oral	
Batch:		Started: 17/05/1996		Stopped:	
l abaratanı İn	waatigatiana				
Laboratory III	vestigations:				
Additional Inf	formation:				
nort Pun : 01/06/200	07 02:45DM Datah	ases: pusimo02	VDB6004		Daga 200 of 202

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
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Case Number: 112592 Seq: 1 Gender: F

 Reported: 28/10/1996
 Weight: 85.00

 Hospitalisation:
 Age: 76Y

 Onset Date: 01/07/1996
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hirsutism		Excessive facial hair growth	

Medicine Details:

vieuicine Delans.					
RENITEC (Other drug)		ı	Reason:	Essential beni	gn hypertension
Tablet	5.0	Milligram	Daily		Oral
Batch:	Started:	L TE	RM	Stopped:	
OROXINE (Other drug)		I	Reason:	Myxedema	
Tablet	50.0	Microgram	Daily		Oral
Batch:	Started: 14/1	2/1995		Stopped:	
MELLERIL (Suspected)		ı	Reason:	Paranoid type	schizophrenia
	30.0	Milligram	Daily		
Batch:	Started: 13/0	6/1996		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 113236
 Seq: 1
 Gender: F

 Reported:
 19/11/1996
 Weight:

Hospitalisation: Age: 22Y
Onset Date: 05/11/1996 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Arthralgia			
Headache			
Hepatitis			
Myalgia			
Nausea			

Medicine Details:

AROPAX (Other drug)		Reason:	Depression	
Tablet	20.0 Milligram	Daily		Oral
Batch:	Started: 09/09/1994		Stopped:	CONTIN
OXAZEPAM (Suspected)		Reason:	Specific disord	ders of sleep
Oral application	15.0 Milligram	As ne	ecessary	Oral
Batch:	Started: 22/10/1996		Stopped:	07/11/1996
THIORIDAZINE HYDROCHLORIDE (Suspe	ected)	Reason:	Otr spec symp	psychopathol nec
Oral application	0.0	As ne	ecessary	Oral
Batch:	Started: 01/01/1994		Stopped:	07/11/1996
CARBAMAZEPINE (Suspected)		Reason:	Otr spec symp	psychopathol nec
Oral application	400.0 Milligram	Daily		Oral
Batch:	Started: 10/10/1996		Stopped:	07/11/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Blood screens revealed hepatocellular and cholestatic picture. reaction occurred within three weeks of starting carbamazepine 200mg. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 113366 Seq: 1 Gender: F

Reported: 25/11/1996 Weight: 46.00 Hospitalisation: Age: 44

Onset Date: DOB: 03/07/1952

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

<u>Medicine Details.</u>			
AUGMENTIN (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
MELLERIL (Suspected)		Reason: Depression	
Tablet	75.0 Milligram	Daily Oral	
Batch:	Started: 01/04/1996	Stonned: 28/07/1996	

Laboratory Investigations:

Date	Туре	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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

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 Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic cirrhosis			

Medicine Details:

PROZAC (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
METHOTREXATE (Suspected)		Reason: Other psoriasis	
	10.0 Milligram	Weekly	
Batch:	Started: 01/06/1994	Stopped: 28/11/1996	
FELDENE (Suspected)		Reason:	
Capsule	0.0	As necessary Oral	
Batch:	Started:	Stopped:	
MELLERIL (Suspected)		Reason: Unspecifid affective psychosis	
	0.0	Daily	
Batch:	Started: 01/01/1978	Stopped: 28/11/1996	

Laboratory Investigations:

Da	ite	Туре	Range	Date Tested	Result	Details
	Liver biopsy				Liver biopsy 13/11/96: secondary biliary cirrhosis	

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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	nΛ	rt	D۵	tail	le.
1/6	μυ	ıι	$rac{1}{2}$	lai	IJ.

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 Details:

Medicine Details:

Micalcinic 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Preferred Term Severity Report Description Treatment Buroleptic malignant syndrome Bulcine Details: Sedicine Details:	Outcome: Unknown action Details: Preferred Term euroleptic malignant syndrome edicine Details: ISPERIDONE (Suspected) Batch: ERICYAZINE (Suspected)	500.0	Re: Microgram	ason: (Causalid scription Otr spec symp psychopessary	Treatment pathol nec
Preferred Term Severity Report Description Treatment euroleptic malignant syndrome Reason: Otr spec symp psychopathol nec	Preferred Term euroleptic malignant syndrome dedicine Details: RISPERIDONE (Suspected) Batch: PERICYAZINE (Suspected)	500.0	Re: Microgram	ason: (Otr spec symp psychopessary	Treatment pathol nec
Report Description Treatment	Preferred Term leuroleptic malignant syndrome ledicine Details: RISPERIDONE (Suspected) Batch: PERICYAZINE (Suspected)	500.0	Re: Microgram	ason: (Otr spec symp psychop essary	pathol nec
Medicine Details: RISPERIDONE (Suspected) Batch: Started: Stopped: 3.0 Dose Unspecified Daily Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: 3D THIORIDAZINE HYDROCHLORIDE (Suspected) Batch: Started: Stopped: Stop	Medicine Details: RISPERIDONE (Suspected) Batch: PERICYAZINE (Suspected)	500.0	Re: Microgram	ason: (Otr spec symp psychop essary	pathol nec
Medicine Details: RISPERIDONE (Suspected) 500.0 Microgram As necessary Batch: Started: Stopped: 2D PERICYAZINE (Suspected) Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: 3D THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec Started: Stopped: 3D THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec 30.0 Milligram Daily Batch: Started: Stopped: 5D	Medicine Details: RISPERIDONE (Suspected) Batch: PERICYAZINE (Suspected)		Microgram		essary	
RISPERIDONE (Suspected) 500.0 Microgram As necessary Batch: Started: Stopped: 2D PERICYAZINE (Suspected) Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Daily Oral THIORIDAZINE HYDROCHLORIDE (Suspected) 30.0 Milligram Daily Batch: Started: Stopped: 5D As necessary Otr spec symp psychopathol nec Stopped: 3D Otr spec symp psychopathol nec Stopped: 3D Otr spec symp psychopathol nec Stopped: 5D Stopped: 5D	RISPERIDONE (Suspected) Batch: PERICYAZINE (Suspected)		Microgram		essary	
Started: Stopped: 2D	Batch: PERICYAZINE (Suspected)		Microgram		essary	
Batch: Started: Stopped: 2D PERICYAZINE (Suspected) Reason: Otr spec symp psychopathol nec Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: 3D THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec 30.0 Milligram Daily Batch: Started: Stopped: 5D Batch: Started: Stopped: 5D	PERICYAZINE (Suspected)		_	As nec		20
PERICYAZINE (Suspected) Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: 3D THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec 30.0 Milligram Daily Batch: Started: Stopped: 5D Aboratory Investigations:	PERICYAZINE (Suspected)	Started:	Re			
Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: 3D THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec 30.0 Milligram Daily Batch: Started: Stopped: 5D Aboratory Investigations:			K6:			
Batch: Started: Stopped: 3D THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Otr spec symp psychopathol nec 30.0 Milligram Daily Batch: Started: Stopped: 5D Laboratory Investigations:	Tablet	3.0				pathol nec
THIORIDAZINE HYDROCHLORIDE (Suspected) 30.0 Milligram Daily Batch: Started: Stopped: 5D -aboratory Investigations:	Ratch:		Dose Orispecified	Daily		3D
30.0 Milligram Daily Batch: Started: Stopped: 5D _aboratory Investigations:			Re	ason: (
Batch: Started: Stopped: 5D aboratory Investigations:	(0.0.)					
_aboratory Investigations:	Batch:		Ü	,	Stopped:	5D
Date Type Range Date rested Result Details		Doto Too	tod Dogult		D	pto il p
	Date Type Range	Date Test	teu Result		De	cialis

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 114729
 Seq: 1
 Gender:
 F

 Reported:
 24/01/1997
 Weight:

Hospitalisation:
Onset Date: 29/09/1996
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction Details.				
Preferred Term	Severity	Report Description	Treatment	
Dysgeusia		Bad taste om mouth		
Coordination abnormal				
Polyuria				
Tremor				

Medicine Details:

modionio Botano.				
FELDENE (Suspected)		Reason:	Lumbalgia	
Capsule	20.0 Milligram	Daily		Oral
Batch:	Started: 25/09/1996		Stopped:	29/09/1996
AMOXIL (Suspected)		Reason:	Ac upr resp inf	f,mult,unsp stes
Oral application	750.0 Milligram	Daily		Oral
Batch:	Started: 25/09/1996		Stopped:	30/09/1996
LITHICARB (Suspected)		Reason:	Depression	
Tablet	1.5 Gram	Daily		Oral
Batch:	Started: 17/09/1996		Stopped:	01/10/1996
ALDAZINE (Suspected)		Reason:	Otr spec symp	psychopathol nec
Tablet	50.0 Milligram	Daily		Oral
Batch:	Started: 18/09/1996		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Serum drug level		01/10/1996	1.57	Lithium level
	Serum drug level		02/10/1996	0.8	Lithium level

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 114729 Reported: 24/01/1997 Hospitalisation: Onset Date: 29/09/1996 Outcome: Unknown Reaction Details:	Seq: 1		Gender: Weight: Age: DOB: Causality:	37Y
Medicine Details:			0, 1, 1, 1,	
ZANTAC (Suspected)	450 O M:111	Reason:	Otr disorders stomach fun	ction
Tablet	150.0 Milligram	Daily	Oral	0.01/2/11
Batch:	Started: 20/09/1996		Stopped:	CONTIN
Laboratory Investigation	s:			
Additional Information:				

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 114943	Seq: 1		Ge	nder: F
Reported: 03/02/199	97		We	ight:
ospitalisation:				Age: 75Y
Onset Date:				DOB:
Outcome: Unknown			Caus	ality: Causality possible
eaction Details:				
Preferred Term	Severity	•	rt Description	Treatment
Jrine analysis abnormal		Bright yellow urin	<u>e</u>	
Medicine Details:		Page		
MACRODANTIN (Suspected) Capsule	0.0	Reas	on: Ora	1
Batch:	Started:		Stopped:	
MELLERIL (Suspected)	Starteu.	Reas		
MELLENIE (Guspecieu)	50.0		Daily	
Batch:	Started:	viiiigiaiii	Stopped:	
ah ayatayı layaatigat	liana.			
_aboratory Investigat	Range Date Teste	ed Result		Details
1,7,60	gc			
Additional Informatio	n:			
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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Rep	ort	Detail	ls:
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 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 Details:

todotion Dotailoi			
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	
Tablet	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:

<u> </u>	y mroonga				
Date	Туре	Range	Date Tested	Result	Details
	Electrocardiograph				Ecg: anterolateral st-t wave changes suggestive cardiac ischaemic.

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:		
Case Number: 115390	Seq: 1	Gender: M
Reported: 19/02/1997		Weight:

Hospitalisation: Admitted to hospital Age: 73
Onset Date: 22/12/1996 DOB: 08/06/1923

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.	eaction betails.						
Preferred Term	Severity	Report Description	Treatment				
Cardiac arrest							
Electrocardiogram QT prolonged							
Hypokalaemia							
Torsade de pointes			Dc conversion				
Ventricular tachycardia							

Medicine Details:

ASPIRIN (Other drug)			Reason:		
Oral application	150.0	Milligram	Daily	Oral	
Batch:	Started:		L TERM	Stopped:	
FRUSEMIDE (Other drug)			Reason:	Essential benign hypertension	
Oral application	40.0	Milligram	Daily	Oral	
Batch:	Started:		L TERM	Stopped:	
CAPTOPRIL (Other drug)			Reason:	Essential benign hypertension	
Tablet	12.5	Milligram	Daily	Oral	
Batch:	Started:		L TERM	Stopped:	
METOPROLOL TARTRATE (Other drug)			Reason:	Chron isch heart dis no hyper	
Oral application	50.0	Milligram	Daily	Oral	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	115390	Seq: 1					Gender:	M	
-	19/02/1997						Weight:		
	Admitted to hospit	tal					Age:		
Onset Date:								08/06/1923	
Outcome:	Recovered					С	ausality:	Causality possible	;
Reaction Detai	ls:								
Medicine Deta	ails:								
	DROCHLORIDE (Sus			Reas					
Tablet) Milligram		Daily		Oral		
Batch:		Started:		L TERM		Stopped:	22/12/1996	3	
Laboratory In	vestigations:								
Additional Inf	ormation:								

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Ren	ort	Deta	ils:
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Case Number: 115828 Seq: 1 Gender: F

Reported: 06/03/1997 Weight: 100.00 Hospitalisation: Age: 32Y

Onset Date: 26/02/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Rash erythematous		Generalised rash including soles and palms	
Lymphadenopathy		Swollen cervical lymph nodes	
Malaise			
Pruritus			
Pyrexia			
Vomiting			

Medicine Details:

ALPRAZOLAM (Other drug)	R	Reason:	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started: 09/01/1997	Stopped:	
TEGRETOL (Suspected)	R	Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 06/02/1997	Stopped:	28/02/1997
EFEXOR (Suspected)	R	Reason:	
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 12/12/1996	Stopped:	27/02/1997
MELLERIL (Suspected)	R	Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 20/01/1997	Stopped:	28/02/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 115862 Seq: 1 Gender: F

Reported: 12/03/1997 Weight: 88.00 Hospitalisation: Age: 68Y

Onset Date: 28/02/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anorexia		Unable to eat	
Insomnia		Unable to sleep	
Constipation			
Dizziness			
Headache			
Hyperkinesia			
Tremor			

Medicine Details:

Reason:	Chron isch heart dis no hyper
₹	eason:

62.5 Milligram Daily

Batch: Started: L TERM Stopped:

TAZAC (Other drug) Reason: Other diseases of esophagus

300.0 Milligram Daily

Batch: Started: L TERM Stopped:

MURELAX (Other drug) Reason: Anxiety neurosis

15.0 Milligram Daily

Batch: Started: Stopped:

EFEXOR (Suspected) Reason: Depression

37.5 Milligram Daily

Batch: Started: 28/02/1997 **Stopped:** 02/03/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has reacted to aurorix, aropax and prozac

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Hospitalisation: Onset Date: Outcome: Reaction Detai	12/03/1997 28/02/1997 Recovered Is:	Seq: 1				Gender: Weight: Age: DOB: ausality:	88.00 68Y	oossible
Medicine Deta								
MELLERIL (Suspe	cted)	40.0	.	Reason:				
			Milligram	Daily				
Batch:		Started:				27/02/1997		
XANAX (Suspected	d)				Anxiety neuros	sis		
			Microgram	Daily		07/00/4007		
Batch:		Started:			Stopped:	27/02/1997		
Laboratory In	vestigations:							
Additional Inf Patient has reacted	ormation: d to aurorix, aropax	and prozac						

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 115921 Gender: F Seq: 1 Reported: 12/03/1997 Weight:

Hospitalisation: **Age:** 73

Onset Date: 10/11/1996 **DOB**: 08/01/1923 Causality: Causality possible

Outcome: Death, maybe drug

Reaction Details:

Ì	Duefe was all Terror	O a consider.	Danast Danasistias	Trootmont		
	Preferred Term	Severity	Report Description	reatment		
	Hepatitis					

Medicine Details:

RULIDE (Suspected) Reason: Pneumonia, unspecified

0.0

Batch: Started: 31/10/1996 **Stopped:** 04/11/1996

RANITIDINE (Suspected) Reason:

> 300.0 Milligram Daily

Batch: Started: Stopped:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason:

> 100.0 Milligram Daily

Batch: Started: Stopped:

DICLOFENAC SODIUM (Suspected) Reason: Other rheumatoid arthritis

> 150.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	0 - 65 IU/L	02/11/1996	121	
	ALT = SGPT	0 - 65 IU/L	04/11/1996	109	
	ALT = SGPT	0 - 65 IU/L	10/11/1996	148	
	ALT = SGPT	0 - 65 IU/L	06/11/1996	129	
	AST = SGOT	0 - 44 IU/L	02/11/1996	93	
	AST = SGOT	0 - 44 IU/L	04/11/1996	138	
	AST = SGOT	0 - 44 IU/L	06/11/1996	142	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Gender: F Case Number: 115921 Seq: 1 Weight: Reported: 12/03/1997

Hospitalisation: **Age:** 73

Onset Date: 10/11/1996 DOB: 08/01/1923

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Medicine Details:

Batch:

Batch:

PENICILLAMINE (Suspected) Reason: Other rheumatoid arthritis

> 1.0 Gram Daily

> > Stopped:

Stopped:

Batch: Started: Stopped:

Started:

ASPIRIN (Suspected) Reason:

150.0 Milligram Daily

PREDNISONE (Suspected)

Reason: Other rheumatoid arthritis

> 5.0 Milligram Daily

Started: **THYROXINE SODIUM (Suspected)** Reason: Myxedema

10.0 Microgram Daily Batch: Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	0 - 44 IU/L	10/11/1996	159	
	Albumin	34 - 50 G/L	02/11/1996	28	
	Albumin	34 - 50 G/L	04/11/1996	30	
	Albumin	34 - 50 G/L	10/11/1996	28	
	Albumin	34 - 50 G/L	06/11/1996	29	
	Bilirubin	2 - 20 UMOL/L	02/11/1996	12	
	Bilirubin	2 - 20 UMOL/L	10/11/1996	49	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 115921
 Seq: 1
 Gender: F

 Reported:
 12/03/1997
 Weight:

Hospitalisation: Age: 73

Onset Date: 10/11/1996 **DOB**: 08/01/1923

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Medicine Details:

COGENTIN (Suspected)

2.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

<u> </u>	,,				
Date	Туре	Range	Date Tested	Result	Details
	Bilirubin	2 - 20 UMOL/L	06/11/1996	22	
	Bilirubin	2 - 20 UMOL/L	04/11/1996	14	
	GGT = SGGT =	0 - 85 IU/L	02/11/1996	1393	
	GGT = SGGT =	0 - 85 IU/L	04/11/1996	1837	
	GGT = SGGT =	0 - 85 IU/L	06/11/1996	2485	
	GGT = SGGT =	0 - 85 IU/L	10/11/1996	3119	
	SAP = ALP	50 - 136 IU/L	02/11/1996	305	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report D	etails:						
Repo Iospitalisa Onset I Outco	Date: 10/11/199 me: Death, m	96	1				
eaction D	etails:						
	-						
Medicine RULIDE (Su				Roa	son:	Pneumonia,unspecified	
NOLIDE (OU	specied)		0.0	Nea	3011.	r neumonia, anspecinea	
Bat	ch:	s	tarted: 31/10/1	996		Stopped : 04/11/1996	}
RANITIDINE	(Suspected)			Rea	son:		
			300.0 Mill	igram	Daily		
Bat	ch:	S	tarted:			Stopped:	
THIORIDAZI	NE HYDROCHLO	RIDE (Suspected			son:		
			100.0 Mill	igram	Daily		
Bat			tarted:			Stopped:	
DICLOFENA	C SODIUM (Suspe	ected)	150 0 Mill		son:	Other rheumatoid arthritis	
Bat	ch:	s	150.0 Mill tarted:	igram	Daily	Stopped:	
Dat	JII.		tarteu.			оторрец.	
	ry Investiga		1				
Date	Type	Range	Date Tested	Result		Detai	S
	SAP = ALP SAP = ALP	50 - 136 IU/L 50 - 136 IU/L	04/11/1996 06/11/1996	378 452			
	SAP = ALP	50 - 136 IU/L	10/11/1996	564			
Additiona	al Informatio	n:					

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Case Number: 115921

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

				Weight:	
ospitalisation:				Age:	73
Onset Date: 10/11/1996				DOB:	08/01/1923
Outcome: Death, maybe drug	J			Causality:	Causality possible
action Details:					
Medicine Details:			Bassani	Other rhaumataid arthritis	
PENICILLAMINE (Suspected)	1.0	Gram	Reason:	Other rheumatoid arthritis	
Batch:		Gram	Daily	Stannadi	
	Started:		Decem	Stopped:	
ASPIRIN (Suspected)	450.0	Millianana	Reason:		
Datah.		Milligram	Daily	Stannadi	
Batch:	Started:		Decem	Stopped: Other rheumatoid arthritis	
PREDNISONE (Suspected)	5.0	Millianana	Reason:	Other meumatoid artinitis	
Detale		Milligram	Daily	Otama adı	
Batch:	Started:		Reason:	Stopped:	
THYROXINE SODIUM (Suspected)	40.0	Misassas		Myxedema	
	10.0	Microgram	Daily		
5	0 4 4 1			•	
Batch:	Started:			Stopped:	
	Started:			Stopped:	
	Started:			Stopped:	
	Started:			Stopped:	
	Started:			Stopped:	
	Started:			Stopped:	
	Started:			Stopped:	
	Started:			Stopped:	
	Started:			Stopped:	
	Started:			Stopped:	
aboratory Investigations:	Started:			Stopped:	
_aboratory Investigations:	Started:			Stopped:	
_aboratory Investigations:	Started:			Stopped:	
aboratory Investigations:	Started:			Stopped:	
Laboratory Investigations:	Started:			Stopped:	

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

-	s:					
Hospitalisation: Onset Date:	12/03/1997 10/11/1996 Death, maybe dru	Seq: 1				
Neaction Detai	13.					
Medicine Deta						
COGENTIN (Suspe	ected)		2.0 Milligram	Reason: Daily		
Batch:		Started		Dany	Stopped:	
						<u> </u>
Laboratory In	vestigations:					
Laboratory In	vestigations:					
Laboratory In	vestigations:					
Laboratory In	vestigations:					
Laboratory In	vestigations:					
Laboratory In						

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 116045 Seq: 1 Gender: F

Reported: 14/03/1997 Weight: 78.00
Hospitalisation: Age: 43Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Continuous movement of the legs and feet.	
Dyskinesia		Orolingual dyskinesia	

Medicine Details:

HALOPERIDOL (Suspected) Reason:

5.0 Milligram As necessary

Batch: Started: 01/05/1996 Stopped: 28/12/1996

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason:

50.0 Milligram As necessary

Batch: Started: 01/05/1996 **Stopped:** 28/12/1996

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

200.0 Milligram Daily

Batch: Started: 01/05/1996 **Stopped:** 28/03/1997

Laboratory Investigations:

Date	Туре	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. 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.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: ** Reported: **		Seq:	1				Gende Weigh		
ospitalisation:							Ag		
Onset Date:							DO		
Outcome:	Jnknown					С	ausalit	y: Causality p	ossible
action Detail	s:								
Preferre	d Term	Se	everity	Report	De	scription		Treatr	ment
pistaxis									
ledicine Deta ZOLOFT (Suspected				Reaso		Depression			
ZOLOFT (Suspected	<i>1)</i>		0.0	Reason	n:	Depression	Oral		
Batch:		9	tarted:			Stopped:	Olai		
MELLERIL (Suspect	tod)		tarteu.	Reaso	<u></u>	Depression			
Tablet	ieu)		0.0	Neason		Бергеззіон	Oral		
Batch:		S.	tarted:			Stopped:	Orai		
aboratory Inv	vestigatio	ons:							
Date 1	уре	Range	Date Tested	Result			De	etails	
dditional Info	ormation								
									_
ort Run: 01/06/2007	02:45PM	Database: pu	usime02	ADF	3 50	04		Page 2	23 of 393



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 116524 Seq: 1 Gender: F
Reported: 08/04/1997 Weight:

Hospitalisation: Age: 76Y
Onset Date: 15/03/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Preferred refini	Seventy	Report Description	Пеашеш
Blood creatine phosphokinase incr			
Consciousness fluctuating			
Dystonia			
Hypotension			
Hypoventilation			
Neuroleptic malignant syndrome			
Pyrexia			
Tachycardia			

Medicine Details:

MONOTARD HM (Other drug)		Reason:	Diabetes mellitus	
	0.0			
Batch:	Started:		Stopped:	
ACTRAPID HM (Other drug)		Reason:	Diabetes mellitus	
	0.0			
Batch:	Started:		Stopped:	
DIDROCAL (Other drug)		Reason:	Osteoporosis	
	0.0			
Batch:	Started: 01/01/1997		Stopped:	
PARACETAMOL (Other drug)		Reason:	Otr&unsp vertebrogen pain synd	
	0.0			
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Dystonia led to chest wall weakness and upper airway restriction causing hypoventilation and svt with hypotension. intubation and ventilation required for 1 week, svt relieved within minutes of intubation, having been refractory to adenosine. 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 116524
 Seq: 1
 Gender:
 F

 Reported:
 08/04/1997
 Weight:

Hospitalisation: Age: 76Y
Onset Date: 15/03/1997
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

Medicine Details.		
NARCOTIC NOS (Other drug)		Reason: Otr&unsp vertebrogen pain synd
	0.0	
Batch:	Started:	Stopped:
MOCLOBEMIDE (Other drug)		Reason: Depression
	300.0 Milligram	Daily
Batch:	Started: 01/02/1997	Stopped : 15/03/1997
MELLERIL (Suspected)		Reason:
	1.0 Dose Unsp	pecified 1 time
Batch:	Started: 15/03/1997	Stopped:

Laboratory Investigations:

Additional Information:

Dystonia led to chest wall weakness and upper airway restriction causing hypoventilation and svt with hypotension. intubation and ventilation required for 1 week, svt relieved within minutes of intubation, having been refractory to adenosine. 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 116542 Seq: 1 Gender: F

 Reported:
 07/04/1997
 Weight:

 Hospitalisation:
 Age:
 AE

 Onset Date:
 31/03/1997
 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	todotion Details.			
	Preferred Term	Severity	Report Description	Treatment
	Pruritus			
	Rash			

Medicine Details:

MELLERIL (Suspected) Reason:

Tablet 10.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Manufactured locally patient on melleril for approx 20 years, changed to new formulation and rash appeared.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Casa Numb										
Report ospitalisati Onset Da		997	q : 1			c	DO	t: e: A2 B:	sality poss	sible
eaction D										
	eferred Term		Severity		ort Desc	ription			Treatme	nt
Jrinary incor	itilierice	I	ре	t wetting						
Medicine I	Details:									
Medicine I				Rea	son:					
INTAL (Other	drug)		0.0	Rea	son:					
INTAL (Other Batcl	drug) h:		0.0 Started:			Stopped:				
INTAL (Other	drug) h:		Started:		son:	Stopped:				
INTAL (Other Batcl BRICANYL (C	drug) h: Other drug)		Started: 0.0							
INTAL (Other Batcl	drug) h: Other drug) h:		Started:	Rea		Stopped:				
INTAL (Other Batcl BRICANYL (C	r drug) h: Other drug) h: Other drug)		Started: 0.0	Rea Rea	son:		Oral			
BRICANYL (C Batcl	h: Other drug) h: Other drug)		Started: 0.0 Started:	Rea Rea	son:		Oral			
BRICANYL (C Batcl TEGRETOL (C	h: Other drug) h: Other drug) ct		0.0 Started:	Rea Rea	son:	Stopped:	Oral			
BRICANYL (C Batcl BRICANYL (C Batcl TEGRETOL (C	h: Other drug) h: Other drug) ct		0.0 Started:	Rea Rea im	son: son: Daily	Stopped:	Oral			
BRICANYL (C Batcl BRICANYL (C Batcl TEGRETOL (C	h: Other drug) h: Other drug) t: th: cuspected)		0.0 Started: 1.2 Gra Started:	Rea Rea im	son: Daily	Stopped:	Oral			
BRICANYL (C Batcl TEGRETOL (C Table Batcl MELLERIL (S	h: Other drug) h: Other drug) other drug) other drug) h: uspected)	ations:	0.0 Started: 1.2 Grastarted: 100.0 Mill	Rea Rea im	son: Daily	Stopped:	Oral			
BRICANYL (C Batcl TEGRETOL (C Table Batcl MELLERIL (S	h: Other drug) h: Other drug) t: th: cuspected)	ations:	0.0 Started: 1.2 Grastarted: 100.0 Mill	Rea Rea im	son: Daily	Stopped:		etails		

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 118126 Gender: M Seq: 1 Reported: 06/06/1997 Weight:

Hospitalisation: Admitted to hospital Age: 28Y Onset Date: 04/01/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Severe	Stiff, drooling	Benztropine given for 2 weeks

Medicine Details: LITHICARB (Other drug)

LITHICARB (Other drug)		Reason: Unspecified psychosis	
	1.0 Gram	Daily	
Batch:	Started:	Stopped:	
MODECATE (Suspected)		Reason: Unspecified psychosis	
MODECATE (Suspected) Injection	0.0	Reason: Unspecified psychosis Intramuscular	

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

> 150.0 Milligram Daily

Started: 01/10/1996 Batch: Stopped: 04/01/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 118372 Seq: 1 Gender: F

 Reported:
 18/06/1997
 Weight:
 66.00

 Hospitalisation:
 Age:
 49Y

 Onset Date:
 04/02/1997
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Agitation			
Anxiety			

Medicine Details:

MELLERIL (Suspected)		Reason:		
Tablet	75.0 Milligram	Daily	Oral	
Batch:	Started:	Sto	pped:	
SINEQUAN (Suspected)		Reason:		
	60.0 Milligram	Daily		
Batch:	Started:	Sto	pped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient stabilised on 75mg melleril since 1982. change of formulation of 50mg and 25mg tablets has caused major upset.

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Case Number: 121896

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Reported: 27/10/1997		Weight:					
lospitalisation:		Age: 41Y					
Onset Date: 15/10/1997			DOB:				
Outcome: Unknown				Causa	lity: Causality possible		
eaction Details:							
Preferred Term	Se	verity	Report	Description	Treatment		
Cold sweat							
Nausea							
Orthostatic hypotension							
Syncope							
Medicine Details:							
THIORIDAZINE HYDROCHLORIDE	Suspected)		Reason		is		
Tablet		75.0 Milli		aily Oral			
Batch:	St	arted: 15/10/19	997	Stopped:			
Laboratory Invostigation	6.						
Laboratory Investigation Date Type	S. Range	Date Tested	Result		Details		
.,,,,,	95						
Additional Information:							
eport Run:01/06/2007 02:45PM D	atabase: pu	sime02	ADR	S004	Page 230 of 393		



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

eport Details:					
Case Number: 122309	Seq: 1			Gender:	F
Reported: 12/11/19	97			Weight:	
spitalisation:				Age:	63Y
Onset Date:				DOB:	
Outcome: Unknown	n		C	ausality:	Causality possible
action Details:					
Preferred Term	Severity	Report	Description		Treatment
seudolymphoma					
ladiaina Dataila.					
		Reaso	1:		
	0.0	Reasoi	n:		
RITALIN (Suspected)	0.0 Started:	Reason			
RITALIN (Suspected) Batch:		Reasoi	Stopped:		
RITALIN (Suspected) Batch:			Stopped:		
RITALIN (Suspected) Batch:	Started:	Reasoi	Stopped:	31/01/1996	6
Batch: Batch: Batch: Batch:	Started: 0.0 Started: 01/01/	Reasoi	Stopped:	31/01/1996	3
Batch: Batch: Batch: Batch:	Started: 0.0 Started: 01/01/	Reaso i 1989	Stopped:	31/01/1996	5
Batch: Batch: Batch: Batch:	0.0 Started: 01/01/ d)	Reaso i 1989	Stopped:	31/01/1996	5
Batch: DGEN (Suspected) Batch: Batch: PROGESTERONE (Suspected)	0.0 Started: 01/01/ d)	Reaso i 1989	Stopped: Stopped:		6
Batch: DGEN (Suspected) Batch: Batch: PROGESTERONE (Suspected)	0.0 Started: 01/01/ d)	Reasoi Reasoi Reasoi	Stopped: Stopped:		6
Batch: Batch: Batch: Batch: Batch: PROGESTERONE (Suspected) Batch: DERALIN (Suspected)	0.0 Started: 01/01/ d) 0.0 Started: 50.0 Started: 50.0	Reason Reason Reason Reason	Stopped: Stopped: Stopped: Anxiety neuros	iis Oral	
Batch: Batch: Batch: Batch: Batch: DERALIN (Suspected) Tablet Batch:	0.0 Started: 01/01/ d) 0.0 Started: 240.0 Mi Started: 01/01/	Reason Reason Reason Reason	Stopped: Stopped: Stopped: Anxiety neuros	iis Oral	
Batch: Batch: Batch: Batch: PROGESTERONE (Suspected) Batch: DERALIN (Suspected) Tablet	0.0 Started: 01/01/ d) 0.0 Started: 240.0 Mi Started: 01/01/	Reason Reason Reason Reason Illigram D	Stopped: Stopped: Stopped: Anxiety neuros	iis Oral	3

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 stort date is not accurate but indicates that stoppage occurred

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	nn	rt	De	tail	ls:
176	μυ		$\mathbf{D}\mathbf{c}$	tai	ιο.

 Case Number:
 122309
 Seq: 1
 Gender: F

 Reported:
 12/11/1997
 Weight:

Hospitalisation: Age: 63Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Medicine Details:

DERALIN (Suspected)		Reason: Anxiety neuro	osis
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 Unsp	pecified 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 stoppage occurred sometime during the year. The dosage start date is not accurate but indicates that stoppage occurred sometime during the year.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Reported	122353	Seq	: 1			Gender:	F
•	: 14/11/199	97				Weight:	
spitalisation:						Age:	
Onset Date:	: 07/11/199	97				DOB:	
Outcome:	Recovere	ed .			C	ausality:	Causality probable
action Deta	ıils:						
Prefer	red Term	Sc	everity	Repo	t Description		Treatment
peech disorde	٢		Slu	ırred speech			
Confusional stat	ie						
ry mouth							
omnolence							
ledicine De							
AURORIX (Other	drug)			Reas	on: Depression		
Detaka		_	0.0	LTEDM	04		
Batch:	alm.e.\	S	Started:	L TERM	Stopped:		
VITAMINS (Other	arug)		0.0	Reas	on:		
Batch:		ç	0.0 Started:	L TERM	Stopped:		
MINERALS (Othe	r drug)			Reas			
•	- -		0.0				
Batch:		S	Started:	L TERM	Stopped:		
FERROUS SULPI	HATE (Other	drug)		Reas	on:		
			0.0			Oral	
Tablet			Started:	L TERM	Stopped:		
Tablet Batch :				· 			
Batch:	nvostinat	tione:					
	nvestigat _{Type}	tions:	Date Tested	Result		Detai	ls .

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	122353	Seq: 1			Gender:	F	
Reported:	14/11/1997	•			Weight:		
Hospitalisation:					Age:		
Onset Date:	07/11/1997				DOB:		
Outcome:				С		Causality probable	
Reaction Detai					,	,,	
Medicine Deta	aile:						
RANITIDINE (Other			Reason:				
(00000	-	0.0					
Batch:		Started:	L TERM	Stopped:			
SULINDAC (Other	drug)	otariou.	Reason:	оторрош			
OULINDAO (Other	uiug)	0.0	reason.				
Batch:		Started:	L TERM	Stopped:			
	DROCHLORIDE (Sus		Reason:	Unspecified ps	vchosis		
THIORIDALINE TH	DROGILORIDE (Gud	25.0 Milligram		Onopcomed pe	y 01 10010		
Batch:		Started: 06/11/1997	Dany	Stonned:	07/11/1997	,	
Duton.		Ctartea: 00/11/1007		оторреа.	0771171007		
Laboratory In	vestigations:						
-	•						
Additional Inf	ormation:						

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 122868 Gender: F Seq: 1 Reported: 27/11/1997 Weight:

Hospitalisation: Age: 45Y

Onset Date: 20/11/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	teaction Betails.			
	Preferred Term	Severity	Report Description	Treatment
	Confusional state	Severe		
	Thrombocytopenia			

Medicine Details:

DIAZEPAM (Other drug)		Reason:	Anxiety neurosis
Oral application	0.0		Oral

Batch: Started: 01/10/1997 Stopped:

PANADEINE FORTE (Other drug) Reason:

6.0 Dose Unspecified Daily

Started: L TERM Stopped: Batch:

NEFAZODONE HYDROCHLORIDE (Suspected) Reason: Depression

Tablet 400.0 Milligram Daily Oral Batch: Started: 06/11/1997

20/11/1997 Stopped:

LOSEC (Suspected) Reason: Other diseases of esophagus Capsule 20.0 Milligram Daily Oral

Batch: Started: L TERM Stopped: 20/11/1997

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets		20/11/1997	89	

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	122868	Seq: 1			Gender:	F	
Reported:	27/11/1997				Weight:		
Hospitalisation:					Age:	45Y	
Onset Date:	20/11/1997				DOB:		
Outcome:	Not yet recovered	I		С	ausality:	Causality possible	
Reaction Detai	ls:						
Madiaina Date	silo.						
Medicine Deta	DROCHLORIDE (Sus	pected)	Reason:	Specific disord	ders of sleep		— 1
Tablet		100.0 Milligram			Oral		
Batch:		Started : 23/10/1997			20/11/1997	,	
				сторрош			
Laboratory In	vestigations:						
Additional Inf	ormation:						

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 123642 Gender: M Seq: 1

Reported: 24/12/1997 Weight: Hospitalisation: Age: A4

Onset Date: 31/12/1997 DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

caction betails.				
Preferred Term	Severity	Report Description	Treatment	
Chest pain			Chest pain treated with nitroglycerine	

Medicine Details: PROTHIADEN (Suspected)

Batch:

PROTHIADEN (Suspected)		Reason:	Depression
	0.0		
Batch:	Started:	L TERM	Stopped:
MELLERIL (Suspected)		Reason:	

Stopped:

0.0

Started:

ZOLOFT (Suspected) Reason: Depression

Tablet 150.0 Milligram Daily Oral Batch: Started: L TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Reporte	e r: 124310) Seq	Seq: 1			Gender: F			
-	ed: 22/01/1	1998		Weight:					
ospitalisatio							Age:	76Y	
	te: 19/12/1						DOB:		
Outcom	e: Recove	ered				C	ausality:	Causality possible	
eaction De									
	erred Term	<u>ı S</u>	everity	_	ort Desc			Treatment	
Jrinary retent	ion		U	rge but unable	to urinat	е	Cea	ased melleril.	
Polydipsia									
Medicine D	otails:								
NORVASC (Oti				Rea	son:				
	3,		2.5 Mi		Daily				
Batch:	:	;	Started:	-	,	Stopped:		CONTIN	
SOLPRIN (Other	er drug)			Rea	ison:				
			150.0 Mi	lligram	Daily				
Batch:	<u>: </u>		Started:			Stopped:		CONTIN	
CHLORPROM <i>F</i>	AZINE HYDRO	OCHLORIDE (Sus	pected)	Rea	son: O	tr spec symp	psychopath	ol nec	
Injectio	n		50.0 Milligram		n 1 time In		Intramuscu	ntramuscular	
Batch:		;	Started: 18/12/	1997	Stopped:				
MELLERIL (Su	spected)			Rea	ison:				
Tablet			20.0 Mi	lligram	Daily Oral				
			Started:			Stopped:	19/12/1997		
Batch:									
	Investia	ıations:							
Batch: aboratory Date	Investig	gations:	Date Tested	Result			Details	S	

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:					
Case Number: 125312	2 Seq: 1	Gender: M			
Reported: 23/02/1	1998	Weight:			

Hospitalisation: Age:
Onset Date: 22/12/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

cuotion Details.							
Preferred Term	Preferred Term Severity Report Description		Treatment				
Dystonia		Jaw drop, tongue rolled over, unable to speak.	Benztropine 2mg imi given and repeat again within 24 hrs with good effect.				
Hypotonia		Unusual lose of tone in upper body					
Catatonia							

Medicine Details:

DIPHTHERIA AND TETANUS VACCINE ADT (Other drug) Reason:						
Injection	1.0	Dose Unspecifie	d 1 tim	е	Intramuscular	
Batch:	Started:			Stopped:	:	
HALOPERIDOL (Other drug)		Re	eason:	Unspecified p	osychosis	
Injection	10.0	Milligram	As ne	ecessary	Intramuscular	
Batch:	Started:			Stopped:	:	
MIDAZOLAM (Other drug)		Re	eason:	Unspecified p	osychosis	
Injection	10.0	Milligram	As ne	ecessary	Intramuscular	
Batch:	Started:			Stopped:	:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Re	eason:	Unspecified p	osychosis	
Injection	50.0	Milligram	1 tim	е	Intramuscular	
Batch:	Started: 20/	12/1997		Stopped:	:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:			
Case Number: 125312 Reported: 23/02/1998 Hospitalisation: Onset Date: 22/12/1997 Outcome: Recovered	Seq: 1	Gender: Weight: Age: DOB:	
Reaction Details:		Causanty.	Causality possible
Medicine Details: THIORIDAZINE HYDROCHLORIDE (Sus	nactad)	Reason: Unspecified psychosis	
Tablet	50.0 Milligram	As necessary Oral	
Batch:	Started: 22/12/1997	Stopped:	
Laboratory Investigations:			
Additional Information:			

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 126428 Seq: 1 Gender: F

Reported: 06/04/1998 Weight: 109.00 Hospitalisation: Age: 40Y

Onset Date: 25/02/1998 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood pressure fluctuation		Autonomic instability with bp 130/80, 140/90.	
Blood creatine phosphokinase incr			
Confusional state			
Hyperhidrosis			
Leukocytosis			
Neuroleptic malignant syndrome			
Pyrexia			
Urinary tract infection			

Medicine Details:

DIAZEPAM (Other drug)		Reason:	Manic-depression psycho,manic
	15.0 Milligram	Daily	
Batch:	Started: 25/02/1998		Stopped: 31/03/1998
LITHIUM CARBONATE (Suspected)		Reason:	Manic-depression psycho,manic
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 19/02/1998		Stopped : 26/02/1998
HALOPERIDOL (Suspected)		Reason:	Manic-depression psycho,manic
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 14/02/1998		Stopped: 24/02/1998
THIORIDAZINE HYDROCHLORIDE (Susp	ected)	Reason:	Manic-depression psycho,manic
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 24/02/1998		Stopped : 25/02/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		14/03/1998	2100	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 126566
 Seq: 1
 Gender:
 F

 Reported:
 09/04/1998
 Weight:

Hospitalisation: Admitted to hospital Age: 70Y
Onset Date: 31/05/1997
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Parkinson's disease	
Gait disturbance		Shuffling gait	
Headache			
Hypertonia			Melleril was ceased with subsequent marked improvement in parkinsonism symptoms. aropax was also ceased. headaches subsequently improved dramatically
Nausea			
Photophobia			

Medicine Details:

ASPIRIN (Other drug)	Reason:					
Oral application	150.0	Milligram	Daily	Oral		
Batch:	Started:			Stopped:	CONTIN	
MODURETIC (Other drug)		Re	ason:			
	1.0	Dose Unspecified	Daily			
Batch:	Started:			Stopped:	CONTIN	
PREPULSID (Other drug)		Rea	ason:			
	7.5	Milligram	Daily			
Batch:	Started:			Stopped:	CONTIN	
PREMARIN (Other drug)		Rea	ason:	Menopausal symptoms		
	3.0	Microgram	Daily			
Batch:	Started:			Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 126566
 Seq: 1
 Gender:
 F

 Reported:
 09/04/1998
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 31/05/1997
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

MELLERIL (Suspected)			Reason:	Specific disord	lers of sleep
Tablet	20.0 M	illigram	Daily		Oral
Batch:	Started:			Stopped:	29/08/1997
AROPAX (Suspected)			Reason:	Depression	
	10.0 Mi	illigram	Daily		
Batch:	Started:			Stopped:	30/08/1997

Laboratory Investigations:

Additional Information:

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

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Reported	: 126764	Seq	: 1				Ge	nder: M
	i: 17/04/19	998					We	ight:
spitalisation	1:							Age : 38
Onset Date) :							DOB : 12/02/1960
Outcome	: Not yet i	recovered					Caus	ality: Causality possible
action Deta	ails:							
Prefe	rred Term	Sc	everity		Repo	ort Desc	cription	Treatment
hinking abnor				Low me	ental state	€.		
isturbance in	attention			Unable	to conce	ntrate		
lallucination								Stopped all medication. diazepam 5-10mg prn oral given.
remor								
ledicine De					Rea	son:		
Altoi Ax (ouspe	icteuj		20.0	Milligram		Daily		
Batch:		ş	Started:	wiiiigiaii		Daily	Stopped:	1W
AURORIX (Susp	ected)				Rea	son:		
			300.0	Milligram	1	Daily		
Batch:		8	started:				Stopped:	1W
MELLERIL (Sus _l	pected)				Rea	son:		
			100.0	Milligram	า	Daily		
Batch:		5	Started:				Stopped:	1W
NEULACTIL (Su	spected)					son:		
			30.0	Milligram	1	Daily		
Batch:			Started:				Stopped:	1W
	Investia:	ations:						
aboratory	IIIVESLIGE		T	الما	Result			Details
aboratory	Type	Range	Date Test	iea i	Resuit			Details

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Numb	er:	126766		Seq:	1				Gend	der: F
Report	ed:	17/04/19		-					Weig	ht:
Hospitalisati									_	ge : 70
Onset Da	te:								D	OB : 06/07/1927
Outcor	ne:	Recove	red						Causal	ity: Causality possible
Reaction De	tai	ils:								
Pre	ferr	ed Term		Se	everity		Rep	ort De	escription	Treatment
Bradycardia						45 b	ppm			Ceased verapamil, nefazadone reduced to 100mg bd and melleril to 10mg bd.
Hypotension Syncope						Sys	t 60			
Medicine I										
BENZTROPIN	E MI	ESYLATE ((Other drug)					ason:		
				_	1.0	Millig	gram	As ne	ecessary	001701
Batch				Si	tarted:				Stopped:	CONTIN
RANITIDINE (tne	r arug)			200.0	N 4:11:		ason:	Gastritis&duodenitis	
Batch	:			St	300.0 tarted: 24/0	_		Daily	Stopped:	CONTIN
LITHIUM CAR	BON	IATE (Othe	er drug)				Re	ason:	Unspecified neurosis	
					500.0	Millig	gram	Daily		
Batch	:			St	tarted: 24/0)2/19	98		Stopped:	CONTIN
NEFAZODON	HY	DROCHLO	ORIDE (Susp	ected)		Re	ason:	Depression	
					400.0	Millig	gram	Daily		
Batch	:			St	tarted: 24/0)2/19	98		Stopped:	
Laborator	, In	voetia	atione:							
Date		Type	Rang	е	Date Test	ed	Result		[Details
		7.	J							
Additional	Inf	formati	on:							
	- - ·		·							

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 126766 Reported: 17/04/1 Hospitalisation: Onset Date: Outcome: Recove Reaction Details:	1998			
Medicine Details:				
VERAPAMIL HYDROCHLOF		Reason:	Essential benign hypertens	sion
	180.0 Milligram	Daily		
Batch:	Started:		Stopped: 11/03/1998	
MELLERIL (Suspected)		Reason:	Unspecified neurosis	
	30.0 Milligram	Daily		
Batch:	Started: 24/02/1998		Stopped:	
Laboratory Investig	ations:			
Additional Informat	ion:			

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 126890 Seq: 1 Gender: F

Reported: 24/04/1998 Weight: 30.00
Hospitalisation: Admitted to hospital Age: 9Y
Onset Date: 28/12/1997 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Skin disorder		Skin lesions left hand and left foot	

Medicine Details:

Medicine Details.					
MAXOLON (Suspected)		Re	eason:		
	30.0	Milligram	Daily		
Batch:	Started:	L TER	М	Stopped:	
EPILIM (Suspected)		Re	eason:		
	1.5	Gram	Daily		
Batch:	Started:	L TER	М	Stopped:	
FRISIUM (Suspected)		Re	eason:		
	45.0	Milligram	Daily		
Batch:	Started:			Stopped:	
MELLERIL (Suspected)		Re	eason:		
	25.0	Milligram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Esri negative, d.dimer negative.
	Platelets		28/12/1997	128	
	White blood cells		28/12/1997	4.4	

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Hospitalisation: Onset Date: Outcome: Reaction Detai	24/04/1998 Admitted to hospid 28/12/1997 Not yet recovered Is:				Gender: Weight: Age: DOB: Causality:	30.00 9Y
Medicine Deta				Reason:		
PREPULSID (Susp	ected)	30	0.0 Milligram	Daily		
Batch:		Started:		,	Stopped:	
Laboratory In	vestigations:					
Additional Inf	ormation:					

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 127785 Seq: 1 Gender: M
Reported: 26/05/1998 Weight:

Hospitalisation: Age: 55Y
Onset Date: 04/05/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Faecal incontinence			
Hypertonia			lv dilantin
Oculogyration			
Urinary incontinence			

Medicine Details:

MELLERIL (Suspected)
Reason:
150.0 Milligram Total

Batch: Started: 02/05/1998 **Stopped:** 03/05/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Previous reaction -rigity to phenergan.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Rei	port	Deta	ails:
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 Case Number:
 128492
 Seq: 1
 Gender:
 F

 Reported:
 18/06/1998
 Weight:

Hospitalisation: Age: 75

Onset Date: DOB: 17/10/1922

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•				
	Preferred Term	Severity	Report Description	Treatment
	Fatigue		Lethargy	Ceased thioridazine
	Dizziness		Pre-syncope	

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (S	uspected)	Reason:	Unspecified psychosis	3
	0.0			
Batch:	Started:		Stopped:	
TEMAZEPAM (Suspected)		Reason:	Specific disorders of s	sleep
	10.0 Milligram	As no	ecessary	
Batch:	Started:		Stopped:	
ATENOLOL (Suspected)		Reason:	Otr&nos disord of hea	rt rhythm
	50.0 Milligram	Daily	,	
Batch:	Started:		Stopped:	CONTIN
CARTIA (Suspected)		Reason:	Otr&nos disord of hea	rt rhythm
	100.0 Milligram	Daily	,	
Batch:	Started:		Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 02:45PM Database: pusime02 ADRS004 Page 250 of 393



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 128492 Seq: 1 Gender: F Reported: 18/06/1998 Weight: Hospitalisation: Onset Date: Outcome: Not yet recovered Causality: Causality possible Reaction Details: Medicine Details: Medicine Details: Medicine Details: Medicine Details: Started: Resson: Paranois 1.0 Milligram Daily Batch: Started: Stopped: CONTIN Laboratory Investigations: Additional Information:	Report Details	·•							
Reason: Paranoia 1.0 Milligram Daily Batch: Started: Stopped: CONTIN Laboratory Investigations:	Reported: Hospitalisation: Onset Date: Outcome:	18/06/1998 Not yet recovered	-			C	Weight: Age: DOB:	75 17/10/1922	
Reason: Paranoia 1.0 Milligram Daily Batch: Started: Stopped: CONTIN Laboratory Investigations:									
Reason: Paranoia 1.0 Milligram Daily Batch: Started: Stopped: CONTIN Laboratory Investigations:									
Batch: Started: Stopped: CONTIN Laboratory Investigations:					Passani	Daranaia			_
Laboratory Investigations:	RISPERIDONE (Sus	specied)		1.0 Milligram					
	Batch:		Started:			Stopped:		CONTIN	
Additional Information:									
	Laboratory Inv	vestigations:							

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 128782 Seq: 1 Gender: M
Reported: 24/06/1998 Weight:

Hospitalisation:
Onset Date: 10/06/1998
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Dotanoi			
Preferred Term	Severity	Report Description	Treatment
Constipation	Severe		
Urinary tract infection	Severe		Amitrptyline, thioridazine and benzotropine ceased.

Medicine Details:

RISPERDAL (Other drug)
Reason:
0.0

Batch: Started: 01/04/1998 **Stopped:** 10/06/1998

AMITRIPTYLINE HYDROCHLORIDE (Suspected) Reason:

0.0

Batch: Started: Stopped: 29/05/1998

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason:

0.0

Batch: Started: Stopped: 29/05/1998

BENZTROPINE MESYLATE (Suspected) Reason:

0.0

Batch: Started: Stopped: 29/05/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 129369
 Seq: 1
 Gender:
 F

 Reported:
 23/07/1998
 Weight:

Hospitalisation: Age: 15Y
Onset Date: 09/07/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Tongue oedema		Tongue swelling	
Fatigue			
Headache	Required Specialist Consultation		
Nausea			
Pyrexia			
Tongue ulceration			Lignocaine, chlorhexidine mouthwash, amosan.
Vomiting			

Medicine Details:

BACTRIM (Suspected)	Reason: Acute to	nsillitis
	2.0 Dose Unspecified Daily	
Batch:	Started : 09/07/1998 Stop	oped: 09/07/1998
MELLERIL (Suspected)	Reason: Unspeci	ified psychosis
Tablet	40.0 Milligram Daily	Oral
Batch:	Started: 01/06/1998 Stop	pped: 16/07/1998

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Twelve hours after starting bactrim patient developed symptoms and over next seven days suffered further symptoms. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 130635
 Seq: 1
 Gender:
 F

 Reported:
 31/08/1998
 Weight:

Hospitalisation: Age: 77Y
Onset Date: 31/03/1997
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Caction Details.		•	
Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Huge loose bowel motions	
Abdominal pain			lv fluids, iv antibiotics and inotropic infusions.
Drug ineffective			1

Medicine Details:

ADRENALINE (Interaction)		Reason:	
Injection, intravenous infusion	0.0	Intravenous	
Batch:	Started:	Stopped:	
ENDEP (Interaction)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started:	Stopped:	
MELLERIL (Interaction)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See seq 01 for other drugs. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 131107
 Seq: 1
 Gender:
 F

 Reported:
 10/09/1998
 Weight:

Hospitalisation: Age: 44Y

Onset Date: 18/05/1998 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

١,	reaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Hypoaesthesia		Numbness around the nose, mouth and cheeks	
	Pain		Pain in arms	
	Paraesthesia		Pins and needles in fingers	
	Rhinitis			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Other drug) Reason: Depression

50.0 Milligram Daily

Batch: Started: Stopped:

PARACETAMOL (Other drug) Reason: Pain

3.0 Gram Daily

Batch: Started: 15/05/1998 Stopped:

PANADEINE (Other drug) Reason: Pain

2.0 Dose Unspecified Daily

Batch: Started: 15/05/1998 Stopped:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Other disturbance of sensation

30.0 Milligram Daily

Batch: Started: 15/05/1998 **Stopped:** 17/05/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt was admitted to hospital for neck pain.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 131148
 Seq: 1
 Gender:
 F

 Reported:
 14/09/1998
 Weight:

Hospitalisation: Age: 40Y
Onset Date: 04/09/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

ы,	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Dystonia		Acute dystonic reaction	
	Confusional state			
	Dysarthria			
	Nausea			
	Visual disturbance			
	Vomiting			

Medicine Details:

VALIUM (Other drug)		Reason:	
	5.0 Milligram	As necessary	
Batch:	Started: 04/09/1998	Stopped:	
ALPRAZOLAM (Other drug)		Reason:	
	1.0 Milligram	As necessary	
Batch:	Started: 04/09/1998	Stopped:	
CITALOPRAM HYDROBROMIDE (Su	ispected)	Reason: Depression	
	10.0 Milligram	Daily	
Batch:	Started: 03/09/1998	Stopped:	06/09/1998
MELLERIL (Suspected)		Reason: Depression	
	75.0 Milligram	Daily	
Batch:	Started: 04/09/1998	Stopped:	06/09/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt admitted after episode of collapse presumed secondary to seizure. posibly benzodiazepine withdrawal

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Preferred Term Syncope Hypotension	Severity	Re Collapsed in s Severe bp dro		Pu	Treatment ut to bed and elevated ended for 30min observation.
				Pı be	It to bed and elevated end
Hypotension		Severe bp dro		~\	
		·	p		
Medicine Details: CLONAZEPAM (Other drug)	2.0	R: Milligram	eason: As necessary		
Batch:	Started: 12/		Stop	ped:	
LITHIUM CARBONATE (Other drug)			eason:		
Batch:	1.7 Started:	Gram	Daily Stop	nod:	CONTIN
TEGRETOL (Other drug)	Starteu.	R	eason:	peu.	CONTIN
	400.0	Milligram	Daily		
Batch:	Started:		Stop	ped:	CONTIN
CLOPIXOL-ACUPHASE (Suspected)	100.0	Milligram	eason: 1 time		
Batch:	Started: 12/	-	Stop	ped:	
sharatary Investigations					
_aboratory Investigations: Date Type Range	e Date Test	ted Result		Deta	ils

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:		
Case Number: 131312 Reported: 17/09/1998 Hospitalisation: Onset Date: Outcome: Recovered Reaction Details:	Seq: 1	Gender: M Weight: Age: 28 DOB: 31/05/1970 Causality: Causality possible
Medicine Details:	4. 10	
THIORIDAZINE HYDROCHLORIDE (Sus		Reason:
	100.0 Milligram	As necessary
Batch:	Started:	Stopped:
Batch:	Started:	Stopped:
Laboratory Investigations:	Started:	Stopped:
	Started:	Stopped:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 131644 Seq: 1 Gender: F

Reported: 30/09/1998 Weight:
Hospitalisation: Age: 67Y

Onset Date: 24/09/1998

Outcome: Recovered

Causality: Causality possible

Reaction Details:

1,	eaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Hypotension		Systplic	
	Syncope			Given haemacel and 4 mg haloxone

Medicine Details:

MELLERIL (Suspected) Reason: Unspecified schizophrenia

200.0 Milligram 1 time

Batch: Started: 24/09/1998 Stopped: 24/09/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt has emphysema and smokes.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 132150 Seq: 1 Gender: F

Reported: 19/10/1998 Weight:
Hospitalisation: Age: 86Y

Onset Date: 31/12/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation			

Medicine Details:

NORVASC (Suspected)			Reason:	Essential benign hypertension	
Tablet	10.0	Milligram	Daily	Oral	
Batch:	Started:	I	L TERM	Stopped:	
VISKEN (Suspected)			Reason:	Essential benign hypertension	
	5.0	Milligram	Daily		
Batch:	Started:			Stopped:	
TEMAZE (Suspected)			Reason:		
	2.0	Milligram	Daily		
Batch:	Started:			Stopped:	
MELLERIL (Suspected)			Reason:		
	10.0	Milligram	Daily		
Batch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt had slight agitation, which seems to have worsened when her dose of norvasc was increased from 5mg to 10mg. pt also has mild alzheimer's disease. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

	132150	Seq: 1				Gender:	F
Reported:	19/10/1998					Weight:	
Hospitalisation:						Age:	86Y
Onset Date:	31/12/1998					DOB:	
Outcome:	Unknown					Causality:	Causality possible
Reaction Detai	ls:						
Medicine Deta	ails:						
PROPANTHELINE	BROMIDE (Suspecte	d)		Rea	son:		
			2.0	Dose Unspecified	Daily		
Batch:		Start	ted:			Stopped:	
ASPIRIN (Suspect	ed)			Rea	son:		
			1.0	Dose Unspecified	Daily		
Batch:		Start	od.				
			.eu.			Stopped:	
			ieu.			Stopped:	
						Stopped:	
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			ieu.			Stopped:	
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Laborator, Irri			.eu.			Stopped:	
Laboratory In	vestigations:		.eu.			Stopped:	
Laboratory In	vestigations:		.eu.			Stopped:	
Laboratory In	vestigations:		.eu.			Stopped:	
Laboratory In	vestigations:		eu.			Stopped:	
Laboratory In	vestigations:		eu.			Stopped:	
Laboratory In	vestigations:		.eu.			Stopped:	
Laboratory In	vestigations:		.eu.			Stopped:	
Laboratory In	vestigations:		eu.			Stopped:	
Laboratory In			eu.			Stopped:	

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 133134
 Seq: 1
 Gender: M

 Reported:
 12/11/1998
 Weight:

Hospitalisation: Age:
Onset Date: 27/10/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Difficulty with salivation and tongue movement	
Dystonia		Dystonic reaction	Benztropine 2mg orally and reduced thioridazine to 200mg daily.

Medicine Details:

RISPERIDONE (Other drug)		Reason:	Unspecified psychosis	
Tablet	1.0 Milligram	Daily	Oral	
Batch:	Started: 23/10/1998		Stopped:	CONTIN
DIAZEPAM (Other drug)		Reason:	Anxiety neurosis	
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 24/10/1998		Stopped:	CONTIN
THIORIDAZINE HYDROCHLORIDE (Suspected)	Reason:	Unspecified psychosis	
Tablet	300.0 Milligram	Daily	Oral	
Batch:	Started: 26/10/1998		Stopped: 27/10/19	98

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	133224	Seq	: 1			Gend	der: M		
Reported:	13/11/1998	-			Weight:				
ospitalisation:						Α	ge: 44Y		
Onset Date:						D	OB:		
Outcome:	utcome: Unknown					Causal	lity: Causality possible		
eaction Detai							T		
	ed Term	Se	everity	Repo	rt Des	cription	Treatment		
ardive dyskines	ia								
a distant	- *1 -								
Medicine Detail ZOLOFT (Other dr				Reas	eon.				
ZOZOI I (Other di	ug,		0.0	rtea.	,011.				
Batch:		ş	Started:			Stopped:			
MELLERIL (Suspe	cted)			Reas	son:				
Tablet	•		0.0			Oral			
Batch:		5	Started:			Stopped:			
_aboratory In	voetinatio	ne:							
Date	Type	Range	Date Tested	Result		[Details		
	,,		1						
•	<u> </u>		<u> </u>						
Additional Inf	formation	:							
oort Run: 01/06/200	07 02:45PM	Database: p	usime02	А	DRS004	1	Page 263 of 393		



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report D	etails:
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 Case Number:
 133326
 Seq: 1
 Gender:
 F

 Reported:
 19/11/1998
 Weight:

Hospitalisation: Age: 82

Onset Date: 27/10/1998 **DOB**: 26/09/1916

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		1. 2	Pt recovered within 6 hours. supportive care only.
Consciousness fluctuating			
Hypoxia			

Medicine Details:

THYROXINE SODIUM (Other drug)			Reason:		
Tablet	50.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
ASPIRIN (Other drug)			Reason:		
	150.0	Milligram	Daily		
Batch:	Started:			Stopped:	
MELLERIL (Suspected)			Reason:		
	20.0	Milligram	Daily		
Batch:	Started: 23	/10/1998		Stopped:	27/10/1998

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Iospitalisati Onset Da Outcor	ate: ne: Unknown	Seq: 1				Gender: F Weight: Age: 6 DOB: Causality: 0		ible
eaction Do	etalis: eferred Term	Sever	itv	Ren	ort Description	1	Treatmer	nt
Cataract		23701	,					
Medicine I				Rea	son:			
			150.0 Milli	igram	Daily			
Batcl	••	Starte	м.		Stopped			
Laborator Date	y Investigatio		te Tested	Result		Details		
Date	туре	Range Da	te rested	Result		Details		
Additional	Information:							
eport Run: 01/0	6/2007 02:45PM	Database: pusim	e02	A	DRS004		Page 265	of 393



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 133931 Seq: 1 Gender: M

Reported: 03/12/1998 Weight:
Hospitalisation: Age: 24Y
Onset Date: 11/09/1998 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Rash maculo-papular		Diffuse rash on chest, face, back & upper arms	Thioridazine ceased

Medicine Details:

noalonio Botano.					
VIGABATRIN (Other drug)		Reason:	Convulsions		
Oral application	1.0 Gram	Daily	Oral		
Batch:	Started: 01/07/1998		Stopped:	CONTIN	
PHENYTOIN SODIUM (Other drug)		Reason:	Convulsions		
Oral application	360.0 Milligram	Daily	Oral		
Batch:	Started: 26/06/1998		Stopped:	CONTIN	
RISPERIDONE (Other drug)		Reason:	Unspecified psychosi	S	
Oral application	6.0 Milligram	Daily	Oral		
Batch:	Started: 18/08/1998		Stopped:	CONTIN	
THIORIDAZINE HYDROCHLORIDE (Sus	pected)	Reason:	Unspecified psychosi	S	
Oral application	50.0 Milligram	As ne	cessary Oral		
Batch:	Started: 31/08/1998		Stopped: 11/09	/1998	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

P/h of allergy to seafood. ate crab on 10/09/98. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Ren	ort	Deta	ils:
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 Case Number:
 134562
 Seq: 1
 Gender: M

 Reported:
 21/12/1998
 Weight:

Hospitalisation: Age: 47

Onset Date: 06/11/1998 **DOB:** 02/09/1951

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonic reaction, stiff jaw and tongue.	Berztropine 2mg oral given.

Medicine Details:

ISOSORBIDE MONONITRATE (Other drug)			Reason:	Angina pectoris w/o hyperten	
	60.0	Milligram	Daily		
Batch:	Started:			Stopped:	CONTIN
METFORMIN HYDROCHLORIDE (Other dru	ıg)		Reason:	Diabetes mellitus	
	500.0	Milligram	Daily		
Batch:	Started:			Stopped:	CONTIN
GLICLAZIDE (Other drug)			Reason:	Diabetes mellitus	
	80.0	Milligram	Daily		
Batch:	Started:			Stopped:	CONTIN
ASPIRIN (Other drug)			Reason:	Prophylaxis	
	150.0	Milligram	Daily		
Batch:	Started:			Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Run: 01/06/2007 02:45PM Database: pusime02 ADRS004 Page 267 of 393



Report Details:

Case Number: 134562

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Outcome: Recovered Causality: Causal action Details: Bedicine Details: COLOXYL (Other drug) 4.0 Dose Unspecified Daily Batch: Started: Stopped: COLOXYL (Other drug) Reason: Depression 20.0 Milligram Daily Batch: Started: Stopped: COLOXYL (Other drug) Reason: Depression 20.0 Milligram Daily Reason: Othr&unspec metabolic diseases 40.0 Milligram Daily	Reason: Constipation cified Daily Stopped: CONTIN Reason: Depression Daily Stopped: CONTIN Reason: Othr&unspec metabolic diseases Daily Othr&unspec metabolic diseases
Outcome: Recovered Causality: Causal action Details: Causality: Causal action Details: Causality: Causal action Details: Causality: Causal action Details: Causality: Causal action Details: Causality: Causality: Causal action Details: Causality: Causality: Causal action Details: Causality:	Reason: Constipation cified Daily Stopped: CONTIN Reason: Daily Stopped: CONTIN Reason: Daily Stopped: CONTIN Reason: Daily Stopped: CONTIN Reason: CONTIN Stopped: CONTIN
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COLOXYL (Other drug) 4.0 Dose Unspecified Daily Batch: Started: Stopped: COLOXYL (Other drug) PAROXETINE HYDROCHLORIDE (Other drug) Batch: Started: Daily Batch: Started: Stopped: COLOXIDE (Other drug) Batch: Started: Stopped: COLOXIDE (Other drug) Reason: Othr&unspec metabolic diseases 40.0 Milligram Daily	Stopped: CONTIN Reason: Depression Daily Stopped: CONTIN Reason: Othr&unspec metabolic diseases Daily Stopped: CONTIN
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PAROXETINE HYDROCHLORIDE (Other drug) 20.0 Milligram Daily Batch: Started: Stopped: COI SIMVASTATIN (Other drug) Reason: Depression COI Stopped: COI Reason: Othr&unspec metabolic diseases 40.0 Milligram Daily	Reason: Depression Daily Stopped: CONTIN Reason: Othr&unspec metabolic diseases Daily Stopped: CONTIN
Batch: Started: Stopped: COI SIMVASTATIN (Other drug) Reason: Othr&unspec metabolic diseases 40.0 Milligram Daily	Daily Stopped: CONTIN Reason: Othr&unspec metabolic diseases Daily Stopped: CONTIN
Batch: Started: Stopped: COI SIMVASTATIN (Other drug) Reason: Othr&unspec metabolic diseases 40.0 Milligram Daily	Stopped: CONTIN Reason: Othr&unspec metabolic diseases Daily Stopped: CONTIN
SIMVASTATIN (Other drug) Reason: Othr&unspec metabolic diseases 40.0 Milligram Daily	Reason: Othr&unspec metabolic diseases Daily Stopped: CONTIN
40.0 Milligram Daily	Daily Stopped: CONTIN
	Stopped: CONTIN
Batch: Started: Stopped: COI	
	Reason: Depression
300.0 Milligram Daily	
Batch: Started: Stopped: COI	Stopped: CONTIN

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Gender: F Case Number: 134981 Seq: 1

Weight: Reported: 06/01/1999 Hospitalisation: **Age:** 43

Onset Date: DOB: 28/05/1955 Outcome: Unknown Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pharyngitis			

Medicine Details:

MELLERIL (Suspected) Reason: Schizophrenia Tablet 50.0 Milligram Daily Oral Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient developed symptoms after melleril treatment was started. melleril was discontinued and symptoms resolved. rechallenged with melleril and same symptoms occurred.

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Report Details:

Case Number: 135196

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Reported: 18/01/1	999	Weight:							
lospitalisation:		Age:							
Onset Date:		DOB: Causality: Causality possible							
Outcome: Unknow	/n								
eaction Details:		,							
Preferred Term	Se	everity	Repo	rt Descri	ption	Treatmer	nt		
Fatigue									
Somnolence									
Medicine Details: MELLERIL (Suspected)			Reas	on: An	kiety neurosis				
Oral application		75.0 Milli		Daily	Oral				
Batch:	ç	started: 05/01/19		_ uy	Stopped:				
Laboratory Investig		15 1							
Date Type	Range	Date Tested	Result		Det	ails			
Additional Informati	on:								
eport Run: 01/06/2007 02:45	PM Database: p	usime02	A	DRS004		Page 270	of 393		



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 135371
 Seq: 1
 Gender: M

 Reported:
 28/01/1999
 Weight:

Hospitalisation:
Onset Date:

Onset Date:

Onset Date:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

MELLERIL (Suspected) Reason: Anxiety neurosis

Tablet 50.0 Milligram Daily Oral

Batch: Started: 01/10/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Reported: 2 spitalisation: Onset Date: Outcome: U	28/01/1999		: 1			`	Gender	
Onset Date: Outcome:						V	Veight:	
Outcome: \							_	: AD
							DOB	
						Ca	usality	: Causality possible
<u>action Details</u>				<u> </u>				
Preferred	J Term	Se	everity		eport De			Treatment
Salactorrhoea				Galactorrhoe medicat.	ea about 1	year after star	ting Is	planned to discontinue elleril.
ledicine Detai			0.0		Reason:			
Batch:		s	o.o started:			Stopped:		
VENLAFAXINE HYD	ROCHLORIDE (Reason:	otoppou.		
	`		0.0					
Batch:		s	tarted:			Stopped:		
MELLERIL (Suspect	ed)				Reason:	Unspecified sch	izophreni	a
Tablet			400.0	Milligram	Daily	(Oral	
Batch:		S	started:			Stopped:		1Y
.aboratory Inv		S: Range	Date Teste	ed Result			Deta	ails

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 135467
 Seq: 1
 Gender: F

 Reported:
 29/01/1999
 Weight:

Hospitalisation: Age: 50Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Chest pain		Burning sensation in chest.	
Depersonalisation		Feeling strange.	
Hypertonia		Stiffness in limbs.	
Agitation			Was given nitrazepam.
Hyperreflexia			
Nausea			

Medicine Details:

<u>wiedicine Details:</u>				
TRYPTANOL (Interaction)		Reason: Depre	ssion	
Tablet	10.0 Milligram	Daily	Oral	
Batch:	Started:	St	opped:	
THIORIDAZINE HYDROCHLORIDE	(Interaction)	Reason: Unspe	cified psychosis	
Tablet	30.0 Milligram	Daily	Oral	
Batch:	Started:	St	opped:	
NEFAZODONE HYDROCHLORIDE	(Interaction)	Reason:		
Tablet	0.0	Daily	Oral	
Batch:	Started:	St	opped:	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

Medical journal of australia 1998, 169(10), 523-525. no washout period. heart rate of 70 bpm and blood pressure of 112/62 mmhg.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 136630
 Seq: 1
 Gender: M

 Reported:
 24/02/1999
 Weight:

Hospitalisation: Age: 28Y
Onset Date: 30/01/1999
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Muscular spasm in jaw and top of arms.	

Medicine Details:

Medicine Details.					
LUVOX (Suspected)		Reason:	Depression		
Tablet	100.0 Milligram	Daily		Oral	
Batch:	Started: 28/01/1999		Stopped:		CONTIN
ALDAZINE (Suspected)		Reason:	Otr spec symp	psychopathol n	ec
Tablet	50.0 Milligram	Daily		Oral	
Batch:	Started: 27/01/1999		Stopped:	17/02/1999	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 136880 Seq: 1 Gender: M

Reported: 02/03/1999 Weight: 48.00 Hospitalisation: Age: 76Y

Onset Date: 10/02/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia			Melleril ceased.

Medicine Details:

MELLERIL (Suspected) Reason:

0.0

Batch: Started: 01/01/1998 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Gp had put patient on melleril late last year & notice acute decrease in wcc. recovered to low (n) when medication was ceased. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls	:
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 Case Number:
 137297
 Seq: 1
 Gender: M

 Reported:
 16/03/1999
 Weight:

Hospitalisation: Age: 54Y
Onset Date: 18/01/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Botans.			
	Preferred Term	Severity	Report Description	Treatment
	Hepatitis	Severe		
	Prothrombin level decreased			

Medicine Details:

THEO-DUR (Other drug)		Rea	son:	Asthma	
	400.0	Milligram	Daily		
Batch:	Started:	L TERM		Stopped:	CONTIN
BECLOFORTE (Other drug)		Rea	son:	Asthma	
	500.0	Microgram	Daily		
Batch:	Started:	L TERM		Stopped:	
SALBUTAMOL (Other drug)		Rea	son:	Asthma	
SALBUTAMOL (Other drug)	2.0	Rea Dose Unspecified		Asthma	
SALBUTAMOL (Other drug) Batch:	2.0 Started:		Daily	Asthma Stopped:	
		Dose Unspecified L TERM	Daily		
Batch:	Started:	Dose Unspecified L TERM	Daily	Stopped:	

Laboratory Investigations:

<u> </u>	i ji iii tootiga				
Date	Туре	Range	Date Tested	Result	Details
	Biochemistry				Peak prothrombin time 21secs., peak alt 3504u/l, bilirubin 171mmol/l, minimal albumin 27g/l.

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1	C	Weight: Age: DOB:	54Y
	Reason: Depression		
20.0 Milligram	Daily	25/01/1000	
		Reason: Depression 20.0 Milligram Daily	Weight: Age: DOB: Causality: Reason: Depression 20.0 Milligram Daily

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 137717
 Seq: 1
 Gender: M

 Reported:
 23/03/1999
 Weight:
 71.00

 Hospitalisation:
 Age: 38Y

Onset Date: 05/03/1999 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		trunk.	10mg oral phenergan on 6.3.99 & 25mg oral phenergan on 8.3.99.
Pruritus		Ranged from 0.5 - 2cm in size.	

Medicine Details:

MELLERIL (Suspected)		Reason:	Otr spec symp	psychopathol nec
Tablet	50.0 Milligram	Daily		Oral
Batch:	Started: 04/03/1999		Stopped:	09/03/1999
EFEXOR (Suspected)		Reason:	Depression	
Tablet	225.0 Milligram	Daily		Oral
Batch:	Started: 17/02/1999		Stopped:	09/03/1999
INDOCID (Suspected)		Reason:	Pain	
Capsule	75.0 Milligram	Daily		Oral
Batch:	Started: 04/03/1999		Stopped:	09/03/1999
VALIUM (Suspected)		Reason:	Otr spec symp	psychopathol nec
Tablet	15.0 Milligram	Daily		Oral
Batch:	Started: 04/03/1999		Stopped:	09/03/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - hypnovel & temaze. macules were very erythematous prurtic & blanched with pressure but were not painful. they ranged from 0.5 - 2cm in size. history: fits on stelazine.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Detail	s:				
Case Number: Reported: Hospitalisation:	137717 23/03/1999	Seq: 1		Gender: Weight: Age:	71.00
Onset Date:				DOB:	
Outcome: Reaction Detai	Not yet recovered Is:			Causality:	Causality possible
Medicine Det	ails:				
MAXOLON (Suspe			Reason: Nausea	and vomiting	
Tablet		10.0 Gram	Daily	Oral	
Batch:		Started : 04/03/1999	Stop	ped: 06/03/1999	
Laboratory In	vestigations:				
Additional Inf					
See original report but were not painfu	for other drug detail II. they ranged from	s - hypnovel & temaze. mac 0.5 - 2cm in size. history:	cules were very eryth fits on stelazine.	nematous prurtio	c & blanched with pressure

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 137792 Seq: 1 Gender: M
Reported: 26/03/1999 Weight:
Hospitalisation: Age: 26Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Delusion		Grandiose delusions.	
Mania			Ceased olanzapine. instituted lithicarb (now 750mg bd).
Nervousness			

Medicine Details:

neulcine Delans.			
MELLERIL (Suspected)		Reason: Disturbance of sleep	
	100.0 Milligram	As necessary	
Batch:	Started: 29/01/1999	Stopped:	
DIAZEPAM (Suspected)		Reason: Disturbance of sleep	
	10.0 Milligram	As necessary	
Batch:	Started: 29/01/1999	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
	10.0 Milligram	Daily	
Batch:	Started: 27/01/1999	Stopped : 02/02/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - clopixol depot.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 138165 Seq: 1 Gender: F

Reported: 07/04/1999 Weight:
Hospitalisation: Age: 45Y

Onset Date: 18/02/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema		Swollen ankles	

Medicine Details:

MELLERIL (Suspected) Reason: Anxiety neurosis

150.0 Milligram Daily

Batch: Started: 04/02/1999 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drugs - cipramil, epilim, propranolol

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Rep	ort	Deta	ails:
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 Case Number:
 138933
 Seq: 1
 Gender:
 F

 Reported:
 30/04/1999
 Weight:

Hospitalisation: Admitted to hospital Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	104011011 20141101			
	Preferred Term	Severity	Report Description	Treatment
	Urticaria			Melleril ceased & treated with antihistamine.

Medicine Details:

MELLERIL (Suspected)		Reason:		
Oral application	0.0	Daily	Oral	
Batch:	Started:	Sto	pped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Allergy to sulphur

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 140458 Seq: 1 Gender: M

 Reported:
 15/06/1999
 Weight:
 57.00

 Hospitalisation:
 Age:
 84Y

 Onset Date:
 04/06/1999
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Ceased allopurinal, fgf, thioridazine.

Medicine Details:

ALLOPURINOL (Suspected)		Rea	ason:		
Oral application	100.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
F.G.F. (Suspected)		Rea	ason:		
Oral application	1.0	Dose Unspecified	Daily		Oral
Batch:	Started:			Stopped:	
THIORIDAZINE HYDROCHLORIDE (Suspected)	Rea	ason:		
	10.0	Milligram	Daily		
Batch:	Started: 02	/06/1999		Stopped:	03/06/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		01/06/1999	24	
	ALT = SGPT		05/06/1999	917	
	ALT = SGPT		06/06/1999	852	
	AST = SGOT		01/06/1999	19	
	AST = SGOT		05/06/1999	607	
	AST = SGOT		06/06/1999	461	
	Bilirubin		01/06/1999	14	

Additional Information:

See original report for other drug details: lasix, slow-k, digoxin, aspirin, & maxolon.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 140458 Seq: 1 Gender: M

Reported: 15/06/1999

Hospitalisation:

Age: 84Y

Onset Date: 04/06/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ALLOPURINOL (Suspected)		Re	eason:		
Oral application	100.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
F.G.F. (Suspected)		Re	eason:		
Oral application	1.0	Dose Unspecifie	d Daily		Oral
Batch:	Started:			Stopped:	
THIORIDAZINE HYDROCHLORIDE (Suspected)	Re	eason:		
	10.0	Milligram	Daily		
Batch:	Started: 02	/06/1999		Stopped:	03/06/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Bilirubin		05/06/1999	20	
	Bilirubin		06/06/1999	21	
	GGT = SGGT =		01/06/1999	62	
	GGT = SGGT =		05/06/1999	111	
	GGT = SGGT =		06/06/1999	123	
	SAP = ALP		01/06/1999	102	
	SAP = ALP		05/06/1999	127	

Additional Information:

See original report for other drug details: lasix, slow-k, digoxin, aspirin, & maxolon.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 140458 Seq: 1 Gender: M

 Reported:
 15/06/1999
 Weight:
 57.00

 Hospitalisation:
 Age:
 84Y

 Onset Date:
 04/06/1999
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ALLOPURINOL (Suspected)		Rea	son:		
Oral application	100.0	Milligram	Daily		Oral
Batch:	Started:			Stopped:	
F.G.F. (Suspected)		Rea	son:		
Oral application	1.0	Dose Unspecified	Daily		Oral
Batch:	Started:			Stopped:	
THIORIDAZINE HYDROCHLORIDE (Suspected)	Rea	son:		
	10.0	Milligram	Daily		
Batch:	Started: 02	/06/1999		Stopped:	03/06/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	SAP = ALP		06/06/1999	131	

Additional Information:

See original report for other drug details: lasix, slow-k, digoxin, aspirin, & maxolon.

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Report Details:

Case Number: 140545

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Reported: 11/06/1999		Weight:				
lospitalisation:		Age:				
Onset Date:			DO	B:		
Outcome: Unknown			Causalit	y: Causality possible		
eaction Details:						
Preferred Term	Severity	Report De	escription	Treatment		
Hypertonia		Stiffness				
Blood creatine phosphokinase in	ncr					
Medicine Details: MELLERIL (Suspected)		Reason:	Unspecified psychosis			
Tablet	0.0		Oral			
Batch:	Started:		Stopped:			
Laboratory Investigation	s:					
	Range Date Test	ed Result	De	etails		
Additional Information:	1					
eport Run:01/06/2007 02:46PM D	atabase: pusime02	ADRSO	004	Page 286 of 393		



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 140655 Seq: 1 Gender: F

Reported: 18/06/1999 Weight:
Hospitalisation: Age: 29Y

Onset Date: 23/05/1999 **DOB**:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Rash on most of body	Betamethasone.

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason:

300.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details: temazepam, diazepam, & prochlorperazine.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 141434
 Seq: 1
 Gender: U

 Reported:
 12/07/1999
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 27/06/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	<u> </u>			
	Preferred Term	Severity	Report Description	Treatment
	Dystonia			Treated with bentropine 2mg oral with good effect.

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspec	ted)	Reason:	
Tablet	100.0 Milligram	1 time	Oral
Batch:	Started: 25/06/1999	Stopped	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection	150.0 Milligram	1 time	Intramuscular

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Please see original report for details of other drugs - diazepam, thioridazine

Report Run: 01/06/2007 02:46PM Database: pusime02 ADRS004 Page 288 of 393



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	142126	Seq: 1		Gend	er: F		
	29/07/1999	•	Weight:				
spitalisation:				_	ge:		
Onset Date:			DOB:				
Outcome:	Unknown			Causali	ty: Causality poss	ible	
action Detai							
Preferre	ed Term	Severity	Repoi	t Description	Treatmen		
ypertonia			Could not move, very minutes.	was frozen for about 20	Treated with injectio unspecified drug.	n of an	
edicine Deta			Reas	•			
Tablet Batch :		0.0 Started:		Oral Stopped:			
aboratory In	vestigations Type R	ange Date Test	ed Result		etails		
Date	туре К	ange Date rest	eu Resuit		retails		
dditional Inf	ormation:						
ort Run: 01/06/200	7 02:46PM Da	tabase: pusime02	AE	PRS004	Page 289	of 393	



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

erity Repo Suspected panci	Weight: Age: DOB: Causality: Causality possible ort Description Treatment creatitis
	DOB: Causality: Causality possible ort Description Treatment
	Causality: Causality possible ort Description Treatment
	ort Description Treatment
Suspected panci	creatitis
	son: Unspecified schizophrenia
	Oral
rted:	Stopped:
Data Tastad Pagult	Details
Date rested Result	Details
	O.0 Ted: Date Tested Result

Rep



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 142637 Seq: 1 Gender: M
Reported: 13/08/1999 Weight:

Reported: 13/08/1999 Weight:
Hospitalisation: Age: A5

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			

Medicine Details:

 MELLERIL (Suspected)
 Reason:
 Unspecified psychosis

 Tablet
 600.0
 Milligram
 Daily
 Oral

 Batch:
 Started:
 L TERM
 Stopped:
 CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms disappeared when dose was reduced to 200mg daily and did not return when dose was increased to 400mg daily. at the time of reaction the patient was also being ivestigated for kidney and prostate problems.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Reported	: 142695	Seq: 1				Gender:	F
	: 16/08/19	199				Weight:	
ospitalisation:						Age:	82Y
Onset Date	: 23/07/19	99				DOB:	
Outcome:	: Unknowr	า				Causality:	Causality possible
action Deta	ails:						
Prefer	red Term	Seve	rity	Repo	rt Descriptio	า	Treatment
lyperkinesia				peractive			
lyperkinesia			Re	stlessness			
gitation							
erebrovascula	<u>r disorder</u>	<u> </u>					
ladiaina Da	toilor						
ledicine De				Reas	on:		
			0.0				
Batch:		Start	ed:		Stop	ped:	
ZANTAC (Other o	drug)			Reas	on:		
			0.0				
Batch:		Start	ed:			ped:	
KEFLEX (Suspec	ted)			Reas	on: Othr dis	eases of urinary tra	act
			0.0		0.4		
Batch:	(0	Start	ea:			ped:	1
TRIMETHOPRIM	(Suspected)		0.0	Reas	on: Othrais	eases of urinary tra	act
		Start			Stor	ped:	
Ratch:		Start	eu.		Stop	peu.	
Batch:						-	
Batch: aboratory l	nvestiga _{Type}	itions:	ate Tested	Result		Detail	

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 1 Reported: 1 Hospitalisation: Onset Date: 2 Outcome: U Reaction Details	6/08/1999 23/07/1999 Jnknown 5:	Seq: 1			Gender: Weight: Age: DOB: ausality:	82Y
Medicine Detai			Reason:	Unspecified ps	evchoeie	
Tablet	ou,	30.0 Milligram	Daily	Onopcomed pe	Oral	
Batch:		Started : 20/07/1999	,	Stopped:	04/08/1999	r
Laboratory Inv	estigations:					
Additional Info	rmation:					

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 142702
 Seq: 1
 Gender:
 F

 Reported:
 16/08/1999
 Weight:

Hospitalisation: Admitted to hospital Age:

Onset Date: 31/12/1999 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Infection		Chest infection	

Medicine Details:

MELLERIL (Suspected) Reason: Anxiety neurosis

Tablet 10.0 Milligram Daily Oral

Batch: **Started**: 01/01/1999 **Stopped**: 5D

Laboratory Investigations:

Date	Туре	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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 142893
 Seq: 1
 Gender: M

 Reported:
 23/08/1999
 Weight:

Hospitalisation: Age: 26

Onset Date: 18/07/1999 **DOB**: 17/12/1972

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Dystonia			Treated with cogentin 2mg orally.
Agitation		Motor restlessness	

Medicine Details:

ZUCLOPENTHIXOL DECANOATE (Suspected)	Reason:	
	200.0 Milligram	Weekly	
Batch:	Started: 12/07/1999	Stopped:	CONTIN
THIORIDAZINE HYDROCHLORIDE	(Suspected)	Reason:	
	50.0 Milligram	As necessary	
Batch:	Started: 16/07/1999	Stopped:	CONTIN
DROPERIDOL (Suspected)		Reason:	
	5.0 Milligram	As necessary	
Batch:	Started: 16/07/1999	Stopped:	CONTIN
DIAZEPAM (Suspected)		Reason:	
	5.0 Milligram	As necessary	
Batch:	Started: 16/07/1999	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reduced thioridazine dose to maximum 600mg/d,

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Hospitalisation: Onset Date:	23/08/1999 18/07/1999 Not yet recovered	Seq: 1		
Medicine Deta				
COGENTIN (Suspe	ected)	0.5 Milligram	Reason: As necessary	
Batch:		Started: 16/07/1999	Stopped:	CONTIN
Laboratory In	vestigations:			
Additional Inf Reduced thioridazi	f ormation: ne dose to maximun	n 600mg/d,		

Report Run: 01/06/2007 02:46PM Database: pusime02 ADRS004 Page 296 of 393



Case Number: 143114

Reported: 27/08/1999

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Weight:

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Outcome: Not yet recovered Causality: Causality possible action Details: Preferred Term Severity Report Description Treatment gitation Somnia ospitalisatio	on: ate: 21/07/199	ıΩ					Age: DOB:			
Preferred Term Severity Report Description Treatment pitation somnia Bedicine Details: HIORIDAZINE HYDROCHLORIDE (Suspected) Batch: Started: Started: 19/07/1999 Batch: Started: Paralysis agitans Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: CONTIN DIANZAPINE (Suspected) Reason: Unspecified schizophrenia Tablet 5.0 Milligram Daily Oral Batch: Started: 20/07/1999 Stopped: CONTIN							c			ible
Preferred Term Severity Report Description Treatment gitation somnia Column			22.0.00				J		caccanty pool	
edicine Details: HIORIDAZINE HYDROCHLORIDE (Suspected) Batch: Started: Stopped: 19/07/1999 SINEMET (Suspected) Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: CONTIN DLANZAPINE (Suspected) Reason: Unspecified schizophrenia Tablet 5.0 Milligram Daily Oral Batch: Started: Stopped: CONTIN			S	everity	Repo	ort De	scription		Treatmer	nt
edicine Details: HIORIDAZINE HYDROCHLORIDE (Suspected) 0.0 Batch: Started: Stopped: 19/07/1999 BiNEMET (Suspected) Reason: Paralysis agitans Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: CONTIN DLANZAPINE (Suspected) Reason: Unspecified schizophrenia Tablet 5.0 Milligram Daily Oral Batch: Started: 20/07/1999 Stopped: CONTIN	gitation			_			•			
Batch: Started: Stopped: 19/07/1999 INEMET (Suspected) Reason: Paralysis agitans Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: CONTIN PLANZAPINE (Suspected) Reason: Unspecified schizophrenia Tablet 5.0 Milligram Daily Oral Batch: Started: 20/07/1999 Stopped: CONTIN	somnia									
Reason:										
Reason: O.0 Batch: Started: Stopped: 19/07/1999 Sinemet (Suspected) Reason: Paralysis agitans Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: CONTIN										
Reason: O.0 Batch: Started: Stopped: 19/07/1999 Sinemet (Suspected) Reason: Paralysis agitans Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: CONTIN										
Reason: O.0 Batch: Started: Stopped: 19/07/1999 Sinemet (Suspected) Reason: Paralysis agitans Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: CONTIN										
Reason:										
HIORIDAZINE HYDROCHLORIDE (Suspected) 0.0 Batch: Started: Stopped: 19/07/1999 Sinemet (Suspected) Reason: Paralysis agitans Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: CONTIN										
Reason: O.0 Batch: Started: Stopped: 19/07/1999										
Reason: O.0 Batch: Started: Stopped: 19/07/1999 Sinemet (Suspected) Reason: Paralysis agitans Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: CONTIN										
Batch: Started: Stopped: 19/07/1999 SINEMET (Suspected) Reason: Paralysis agitans Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: CONTIN DLANZAPINE (Suspected) Reason: Unspecified schizophrenia Tablet 5.0 Milligram Daily Oral Batch: Started: 20/07/1999 Stopped: CONTIN										
Batch: Started: Stopped: 19/07/1999 BINEMET (Suspected) Reason: Paralysis agitans Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: CONTIN DLANZAPINE (Suspected) Reason: Unspecified schizophrenia Tablet 5.0 Milligram Daily Oral Batch: Started: 20/07/1999 Stopped: CONTIN	HIORIDAZINI	E HYDROCHLOR	IDE (Suspecte		Rea	son:				
Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: CONTIN DLANZAPINE (Suspected) Reason: Unspecified schizophrenia Tablet 5.0 Milligram Daily Oral Batch: Started: 20/07/1999 Stopped: CONTIN	D-4-1		,				04	40/07/4000		
Tablet 3.0 Dose Unspecified Daily Oral Batch: Started: Stopped: CONTIN CLANZAPINE (Suspected) Reason: Unspecified schizophrenia Tablet 5.0 Milligram Daily Oral Batch: Started: 20/07/1999 Stopped: CONTIN CANTINE (Suspected) CONTIN			-	Started:	Pos	con:			9	
Batch: Started: Stopped: CONTIN CLANZAPINE (Suspected) Reason: Unspecified schizophrenia Tablet 5.0 Milligram Daily Oral Batch: Started: 20/07/1999 Stopped: CONTIN CONTIN				3.0 Dos			raialysis aylla			
Tablet 5.0 Milligram Daily Oral Batch: Started: 20/07/1999 Stopped: CONTIN			•		ie Orispecineu	Daily	Stopped:	Olai	CONTIN	
Tablet 5.0 Milligram Daily Oral Batch: Started: 20/07/1999 Stopped: CONTIN aboratory Investigations:				, tui toui	Rea	son:		hizophrenia		
Batch: Started: 20/07/1999 Stopped: CONTIN aboratory Investigations:				5.0 Mill	igram	Daily	•			
	Batch	1:	5				Stopped:		CONTIN	
	ob ovotow	v lovesticat	ionor							
				Date Tested	Result			Detai	ls	
		1,712								
				•						
	dditional	Information	n:							
dditional Information:										
dditional Information:										
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dditional Information:	ort Run: 01/0	6/2007 02:46PN	l Database: p	ousime02	A	DRS00	04		Page 297	of 39
			F		•				. age 201	0, 00



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

eport Det	tails:								
	er: 144206	Seq:	1				Gende		
-	ed: 29/09/1999	}					Weight		
spitalisatio							Age		
	ite: 31/08/1999)					DOE		
	ne: Unknown					C	Causality	/ : Causa	ality possible
action De									
	ferred Term	Sev	verity	Rep	ort Desc	ription		•	Treatment
yperhidrosis	3								
la diaina F	Notaila.								
	Details: NE HYDROCHLOR	IDE (Other drug	3)	Rea	son:				
		IDE (Other drug	g) 0.0	Rea	son:				
	NE HYDROCHLOR			Rea	son:	Stopped:			
AMITRIPTYLIN Batch	NE HYDROCHLOR		0.0		son:	Stopped:			
AMITRIPTYLIN Batch	NE HYDROCHLOR		0.0			Stopped:			
AMITRIPTYLIN Batch	NE HYDROCHLOR :: E (Other drug)	Sta	0.0 arted:			Stopped:			
AMITRIPTYLIN Batch OMEPRAZOLI Batch	NE HYDROCHLOR :: E (Other drug) ::	Sta	0.0 earted:	Rea					
AMITRIPTYLIN Batch OMEPRAZOLI Batch	NE HYDROCHLOR :: E (Other drug) ::	Sta	0.0 earted:	Rea	son:				
AMITRIPTYLIN Batch OMEPRAZOLI Batch	NE HYDROCHLOR :: E (Other drug) :: Other drug)	Sta Sta	0.0 arted: 0.0 arted:	Rea	son:				
AMITRIPTYLIN Batch OMEPRAZOLI Batch CISAPRIDE (C	NE HYDROCHLOR :: E (Other drug) :: Other drug)	Sta Sta	0.0 arted: 0.0 arted: 0.0	Rea Rea	son:	Stopped:			
AMITRIPTYLIN Batch OMEPRAZOLI Batch CISAPRIDE (C	NE HYDROCHLOR I: E (Other drug) I: Other drug) I: Uspected)	Sta Sta	0.0 arted: 0.0 arted: 0.0	Rea Rea Rea	son:	Stopped:			
Batch OMEPRAZOLI Batch CISAPRIDE (C	NE HYDROCHLOR I: E (Other drug) I: Other drug) I: Uspected)	Sta Sta	0.0 arted: 0.0 arted: 0.0 arted:	Rea Rea gram	son: son: U	Stopped:	sychosis	CC	ONTIN
Batch OMEPRAZOLI Batch CISAPRIDE (C Batch MELLERIL (Su Tablet Batch	NE HYDROCHLOR Control Contro	Sta Sta Sta	0.0 arted: 0.0 arted: 0.0 arted: 50.0 Millig	Rea Rea gram	son: son: U	Stopped: Stopped:	sychosis	CC	DNTIN
Batch OMEPRAZOLI Batch CISAPRIDE (C Batch MELLERIL (Su Tablet Batch	NE HYDROCHLOR I: E (Other drug) I: Other drug) I: Uspected)	Sta Sta Sta	0.0 arted: 0.0 arted: 0.0 arted: 50.0 Millig	Rea Rea gram	son: son: U	Stopped: Stopped:	sychosis Oral	CC	DNTIN

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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 144225
 Seq: 1
 Gender: M

 Reported:
 30/09/1999
 Weight:

Hospitalisation: Age: 71

Onset Date: **DOB**: 24/12/1927

Outcome: Recovered Causality: Causality possible

Reaction Details:

•	todotion Botano.				
	Preferred Term	Preferred Term Severity Report Description			
	Renal failure acute		Acute on chronic renal failure.		
	Constipation			Hydration, laxatives. melleril & modecate ceased.	

Medicine Details:

MODECATE (Suspected)			Reason:	Unspecified so	hizophrenia
Injection	50.0	Milligram	Month	nly	Intramuscular
Batch:	Started:	LT	ERM	Stopped:	17/08/1999
STELAZINE (Suspected)			Reason:	Unspecified so	hizophrenia
Tablet	20.0	Milligram	Daily		Oral
Batch:	Started:	LT	ERM	Stopped:	
MELLERIL (Suspected)			Reason:	Unspecified so	hizophrenia
Tablet	400.0	Milligram	Daily		Oral
Batch:	Started:	LT	ERM	Stopped:	17/08/1999
OLANZAPINE (Suspected)			Reason:	Unspecified so	hizophrenia
T-1-1-4		Milliarom	Daily		Oral
Tablet	5.0	Milligram	Daily		Orai

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:					
Case Number: 144225 Reported: 30/09/1999 Hospitalisation: Onset Date: Outcome: Recovered Reaction Details:	Seq: 1				
Medicine Details: COGENTIN (Suspected)			Reason:	Unspecified schizophrenia	
Tablet Batch:	2.0 Started:	Milligram	Daily TERM	Oral Stopped :	
Laboratory Investigations:					
Additional Information:					

Report Run: 01/06/2007 02:46PM Database: pusime02 ADRS004 Page 300 of 393



Case Number: 144266

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: U

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

ospitalisatio Onset Dat		99			Wei	ght: 100.00
Onset Dat	n:					Age:
	te: 23/09/199	99			[OOB:
	e: Unknown				Causa	ality: Causality possible
action De						T
	erred Term	Se	everity	Repo	ort Description	Treatment
lydriasis						
omnolence rinary retenti						
ledicine D						
COGENTIN (Su	spected)			Rea	son:	
			0.0			
Batch:		S	tarted:		Stopped:	
MELLERIL (Sus	spected)			Rea	son:	
			0.0			
Batch:		S	tarted:		Stopped:	
ahoratory	Investigat					Details
Date	Type	Range	Date Tested	Result		Details

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	144713	Seq: 1			Gen	ider: F		
Reported:	18/10/1999	-			Wei	Veight:		
ospitalisation:	Admitted to	hospital		Age: 76Y				
Onset Date:						OOB:		
Outcome:	Unknown				Causa	ality: Causality possible		
action Detai								
	ed Term	Severity		Report De	escription	Treatment		
oma								
yponatraemia								
ladiaina Dat	oilo							
edicine Det				Reason:				
ir Exort XII (odo)	,cotou,	75 () Milligram		,			
Batch:		Started:	9.	24)	Stopped:			
MELLERIL (Suspe	cted)			Reason:	20066200			
	,	50.() Milligram		,			
Batch:		Started:	J	,	Stopped:			
	41 41							
aboratory In	Type	NS: Range Date Te	eted E	Result		Details		
Date	Туре	Nange Date re	sied i	Count		Details		
I								
dditional Inf	ormation							
aaitionai iii	o mado m	ı						
ort Dun . 04/00/00	7 00.40084	Databases =========		ADDOC	004	D 000 (000		
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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 145559
 Seq: 1
 Gender: M

 Reported:
 09/11/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 83Y
Onset Date: 22/08/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal failure acute			Admitted to hospital

Medicine Details:

GLYCERYL TRINITRATE (Suspected)		Rea	son:	Unspecified so	chizophrenia
	1.0	Dose Unspecified	1 time)	
Batch:	Started:	L TERM		Stopped:	22/08/1998
DIGOXIN (Suspected)		Rea	son:	Chron isch he	art dis no hyper
Tablet	2.0	Dose Unspecified	Daily		Oral
Batch:	Started:	L TERM		Stopped:	22/08/1998
ANDROCUR (Suspected)	Reason:				
Tablet	1.0	Dose Unspecified	Daily		Oral
Batch:	Started:	L TERM		Stopped:	24/08/1998
LASIX (Suspected)		Rea	son:	Chron isch he	art dis no hyper
Oral application	80.0	Milligram	Daily		Oral
Batch:	Started:	L TERM		Stopped:	24/08/1998

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatinine				Creatinine - 490.
	Potassium				Potassium - 5.4
	Serum drug level				Digoxin level - 4.5

Additional Information:

See original report for details of other drugs. - slow k and aspirin.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 145559
 Seq: 1
 Gender: M

 Reported:
 09/11/1999
 Weight:

Hospitalisation: Admitted to hospital Age: 83Y
Onset Date: 22/08/1998
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Medicine Details:

CARDIZEM (Suspected)			Reason:	Chron isch hea	art dis no hyper
Tablet	120.0	Milligram	Daily		Oral
Batch:	Started:	L	TERM	Stopped:	24/08/1998
AROPAX (Suspected)			Reason:	Chron isch hea	art dis no hyper
Tablet	10.0	Milligram	Daily		Oral
Batch:	Started:	L	TERM	Stopped:	24/08/1998
MELLERIL (Suspected)			Reason:	Unspecified so	chizophrenia
Tablet	10.0	Milligram	Daily		Oral
Batch:	Started:	L	. TERM	Stopped:	24/08/1998
MACRODANTIN (Suspected)			Reason:	Unspecified so	chizophrenia
	50.0	Milligram	Daily		
Batch:	Started:	L	TERM	Stopped:	24/08/1998

Laboratory Investigations:

Additional Information:

See original report for details of other drugs. - slow k and aspirin.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1			Gen	dar.	M
				_	65.00
				\ge:	33Y
				OB:	
			Causa	lity:	Causality possible
Severity		Report De	scription		Treatment
		Reason:			
50.0	Milligram	Daily			
Started:			Stopped:		CONTIN
		Reason:	Depression		
100.0	Milligram	Daily			
Started:			Stopped:		CONTIN
e Date Teste	ed Resu	ıt İ		Detail	s.
5 Bute 100th	11000			Dotail	
	Started: 100.0 Started:	100.0 Milligram Started:	Started: Reason: 100.0 Milligram Daily Started:	Started: Stopped: Reason: Depression 100.0 Milligram Daily Started: Stopped:	Started: Stopped: Reason: Depression 100.0 Milligram Daily Started: Stopped:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 145805
 Seq: 1
 Gender:
 F

 Reported:
 11/11/1999
 Weight:

Hospitalisation: Age: 30

Onset Date: 05/11/1999 **DOB:** 19/02/1969

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Congenital foot malformation			Planning surgery to remove three toes and possibly a metatarsal bone at one year of age.
Neonatal disorder		Permanent deformity	

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

0.0

Batch: Started: 01/01/1997 **Stopped:** 28/04/1999

ZACTIN (Suspected) Reason:

0.0

Batch: Started: 01/04/1999 Stopped: 28/07/1999

LARGACTIL (Suspected) Reason:

0.0

Batch: Started: Stopped:

MELLERIL (Suspected) Reason: Depression

Tablet 3.0 Dose Unspecified Daily Oral

Batch: Started: 01/01/1997 **Stopped:** 28/04/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Hypertrophic foot from his mid foot distally with an extra toe diagnosed as localised giantism.

Additional Information:

In 1997 mother started taking zoloft and 6 mths later started taking melleril. then she became pregnant. she was taking zoloft, melleril, zactin and largactil during pregnancy, also smoking 20-30 cigarettes per day, no alcohol. she is heb b vacc., syphilis neg. and rubella immunised. on 5/11/99 she had her 4th baby boy, born by spontaneous vaginal delivery at full term. he was noted as having a congenital abnormality of his left foot. he had a hypertrophic foot from his mid foot distally with an extra toe. his first two toes and his little toe and the medial side of his foot are normal. he has been seen by an orthopaedic surgeon and diagnosed with localised giantism. surgery is planned, otherwise the baby is doing well, he is bottle fed and gaining weight normally, he is due to

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 146079 Seq: 1 Gender: F

Reported: 22/11/1999 Weight:
Hospitalisation: Age: 38Y

Onset Date: 31/12/1999

Outcome: Unknown

DOB:

Causality: Causality possible

Reaction Details:

Neaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Speech disorder		Started to mumble some words over and over	

Medicine Details:

Medicine Details.				
RISPERDAL (Other drug)	_	Reason:		
	0.0			
Batch:	Started:		Stopped:	
MELLERIL (Suspected)		Reason:		
Oral application	0.0		Oral	
Batch:	Started:	S TERM	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient started to mumble some words over and over between lucid sentences while on melleril, which was recently commenced. she seems to be fixated on certain words. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 147321 Seq: 1 Gender: F

Reported: 23/12/1999 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1999 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Dotano			
Preferred Term	Severity	Report Description	Treatment
Pyrexia		Increased body temperature	
Pain		Increased pain	
Therapeutic response decreased			

Medicine Details:

MELLERIL (Suspected)		Reason:				
Tablet	10.0	Milligram	Daily	Oral		
Batch:	Started:			Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

This report is also a product complaint no: 199900333. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 148649 Seq: 1 Gender: M

Reported: 07/02/2000 **Weight:** 68.00

Hospitalisation: Age: 17Y

Onset Date: 09/10/1999 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Saction Botano							
Preferred Term	Severity	Report Description	Treatment				
Hypotension		20:00 - hr=46, bp=110/50; 22:00 - hr=39, bp=97/44.					
Bradycardia		Pulse = 46.	Given normal saline.				

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

100.0 Milligram As necessary

Batch: **Started**: 09/10/1999 **Stopped**: 09/10/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient's ecg was normal.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 149446 Seq: 1 Gender: F

Reported: 21/02/2000 Weight:
Hospitalisation: Age: 47

Onset Date: 31/12/1999 DOB: 29/05/1952

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapeutic response decreased			

Medicine Details:

Medicine Details.			
ALLEGRON (Other drug)		Reason: Depression	
Tablet	100.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
MELLERIL (Suspected)		Reason: Depression	
Tablet	150.0 Milligram	Daily Oral	
Batch:	Started: 01/01/1997	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient describes that they experienced more anxiety and depression on the new formulation of melleril than on the old formulation. - 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 149906 Seq: 1 Gender: F

Reported: 02/03/2000 Weight:
Hospitalisation: Age: 50Y

Onset Date: 26/02/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

todotion Botanoi			
Preferred Term	Severity	Report Description	Treatment
Hypertension		Bp 200/100.	
Headache		Severe headache in morning 26,27,28 february.	

Medicine Details:

MELLERIL (Interaction)		Reason:	Depression
	0.0		

Batch: **Started**: 17/02/2000 **Stopped**: 25/02/2000

PARNATE (Interaction) Reason: Depression

30.0 Milligram Daily

Batch: Started: 18/02/2000 **Stopped:** 28/02/2000

STELAZINE (Interaction) Reason: Depression

3.0 Milligram Daily

Batch: Started: 25/02/2000 **Stopped:** 28/02/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	por	t D	etai	ils:
	Ρ-			

Case Number: 150509 Seq: 1 Gender: M
Reported: 17/03/2000 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term Severit		Report Description	Treatment		
Diarrhoea					

Medicine Details:

AROPAX (Suspected)		Reason: De	pression	
Tablet	20.0 Milligram	Daily	Oral	
Batch:	Started: 10/02/2000		Stopped:	CONTIN
MELLERIL (Suspected)		Reason: An	xiety neurosis	
Tablet	100.0 Milligram	Daily	Oral	
Batch:	Started: 10/02/2000		Stopped:	CONTIN
XANAX (Suspected)		Reason: An	xiety neurosis	
Tablet	1.0 Milligram	Daily	Oral	
Batch:	Started: 10/02/2000		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 150678 Seq: 1 Gender: M

Reported: 22/03/2000 Weight:

Hospitalisation: Age: 29

Onset Date: 31/12/1998 **DOB:** 25/03/1969

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia		Grow breasts equal to a womans in 1998	
Weight increased		Weight gain from 75kg to 92kg.	
Dry mouth			

Medicine Details:

MELLERIL (Suspected) Reason: Unspecified schizophrenia

Tablet 75.0 Milligram Daily Oral

Batch: Started: 01/01/1994 L TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking endep, kalma and losec. patient history: patient grew breasts equal to a woman's in 1998, 4 years after commencing melleril. due to a back injury in 1994, unable to do physical excercise every day for a long time. - 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.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Repoi Iospitalisat Onset D	Date:	Seq: 0	1	Gender: U Weight: Age: DOB:					
	me: Unknown					С	ausality: (Causality poss	ible
eaction D	eferred Term	Se	everity	Reno	ort Desc	rintion		Treatme	nt
Generalised			Verity	ТОР	л Всос	приоп		Treatmen	
Medicine MELLERIL (Rea	son:				
Tabl			0.0		Daily		Oral		
Bate	ch:	S	tarted:			Stopped:			
	ry Investigat								
Date	Туре	Range	Date Tested	Result			Details		
Additiona	al Informatio	n:							
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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 150847 Seq: 1 Gender: M

Reported: 28/03/2000 Weight:
Hospitalisation: Age: 61Y

Onset Date: 14/02/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Moter restlessness	
Agitation			Cogentin 2mg oral

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

400.0 Milligram Daily

Batch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking salbutamol, nitrate patch, sodium valproate, aspirin, benztropine.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 150906 Seq: 1 Gender: F

Reported: 28/03/2000 Weight: 105.00 Hospitalisation: Age: 30

Onset Date: 20/10/1999 **DOB**: 02/07/1969

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

•	toaction Botano.			
	Preferred Term	Severity	Report Description	Treatment
	Diabetes mellitus			
	Weight decreased			

Medicine Details:

RISPERDAL (Suspected)		Reason:	Unspecified psychosis
Oral application	1.0 Milligram	Daily	Oral
Batch:	Started: 31/03/1998		Stopped:
ALDAZINE (Suspected)		Reason:	Specific disorders of sleep
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 24/06/1998		Stopped:
AROPAX (Suspected)		Reason:	Depression
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 31/03/1998		Stopped:
SODIUM VALPROATE (Suspected)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 07/04/1998		Stopped:

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ		Other data			Lost a lot of weight 15-20 kgs.	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 151049 Seq: 1 Gender: M
Reported: 28/03/2000 Weight:
Hospitalisation: Age: 20Y

Onset Date: 27/10/1998 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

teaction Details.			
Preferred Term	Severity	Report Description	Treatment
Saliva altered		Difficulty with salivation and tongue movements.	
Dystonia			Benztropine 2mg given orally. thioridazine reduced to 150mg/d.

Medicine Details:

Medicine Details.					
THIORIDAZINE HYDROCHLORIDE (Suspected)	Reason: Unsp	ecified psychosis		
Tablet	300.0 Milligram	Daily	Oral		
Batch:	Started: 26/10/1998	s	topped: 27/10/19	98	
RISPERIDONE (Suspected)		Reason: Unsp	ecified psychosis		
Tablet	1.0 Milligram	Daily	Oral		
Batch:	Started: 23/10/1998	S	topped:	CONTIN	
DIAZEPAM (Suspected)		Reason: Anxie	ety neurosis		
Tablet	15.0 Milligram	Daily	Oral		
Batch:	Started: 24/10/1998	S	topped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 151064
 Seq: 1
 Gender: M

 Reported:
 28/03/2000
 Weight:

Hospitalisation: Age: 38

Onset Date: 29/11/1999 **DOB**: 15/07/1961

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity Report Description		Treatment
Blood creatine phosphokinase incr			
Convulsion			Dilartin tds ivi, acylovir ivi (hsv possible) 500mg tds x 4 doses. zoloft (sertraline ceased).
Hyperpyrexia Hyperreflexia			
Hypertonia			

Medicine Details:

ZOLOFT (Suspected)		Reason:	Depression	
	100.0 Milligram	Daily		
Batch:	Started: 26/11/1999		Stopped:	29/11/1999
LITHIUM CARBONATE (Suspected)		Reason:		
Tablet	1.5 Gram	Daily		Oral
Batch:	Started:		Stopped:	02/12/1999
THIORIDAZINE HYDROCHLORIDE (Sus	pected)	Reason:	Otr spec symp	psychopathol nec
	100.0 Milligram	Daily		
Batch:	Started: 27/11/1999		Stopped:	29/11/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Creatine		26/11/1999	73	
	Creatine		03/12/1999	2515	

Additional Information:

Serotonin syndrone most probable neuroleptic malignant syndrome.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 151161 Seq: 1 Gender: F

Reported: 03/04/2000 Weight: 117.00 Hospitalisation: Age: 41Y

Onset Date: 16/03/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
	Syncope		1 x faint.	
	Dizziness			100mg melleril next day.

Medicine Details:

Medicine Details.				
SERZONE (Interaction)		Reason:	Depression	
Tablet	600.0 Milligram	Daily	Oral	
Batch:	Started: 01/12/1999		Stopped:	CONTIN
MELLERIL (Interaction)		Reason:	Specific disorders of sleep	
Oral application	200.0 Milligram	Daily	Oral	
Batch:	Started: 15/03/2000		Stopped: 21/03/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 151223 Seq: 1 Gender: M

Reported: 03/04/2000 Weight:
Hospitalisation: Age: 64

Onset Date: 31/03/1999 **DOB**: 12/04/1934

Outcome: Unknown Causality: Causality possible

Reaction Details:

,	caction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Thinking abnormal		Reduced mental agility.	
	Somnolence			

Medicine Details:

MELLERIL (Suspected) Reason:

Tablet 100.0 Milligram Daily Oral

Batch: Started: 01/09/1998 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction commenced approximately one year ago when the dosage of melleril was increased from 75mg to 100mg. - 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 151288 Seq: 1 Gender: M

Reported: 06/04/2000 Weight:
Hospitalisation: Age: 74Y

Onset Date: 20/01/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

i todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Leukopenia			
Neutropenia			

Medicine Details:

Medicine Details.				
TOLVON (Suspected)		Reason:	Depression	
Tablet	160.0 Milligram	Daily		Oral
Batch:	Started: 31/12/1999		Stopped:	16/02/2000
MELLERIL (Suspected)		Reason:	Otr spec symp	psychopathol nec
Tablet	40.0 Milligram	Daily		Oral
Batch:	Started: 06/01/2000		Stopped:	22/02/2000

Laboratory Investigations:

 	<u> </u>				
Date	Туре	Range	Date Tested	Result	Details
	Neutrophils		29/12/1999	4.2	
	Neutrophils		17/02/2000	0.7	
	White blood cells		29/12/1999	5.2	
	White blood cells		17/02/2000	1.7	

Additional Information:

Patint was also taking coversyl, lipitor. allergic to aspirin.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 151558 Seq: 1 Gender: F

Reported: 11/04/2000 Weight: 69.00 Hospitalisation: Age: 56Y

Onset Date: 03/08/1999 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

-				
	Preferred Term	Severity	Report Description	Treatment
	Urinary incontinence			

Medicine Details:

CIPRAMIL (Suspected) Reason: Depression

Tablet 40.0 Milligram Daily Oral

Batch: Started: 13/07/1999 **Stopped:** 06/03/2000

MELLERIL (Suspected) Reason: Depression

100.0 Milligram Daily

Batch: Started: 13/07/1999 Stopped: 05/01/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

	etails:						
	nber: 151810 rted: 17/04/2000 tion:	Seq:	: 1			Gender: Weight: Age:	
Onset D						DOB:	
	me: Unknown				Ca	usality:	Causality possible
eaction <u>C</u>						1	
	referred Term	Se	everity	Repo	ort Description	N.4 -	Treatment
Hypertensic	on					tha	lleril therapy ceased more n 5 years ago.
Medicine MELLERIL (Details: Suspected)			Rea	son:		
			0.0				
Bate	ch:	S	tarted:		Stopped:		
_aborato	ry Investigatio						
Laborato Date	ry Investigatio	ONS: Range	Date Tested	Result		Detail	S
			Date Tested	Result		Detail	S

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 153016 Seq: 1 Gender: F

Reported: 24/05/2000 Weight: 58.00 Hospitalisation: Age: 19

Onset Date: 31/03/2000 **DOB**: 16/07/1980

Outcome: Recovered Causality: Causality probable

Reaction Details:

itaction betails.									
	Preferred Term	Severity	Report Description	Treatment					
	Headache								
	Hypotension								
	Tremor			Monitoring condition.	ĺ				

Medicine Details:

MELLERIL (Suspected) Reason: Otr spec symp psychopathol nec

 Tablet
 100.0
 Milligram
 Daily
 Oral

 Batch:
 Started: 31/03/2000
 Stopped: 31/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

First episode of exposure to melleril. patient was also taking avemlafaxine, olanzipine.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 153407 Seq: 1 Gender: F

Reported: 05/06/2000 Weight:
Hospitalisation: Age:
Onset Date: 31/12/1995 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Neuralgia		Neuralgia makes her face painful.	
Tardive dyskinesia			Melleril ceased.

Medicine Details:

MELLERIL (Suspected)Reason:Tablet25.0 MilligramDailyOral

Batch: Started: Stopped: 31/01/1995

Laboratory Investigations:

Date	Туре	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 stop date is not accurate but indicates that stoppage occurred sometime during the year.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 153689
 Seq: 1
 Gender: M

 Reported:
 15/06/2000
 Weight:

 Hospitalisation:
 Age: 43

 Onset Date: 09/12/1999
 DOB: 19/05/1956

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Dysarthria		The patient could not talk properly.	
Dyspnoea			
Hypersensitivity			Celebrex ceased.
Tongue oedema	Required Specialist Consultation		

Medicine Details:

Medicine Details.				
THIORIDAZINE HYDROCHLORIDE	Reason:			
Tablet	0.0		Oral	
Batch:	Started:		Stopped:	CONTIN
CELEBREX (Suspected)		Reason:	Otr nerve injury multip	I sitesno mention of open
Capsule	200.0 Milligram	Daily	Oral	
Batch:	Started: 09/12/1999		Stopped: 10/12/	1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking indomethacin, ranitidine, paracetamol, codeine and diazepam.

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Report Details:

Case Number: 153787

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Date	Type Type	Range	Date Teste	ed Result			Details		
			Date Teste	ed Result			Details	<u>.</u>	
			Date Teste	ed Result			Details	<u> </u>	
			Date Teste	ed Result			Details	5	
			Date Teste	d Result	T		Details		
Bate			ziarteu.			оторрец.			
Table Batc		(100.0 Started:	Milligram	Daily	Oral Stopped:			
	NE HYDROCHLOF	RIDE (Suspecte			ason:	_			
<i>f</i> ledicine	Details:								
				modii.					
aruive uysk	kinesia		-	Increased facial movements involving mouth.					
	etails: eferred Term	S	everity	Rer	ort Desc	ription		Treatmen	1
Pre	4	covered		Causality:			ality:	Causality possi	ble
action D	me: Not yet re							30/05/1952	
action D	ate: me: Not yet re					•	•		
ospitalisati Onset D Outcor eaction D	ate:						ight: Age:	48	



Report Details:

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Repoi Iospitalisat Onset D		Seq: 1		Weig A D	der: M ght: Age: 85 OOB: 01/01/1915 Ility: Causality possible
eaction D				OddSd	inty. Caddality possible
	eferred Term	Severity	Rep	ort Description	Treatment
Bronchitis			Chest infection.	·	
Medicine MELLERIL (S			Rea	son:	
Table	et	50.0 N	/lilligram	As necessary Oral	
Bato	ch:	Started:		Stopped:	
_aborato	ry Investigatio	ons: Range Date Teste	d Result		Details
	,,				
Additiona	ıl Information	ı:			
eport Run: 01/	06/2007 02:46PM	Database: pusime02	-	ADRS004	Page 328 of 393



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 155035 Seq: 1 Gender: U

Reported: 19/07/2000 Weight:
Hospitalisation: Age:
Onset Date: 27/06/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Insomnia		Can not get to sleep before midnight.	

Medicine Details:

MELLERIL (Suspected) Reason:

Tablet 0.0 Oral

Batch: Started: 01/01/1966 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
	\sim		-	u	

Case Number: 155053 Seq: 1 Gender: F

Reported: 20/07/2000 Weight:
Hospitalisation: Age: 44

Onset Date: 01/07/2000 **DOB:** 10/08/1955

Outcome: Recovered Causality: Causality probable

Reaction Details:

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Urinary incontinence	Severe		Therapy changed to chlorpromazine.

Medicine Details:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason:

Tablet 50.0 Milligram As necessary Oral

Batch: Started: 28/06/2000 Stopped: 04/07/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 155177
 Seq: 1
 Gender: M

 Reported:
 20/07/2000
 Weight:

Hospitalisation: Age: 25

Onset Date: 23/06/2000 **DOB**: 05/11/1974

Outcome: Unknown Causality: Causality possible

Reaction Details:

٠,	todotion Dotanoi			
	Preferred Term	Severity	Report Description	Treatment
	Dystonia			Benztropine 2mg imi 23/6 and again 24/6. melleril ceased
	Tongue oedema		Swollen tongue	

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
	5.0 Milligram	1 time	
Batch:	Started: 22/06/2000	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason: Unspecified neurosis	
Injection	50.0 Milligram	1 time Intramuscular	
Batch:	Started: 22/06/2000	Stopped:	
MELLERIL (Suspected)		Reason: Unspecified neurosis	
	300.0 Milligram	Daily	
Batch:	Started: 22/06/2000	Stopped: 24/06/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Only 5 doses of melleril 100mg given in conjunction with zyclopenthixol then ceased, no further dytonic reactions since then.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 155178
 Seq: 1
 Gender: U

 Reported:
 20/07/2000
 Weight:

Hospitalisation: Age: 21

Onset Date: 30/06/2000 **DOB**: 03/06/1979

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia			Cogentin 2mg imi given 30/6/00.

Medicine Details:

DIAZEPAM (Other drug) Reason: Anxiety neurosis

5.0 Milligram As necessary

Batch: Started: Stopped: CONTIN

ZUCLOPENTHIXOL ACETATE (Suspected) Reason: Unspecified psychosis

Injection 50.0 Milligram 1 time Intravenous

Batch: Started: 29/06/2000 Stopped:

THIORIDAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified psychosis

100.0 Milligram As necessary

Batch: Started: 30/06/2000 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

2nd dose of zuclopenthixol acetate no ill effects. used speed prior to admission to hospital iv and amphetamine use for 1 year.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 155668 Seq: 1 Gender: M
Reported: 31/07/2000 Weight:

Hospitalisation: Age: 16Y
Onset Date: 16/07/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

touotion Dotailoi			
Preferred Term	Severity	Report Description	Treatment
Hypertension		Elevated systolic blood pressure, 170/80mm/hg.	

Medicine Details:

CLOZARIL (Suspected)			Reason:	Unspecified sc	hizophrenia	
Tablet	250.0	Milligram	Daily		Oral	
Batch:	Started:	l	TERM	Stopped:		CONTIN
PAROXETINE HYDROCHLORIDE (Suspec	cted)		Reason:			
Tablet	10.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		CONTIN
THIORIDAZINE HYDROCHLORIDE (Susp	ected)		Reason:	Otr spec symp	psychopathol ne	C
Tablet	25.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		
TEMAZEPAM (Suspected)			Reason:			
Tablet	10.0	Milligram	Daily		Oral	
Batch:	Started:			Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
----	----	----	----	-----	-----

Case Number: 155821 Seq: 1 Gender: M
Reported: 10/05/2000 Weight:
Hospitalisation: Age: 62

Onset Date: 30/01/2000 DOB: 18/08/1937

Outcome: Death Causality: Causality possible

Reaction Details:

١,	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Cardiac arrest			
	Electrocardiogram QT prolonged			
	Pulmonary oedema			
	Sudden death			

Medicine Details:

SODIUM VALPROATE (Suspected)		Reason:
	0.0	
Batch:	Started:	Stopped:
MELLERIL (Suspected)		Reason: Otr spec symp psychopathol nec
Tablet	600.0 Milligram	Daily Oral
Batch:	Started: 21/01/2000	Stopped: 30/01/2000
EFEXOR (Suspected)		Reason:
	75.0 Milligram	Daily
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Electrocardiograph				Electrocardiogram taken 27.1.00, shortly before death had a qt interval of 13.8mm, which is prolonged.
	Other data				Post-mortem showed coronary artery disease, pulmonary oedema and signs of frontal lob dementia. further information: autopsy report stated that the direct cause of death was "combined effects of melleril toxicity and ischaemic hear disease".

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	no	rt	De	tail	ls:
176	μυ		\mathbf{r}	tai	.

 Case Number:
 155821
 Seq: 1
 Gender: M

 Reported:
 10/05/2000
 Weight:

Hospitalisation: Age: 62

Onset Date: 30/01/2000 **DOB**: 18/08/1937

Outcome: Death Causality: Causality possible

Reaction Details:

Medicine Details:

SODIUM VALPROATE (Suspected)		Reason:		
	0.0			
Batch:	Started:		Stopped:	
MELLERIL (Suspected)		Reason: Otr	r spec symp psychopathol nec	
Tablet	600.0 Milligram	Daily	Oral	
Batch:	Started: 21/01/2000		Stopped: 30/01/2000	
EFEXOR (Suspected)		Reason:		
	75.0 Milligram	Daily		
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Other data				Proportion each factor contributed.
	Other data				At post mortem the pathological features were of an arrthymia/cardiac death (cardiac arrest). prolongation of the qt interval is associated with an increased risk of heart arrthymias and sudden death. so is coronary artery narrowing. the deceased had both. both appeared to be significant. they both probably contributed to death, however it is impossible to say what

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

eport De	etails:							
Repor spitalisat Onset D	ber: 155821 rted: 10/05/200 ion: Date: 30/01/200 me: Death	00	ק: 1			c		
action D	etails:							
	Details: LPROATE (Suspec	eted)		Re	ason:			
		,	0.0					
Bato			Started:			Stopped:		
	Suspected)					Otr spec symp		nol nec
Table			600.0 Milli	-	Daily		Oral	_
Bato			Started: 21/01/20			Stopped:	30/01/2000)
FEXOR (Su	ispected)		75.0 Milli		ason: Daily			
Bato	sh.		Started:	gram	Dally	Stopped:		
aborator Date	ry Investigat	ions:	Date Tested	Result	T		Detai	ls
	Pharmacokinetics	agc	2410 100100	,,ooun	thiorida range: (presen 0.033-0	zine - therapeı I-5mg/l and re /.) 3.8mg/l. ver	owed melleri utic blood lev ported fatal r nlafaxine - the blood range	l concentration - 3.8mg/l. /el: 0.05-5mg/l, toxic blood range: >2mg/l. blood lerapeutic blood level: e n/a and reported fatal rang
dditiona	ıl Informatio	n:			ı			

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

eport De	etails:								
Case Num	ber: 155821	Se	q : 1				Gender	: M	
Repor	ted: 10/05/200		•				Weight:		
spitalisat							Age:		
-	Date: 30/01/200	00					_	: 18/08/1	937
	me: Death					C			ity possible
action D									, μ
uotion b	otulis.								
odicino	Dataile								
	Details:	cted)		Res	ason.				
	Details: LPROATE (Suspec	cted)	0.0	Rea	ason:				
	LPROATE (Suspe	cted)	0.0 Started:	Rea	ason:	Stopped:			
SODIUM VAI Bato	LPROATE (Suspec	cted)				Stopped: Otr spec sym		thol nec	
SODIUM VAI Bato	LPROATE (Suspec ch: Suspected)	cted)	Started:	Rea	ason:	Stopped: Otr spec sym		thol nec	
Bato Bato MELLERIL (S Table	LPROATE (Suspected) et	cted)	Started: 600.0 Milli	Re a		Otr spec sym	p psychopat Oral		
Bato Bato MELLERIL (S Table Bato	LPROATE (Suspector) Suspected) et ch:	cted)	Started:	Re a gram 000	ason: Daily	Otr spec sym	p psychopat		
Bato Bato MELLERIL (S Table Bato	LPROATE (Suspector) Suspected) et ch:	cted)	Started: 600.0 Milling Started: 21/01/20	Rea gram 000	ason: Daily ason:	Otr spec sym	p psychopat Oral		
Bato Bato MELLERIL (S Table Bato EFEXOR (Su	ch: Guspected) et ch: spected)	cted)	600.0 Million Started: 21/01/20 75.0 Million	Rea gram 000	ason: Daily	Otr spec sym Stopped:	o psychopa Oral 30/01/200		
Bato Bato MELLERIL (S Table Bato	ch: Guspected) et ch: spected)	cted)	Started: 600.0 Milling Started: 21/01/20	Rea gram 000	ason: Daily ason:	Otr spec sym	o psychopa Oral 30/01/200		
Bato Bato MELLERIL (S Table Bato EFEXOR (Su	ch: Guspected) et ch: spected)	cted)	600.0 Million Started: 21/01/20 75.0 Million	Rea gram 000	ason: Daily ason:	Otr spec sym Stopped:	o psychopa Oral 30/01/200		
Bato Bato MELLERIL (S Table Bato EFEXOR (Su	ch: Guspected) et ch: spected)	cted)	600.0 Million Started: 21/01/20 75.0 Million	Rea gram 000	ason: Daily ason:	Otr spec sym Stopped:	o psychopa Oral 30/01/200		
Bato Bato MELLERIL (S Table Bato EFEXOR (Su	ch: Guspected) et ch: spected)	cted)	600.0 Million Started: 21/01/20 75.0 Million	Rea gram 000	ason: Daily ason:	Otr spec sym Stopped:	o psychopa Oral 30/01/200		
Bato Bato Bato Bato Bato Bato Bato Bato	ch: Suspected) et ch: spected)		600.0 Million Started: 21/01/20 75.0 Million	Rea gram 000	ason: Daily ason:	Otr spec sym Stopped:	o psychopa Oral 30/01/200		
Bato Bato Bato Bato Bato Bato Bato Bato	ch: Suspected) et ch: spected) ch:		600.0 Million Started: 21/01/20 75.0 Million	Rea gram 000	ason: Daily ason:	Otr spec sym Stopped:	o psychopa Oral 30/01/200	00	
Bato MELLERIL (S Table Bato EFEXOR (Su Bato Date	ch: Suspected) et ch: spected)	tions:	Started: 600.0 Milling Started: 21/01/20 75.0 Milling Started:	Rea gram 000 Rea gram	ason: Daily ason: Daily Valproic	Stopped: Stopped:	p psychopai Oral 30/01/200 Deta	iils	00mg/l, toxic blo
Bato MELLERIL (S Table Bato EFEXOR (Su Bato Date	ch: Suspected) et ch: (spected) ch: (spected) ch: Type	tions:	Started: 600.0 Milling Started: 21/01/20 75.0 Milling Started:	Rea gram 000 Rea gram	ason: Daily ason: Daily Valproic	Stopped: Stopped:	p psychopai Oral 30/01/200 Deta	iils	l0mg/l, toxic bloo 389mg/l. blood
Bato MELLERIL (S Table Bato EFEXOR (Su Bato Date	ch: Suspected) et ch: (spected) ch: (spected) ch: Type	tions:	Started: 600.0 Milling Started: 21/01/20 75.0 Milling Started:	Rea gram 000 Rea gram	Daily Daily Daily Valproic range: 4 (preserv	Stopped: Stopped:	p psychopai Oral 30/01/200 Deta eutic blood d reported f	nils level: 40-10 atal range:	389mg/l. blood

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number:157905Seq: 1Gender: MReported:20/09/2000Weight:Hospitalisation:Admitted to hospitalAge: 32

Onset Date: 28/08/2000 **DOB**: 05/02/1968

Outcome: Recovered Causality: Causality possible

Reaction Details:

Cuclion Belans.			
Preferred Term	Severity	Report Description	Treatment
Tachycardia		Hr was 140 beats/minute.	
Hypertonia		Occasional muscle jerks.	
Serotonin syndrome		Serotonergic syndrome.	Patient was hospitalised. date of recovery 30.8.00. treated with periactin 8mg po.
Anxiety			
Chills			
Hypertonia			

Medicine Details:

CITALOPRAM HYDROBROMIDE	(Interaction)	Reason:			
	0.0				
Batch:	Started:	Stopped			
THIORIDAZINE HYDROCHLORID	E (Interaction)	Reason:			
	150.0 Milligram	Daily			
Batch:	Started:	Stopped			
EFEXOR (Interaction)		Reason: Depression			
	150.0 Milligram	Daily			
Batch:	Started: 20/08/2000	Stopped:	30/08/2000		
DEXAMPHETAMINE SULPHATE	(Interaction)	Reason:			
	15.0 Milligram	Daily			
Batch:	Started: 01/02/2000	Stopped:	CONTIN		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 159062 Seq: 1 Gender: M
Reported: 03/11/2000 Weight:
Hospitalisation: Age: 46Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Speech disorder		Bizarre speech contents.	
Confusional state			
Drug ineffective			

Medicine Details:

<u>Medicine Details:</u>				
ALDAZINE (Suspected)		Reason:		
Tablet	100.0 Milligram	Daily	Oral	
Batch:	Started:	Stopped:		1M
EPILIM (Suspected)		Reason:		
	2.4 Gram	Daily		
Batch:	Started:	Sto	nned: 26/09/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Death of patient as a result of septicemia (fungemia).

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 159252
 Seq: 1
 Gender:
 F

 Reported:
 14/11/2000
 Weight:

Hospitalisation: Age: 48

Onset Date: DOB: 24/03/1952

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cyanosis		Blue lips	
Salivary hypersecretion		Frothing at the mouth	

Medicine Details:

MELLERIL (Suspected) Reason:

Tablet 100.0 Milligram Daily Oral

Batch: Started: 01/01/1990 **Stopped:** 31/01/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking tegretol, lithium. reaction continues, patient is profoundly disabled. 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 159359
 Seq: 1
 Gender: M

 Reported:
 16/11/2000
 Weight:

Hospitalisation: Age: 46

Onset Date: 31/08/2000 **DOB**: 13/03/1954

Outcome: Unknown Causality: Causality possible

Reaction Details:

١,	reaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Speech disorder		Bizarre speech	
	Thinking abnormal		Occasional vagueness	
	Confusional state			

Medicine Details:

Medicine Details.				
ALDAZINE (Suspected)		Reason:		
Oral application	100.0 Milligra	am Daily		Oral
Batch:	Started:		Stopped:	
EPILIM (Suspected)		Reason:		
Oral application	2.5 Gram	Daily		Oral
Batch:	Started: 01/08/2000)	Stopped:	26/09/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking monopril, solone, plaquenil, ranihexal. - 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.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 159360
 Seq: 1
 Gender: M

 Reported:
 16/11/2000
 Weight:

Hospitalisation: Age: 46

Onset Date: 16/09/2000 **DOB**: 13/03/1954

Outcome: Unknown Causality: Causality possible

Reaction Details:

teaction betains.					
Preferred Term	Severity	Report Description	Treatment		
Chills					
Coordination abnormal					
Cough					
Headache					
Pyrexia					
Rash maculo-papular					
Tremor					

Medicine Details:

ALDAZINE (Suspected)	F	Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
EPILIM (Suspected)	F	Reason:	
Oral application	2.5 Gram	Daily	Oral
Batch:	Started: 01/08/2000	Stopped:	26/09/2000
LAMICTAL (Suspected)	F	Reason:	
Oral application	20.0 Milligram	Daily	Oral
Batch:	Started: 12/09/2000	Stopped:	23/09/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking monopril, solone, plaquenil, ranihexal. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 159580
 Seq: 1
 Gender: M

 Reported:
 29/11/2000
 Weight:
 92.00

Hospitalisation: Admitted to hospital **Age:** 68

Onset Date: 13/10/2000 DOB: 09/12/1931
Outcome: Unknown Causality: Causality possible

Reaction Details:

Neaction Details.			
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Fluid restriction, regular lasix 40mg mane, 20mg midi, slow sodium infusion 40 mg/hr-> increased to 3 % sodium chloride. patient was hospitalised

Medicine Details:

TEMAZE (Suspected)	Reason:				
	10.0 Milligram	As necessary			
Batch:	Started:	Stopped: 17/10/2000			
MELLERIL (Suspected)		Reason:			
	300.0 Milligram	Daily			
Batch:	Started:	Stopped: 16/10/2000			
CELEBREX (Suspected)		Reason: Unspecified arthritis			
	20.0 Milligram	Daily			
Batch:	Started: 13/10/2000	Stopped : 15/10/2000			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium		10/10/2000	132	
	Sodium		12/10/2000	123	
	Sodium		13/10/2000	120	
	Sodium		15/10/2000	116	
	Sodium		15/10/2000	113	

Additional Information:

Patient was also taking flixotide, cartia, oroxin, mixtard 30/70, panadeine, zestril, epilim, solone, ventolin, atrovent. no previous exposure to celebrex but sodium levels fell rapidly after commencement of this drug.

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Report Details:

Case Number: 159755

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Reported: 23/11/2000			Weight			
ospitalisation:		Age: 39Y				
Onset Date:			DOB	3:		
Outcome: Not yet recovere	d		Causality	: Causality possible		
eaction Details:	T	T				
Preferred Term	Severity	Report Description		Treatment		
Nightmare		Horrific lifelike nightmares				
Chills		Muscle rigidity				
Tachycardia		Racing pulse up to 100 and 120				
Suicide attempt		Suicidal thoughts				
Medicine Details:						
MELLERIL (Suspected)	0.0	Reason:				
Batch:	0.0 Started:	Stopped				
Laboratory Investigations:		tad David	Det	-11-		
Date Type Rar	nge Date Test	ted Result	Deta	alis		
Additional Information:						
eport Run: 01/06/2007 02:46PM Data	base: pusime02	ADRS004		Page 344 of	393	



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 159765
 Seq: 1
 Gender: M

 Reported:
 22/11/2000
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 23/09/2000
DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Increased sleep +++	
Chills			
Coordination abnormal			
Cough			
Gastritis			
Headache			
Rash maculo-papular			Lamictal ceased iv antibiotics including cefotaxime, dicloxacillin, erythromycin, meropenem and ampotericin.
Tremor			

Medicine Details:

SOLONE (Other drug)		Reason:	Systemic lupus	s erythematosus	
Tablet	5.0 Milligram	Daily		Oral	
Batch:	Started:		Stopped:	23/09/2000	2Y
ALDAZINE (Suspected)		Reason:			
Tablet	100.0 Milligram	Daily		Oral	
Batch:	Started:		Stopped:		1M
EPILIM (Suspected)		Reason:			
Tablet	4.2 Gram	Daily		Oral	
Batch:	Started:		Stopped:	26/09/2000	
LAMICTAL (Suspected)		Reason:			
Tablet	20.0 Milligram	Daily		Oral	
Batch:	Started: 12/09/2000		Stopped:	21/09/2000	

Laboratory Investigations:

L	Date	Type	Range	Date Tested	Result	Details
Г		Creatinine	30 - 120	01/09/2000	108	
		Creatinine	30 - 120	23/09/2000	257	
		Creatinine	30 - 120	24/09/2000	232	
		Microbiology				Candida albicans isolated in a blood culture taken on 28/9/00.
		Other data				Post mortem 4/10/00: immediate cause of death diffuse acute haemorrhagic ulcerating gastritis with candida overgrowth candida septicaemia.

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 159765 Seq: 1 Gender: M

Reported: 22/11/2000 Weight:
Hospitalisation: Admitted to hospital Age: 46Y
Onset Date: 23/09/2000 DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Medicine Details:

LAMICTAL (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily Ora	d
Batch:	Started: 22/09/2000	Stopped: 23/	09/2000
MONOPRIL (Suspected)		Reason: Essential benign hy	ypertension
Tablet	10.0 Milligram	Daily Ora	d
Batch:	Started:	Stopped: 23/	09/2000 2Y
PLAQUENIL (Suspected)		Reason: Systemic lupus ery	thematosus
Tablet	400.0 Milligram	Daily Ora	d
Batch:	Started:	Stopped:	02Y

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Platelets	150 - 500	01/09/2000	245	
	Platelets	150 - 500	24/09/2000	66	
	Platelets	150 - 500	28/09/2000	315	
	Platelets	150 - 500	26/09/2000	137	
	Platelets	150 - 500	23/09/2000	96	
	Urea	2.5 - 7.5	01/09/2000	7.0	
	Urea	2.5 - 7.5	23/09/2000	14.4	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls:
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Case Number: 159765 Seq: 1 Gender: M
Reported: 22/11/2000 Weight:

Hospitalisation: Admitted to hospital Age: 46Y
Onset Date: 23/09/2000 DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

Medicine Details:

SOLONE (Other drug)		Reason:	Systemic lupu	s erythematosus	
Tablet	5.0 Milligram	Daily		Oral	
Batch:	Started:		Stopped:	23/09/2000	2Y
ALDAZINE (Suspected)		Reason:			
Tablet	100.0 Milligram	Daily		Oral	
Batch:	Started:		Stopped:		1M
EPILIM (Suspected)		Reason:			
Tablet	4.2 Gram	Daily		Oral	
Batch:	Started:		Stopped:	26/09/2000	
LAMICTAL (Suspected)		Reason:			
Tablet	20.0 Milligram	Daily		Oral	
Batch:	Started: 12/09/2000		Stopped:	21/09/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Urea	2.5 - 7.5	24/09/2000	17.4	

Additional Information:

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Report Details:

Case Number: 159765

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

-	22/11/2000					Weight:	40)/	
Onset Date:	Admitted to hospital					Age: 4 DOB:	40 Y	
					_		Causality possib	ما
eaction Detail	Death, maybe drug				C	ausanty. V	Causality possib	ie
a. P. L. B. (. 11 -							
ledicine Deta				Reason:				
Tablet	steaj	40 0	Milligram	Daily		Oral		
Batch:		Started: 22	-	Dany	Stopped:	23/09/2000		
MONOPRIL (Suspe	ected)			Reason:	Essential beni		on	
Tablet	,	10.0	Milligram	Daily		Oral		
Batch:		Started:	ŭ	,	Stopped:	23/09/2000	2Y	
PLAQUENIL (Susp	ected)			Reason:	Systemic lupu			
Tablet		400.0	Milligram	Daily		Oral		
Batch:		Started:			Stopped:		02Y	
aboratory In	vestigations:							
dditional Inf	ormation:							

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 160773 Seq: 1 Gender: F

Reported: 18/01/2001 Weight: 89.00
Hospitalisation: Age: 37Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

,	teaction Details.			
	Preferred Term	Severity	Report Description	Treatment
	Hallucination	llucination		
	Psychotic disorder		Slashed wrists and breasts.	

Medicine Details:

Medicine Details.			
ALDAZINE (Interaction)			
	50.0 Milligram	As necessary	
Batch:	Started:	Stopped:	
ZYBAN SR (Interaction)		Reason:	
	300.0 Milligram	Daily	
Batch:	Started: 13/11/2000	Stopped: 04/01/2001	
RISPERDAL (Interaction)		Reason:	
	4.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking adventan, akineton, aldazine, betnovate, depo-ralovera, diazepam, difflam, efexor-xr, ergodryl mono, metoclopramide and panadeine forte. allergies to cephalexin, cortisone im, cotrimoxazole, doxycycline, erythromycin, gentamicin, lincomycin, neomycin, septrin, sodium, streptomycin and theophylline.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 162273 Seq: 1 Gender: F

Reported: 05/03/2001 Weight: 50.00 Hospitalisation: Age: 83

Onset Date: 12/01/2001 **DOB**: 16/12/1917

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Jaundice			Melleril ceased. date of recovery: 17/2/2001.

Medicine Details:

MELLERIL (Suspected) Reason:

0.0

Batch: **Started**: 03/01/2001 **Stopped**: 12/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking largactil. nil known allergies.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	port	: Deta	ils:
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Case Number:163385Seq: 1Gender: UReported:02/04/2001Weight:Hospitalisation:Admitted to hospitalAge:

Onset Date: 28/03/2001 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion botans.			
Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome			Patient was admitted to hospital after ceasing melleril, the patient was switched over to olanzapine for maintenance therapy.

Medicine Details:

MELLERIL (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 164049 Seq: 1 Gender: M

Reported: 09/02/2001 Weight:
Hospitalisation: Age: 50

Onset Date: 28/12/2000 DOB: 15/05/1950

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Micturition disorder		Difficulty in urination	
Drug withdrawal syndrome			

Medicine Details:

Medicine Details.				
OLANZAPINE (Other drug)		Reason:		
	7.5 Mil	ligram Daily		
Batch:	Started:		Stopped:	
MELLERIL (Suspected)		Reason:		
Tablet	100.0 Mil	ligram Daily		Oral
Batch:	Started:		Stopped:	28/12/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose of onset is not necessarily accurate but indicates onset sometime in the month. the dose stop date is not necessarily accurate but indicates the drug was stop ped sometime in the month

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Reported: 19/03/200	Seq: 01	: 1				Gender: Weight:	F
spitalisation:	- *					Age:	36
Onset Date:						_	20/01/1965
Outcome: Not yet re	ecovered				С	ausality:	Causality possible
action Details:						•	
Preferred Term	Se	everity	Repo	rt Desc	ription		Treatment
rug withdrawal syndrome		Increased behavioural s			mptoms.		
edicine Details:			Reas	son:			
Oral application		2.2 Milli	igram	Daily		Oral	
Datah.	S	tarted:			Stopped:		
Batch:							
PREPULSID (Other drug)			Reas	son:			
PREPULSID (Other drug) Oral application		20.0 Milli		son: Daily		Oral	
PREPULSID (Other drug) Oral application Batch:		20.0 Milli	igram	Daily	Stopped:	Oral	
PREPULSID (Other drug) Oral application		itarted:	igram Reas	Daily son:		Oral	
Oral application Batch: OSEC (Other drug)	s	started: 20.0 Milli	igram Reas	Daily	Stopped:	Oral	
PREPULSID (Other drug) Oral application Batch: OSEC (Other drug) Batch:	s	itarted:	igram Reas igram	Daily son: Daily		Oral	
Oral application Batch: COSEC (Other drug) Batch: MELLERIL (Suspected)	s	20.0 Milli	igram Reas igram Reas	Daily son: Daily son:	Stopped:		
PREPULSID (Other drug) Oral application Batch: OSEC (Other drug) Batch: MELLERIL (Suspected) Tablet	s	20.0 Milli itarted: 150.0 Milli	igram Reas igram Reas	Daily son: Daily	Stopped:	Oral	
Oral application Batch: OSEC (Other drug) Batch:	s	20.0 Milli	igram Reas igram Reas	Daily son: Daily son:	Stopped:		
Oral application Batch: OSEC (Other drug) Batch: Batch: Batch: MELLERIL (Suspected) Tablet	s s	20.0 Milli itarted: 150.0 Milli	igram Reas igram Reas	Daily son: Daily son:	Stopped:		

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 164396
 Seq: 1
 Gender: M

 Reported:
 10/05/2001
 Weight:
 80.00

Hospitalisation: Admitted to hospital **Age**: 38

Onset Date: 16/11/2000 DOB: 15/08/1962
Outcome: Recovered 05/12/2000 Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vasculitis	to Doctor	1	Fluids and insulin, Melleril ceased
Vasculitis			Melleril ceased. required a visit to doctor. date of recovery 05/12/00 pt hospitalised

Medicine Details:

MELLERIL (Suspected) Reason: Unspecified schizophrenia

0.0

Batch: Started: 10/11/2000 Stopped: 17/11/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
10/05/2001	Other data				
10/05/2001	Skin biopsy				

Additional Information:

Background included schizophrenia, type 2 diabetes and deep venous thrombosis (DVT). British Journal of dermatology 147, 1264-1281. The patient recommenced thioridazine from his own supply with recurrence of the vasculitic rash 24hrs later. Sequelae: Thigh DVT with extension above the common femoral vein.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	oa	rt	De	tai	ls:
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Case Number: 164435 Seq: 1 Gender: F

Reported: 11/05/2001 Weight: 50.00
Hospitalisation: Admitted to hospital Age: 93

Onset Date: 08/03/2001 **DOB**: 01/08/1907

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia			Patient was hospitalised. changed to olanzapine.

Medicine Details:

RAMIPRIL (Other drug)			Reason:	Essential beni	gn hypertension
	10.0	Milligram	Daily		
Batch:	Started:	I	L TERM	Stopped:	CONTIN
ATENOLOL (Other drug)			Reason:	Essential beni	gn hypertension
	50.0	Milligram	Daily		
Batch:	Started:	I	L TERM	Stopped:	CONTIN
RANITIDINE (Other drug)			Reason:		
	300.0	Milligram	Daily		
Batch:	Started:	I	L TERM	Stopped:	CONTIN
THIORIDAZINE HYDROCHLORIDE (Suspec	ted)		Reason:	Paranoia	
	100.0	Milligram	Daily		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Started:	Stiffness. Milligram	Report De Reason: Daily Reason: Daily	Caus	nder: F sight: 73.00 Age: 73 DOB: 25/05/1927 sality: Causality probable Treatment Required a visit to doctor. date of recovery 20.4.01. melleril ceased.
750.0 Started:	Milligram	Reason: Daily Reason:	Stopped:	Treatment Required a visit to doctor. date of recovery 20.4.01. melleril ceased.
750.0 Started:	Milligram	Reason: Daily Reason:	Stopped:	Required a visit to doctor. date of recovery 20.4.01. melleril ceased.
750.0 Started:	Milligram	Reason: Daily Reason:	Stopped:	Required a visit to doctor. date of recovery 20.4.01. melleril ceased.
Started:	Milligram	Daily Reason:	Stopped:	of recovery 20.4.01. melleril ceased.
Started:		Daily Reason:	Stopped:	oms
Started:		Daily Reason:	Stopped:	oms
Started:		Daily Reason:	Stopped:	oms
Started:		Reason:	Stopped:	oms
20.0	Milligram			oms
	Milligram		Menopausal sympto	oms
	Milligram	Daily		
Started:		Dany		
		Decem	Stopped:	
50.0	Milligram	Reason: Daily	Depression	
Started:	wiinigram	Dany	Stopped:	
		Reason:		
150.0	Milligram	Daily		
Started:			Stopped:	
ns:				
	sted Res	sult		Details
	Started:	าร:	Started:	Started: Stopped:

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Report Details:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

	164481	Seq: 1			Gender:	F	
Reported:	14/05/2001				Weight:	73.00	
Hospitalisation:					Age:	73	
Onset Date:	21/03/2001				DOB:	25/05/1927	
Outcome:	Recovered				Causality:	Causality probable	
Reaction Detail	ls:				_		
Medicine Deta	aile:						
ZESTRIL (Other dru				Reason:	Essential benign hypertens	sion	1
	~9 <i>)</i>	5.0	Milligram	Daily	Locolitian bornight hyportonic	5.611	
Batch:		Started:	wiiiigiaiii	Dany	Stopped:		
MELLERIL (Suspec	cted)			Bassani	оторрош.		
				Reason:			
` .	•	10.0	Milligram	Reason: Daily			
	,		Milligram	Daily	Stopped:		
Batch:	,	10.0 Started:	Milligram		Stopped:		
	,		Milligram		Stopped:		
			Milligram		Stopped:		
	, 		Milligram		Stopped:		
	, 		Milligram		Stopped:		
	<u>, </u>		Milligram		Stopped:		
	,		Milligram		Stopped:		
Batch:			Milligram		Stopped:		
			Milligram		Stopped:		
Batch:			Milligram		Stopped:		
Batch:			Milligram		Stopped:		
Batch:			Milligram		Stopped:		
Batch:			Milligram		Stopped:		
Batch:			Milligram		Stopped:		
Batch:			Milligram		Stopped:		
Batch:	vestigations:		Milligram		Stopped:		
Batch:	vestigations:		Milligram		Stopped:		
Batch:	vestigations:		Milligram		Stopped:		
Batch:	vestigations:		Milligram		Stopped:		
Batch:	vestigations:		Milligram		Stopped:		
Batch:	vestigations:		Milligram		Stopped:		

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number:165276Seq: 1Gender: MReported:12/06/2001Weight: 76.00Hospitalisation:Admitted to hospitalAge: 79

Onset Date: 19/02/2001 **DOB**: 24/11/1921

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Bp 70-90.	
Aphasia		Mutism.	
Arrhythmia		Pulse very slow and irregular.	
Neuroleptic malignant syndrome	Severe	Severe neuroleptic nalignant syndrome.	
Bradycardia			
Hypertonia			Patient was hospitalised. required a visit to doctor. reaction was life threatening. treated with baclofen 1 bd. melleril ceased.

		-	_		
M	ihد	cin	ו או	Deta	ıile:

GINKGO BILOBA (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
VITAMINS (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
TENORMIN (Other drug)		Reason:	
	25.0 Milligram	Daily	
Batch:	Started:	Stopped:	
CARTIA (Other drug)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose start date for risperdal is not accurate but indicates the drug was started sometime in the year. patient had been taking melleril 10mg regularly at 5pm instead of only prn.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 165276
 Seq: 1
 Gender:
 M

 Reported:
 12/06/2001
 Weight:
 76.00

Hospitalisation: Admitted to hospital **Age:** 79

Onset Date: 19/02/2001 **DOB**: 24/11/1921

Outcome: Recovered Causality: Causality possible

Reaction Details:

Medicine Details:

ARICEPT (Other drug)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	
FOLIC ACID (Other drug)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	
MELLERIL (Suspected)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Otr spec symp psychopathol nec	
	0.5 Milligram	Daily	
Batch:	Started: 01/01/2000	Stopped: 22/02/2001	

Laboratory Investigations:

Additional Information:

The dose start date for risperdal is not accurate but indicates the drug was started sometime in the year. patient had been taking melleril 10mg regularly at 5pm instead of only prn.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 165734
 Seq: 1
 Gender: M

 Reported:
 25/06/2001
 Weight:

Hospitalisation: Admitted to hospital Age: 65Y
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Cognitive decline	
Drug withdrawal syndrome	Required Specialist Consultation		Treated with benztropine
Dyskinesia			
Tardive dyskinesia			

Medicine Details:

THIORIDAZINE HYDROCHLO	RIDE (Suspected)	Reason:	
	0.0		
Batch:	Started:	Stopped: 28/02/2001	

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

The patient has a medical history of taking thioridazine 100mg for the past 30 years without events and was abruptly ceased. the dose stop date is not necessarily accurate but indicates thioridazine was stopped sometime in february.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

16/07/2001		ı: 1					Gender:	IVI
A 1							Weight:	
Admitted to	hospital						Age:	57Y
							DOB:	
Recovered						С	ausality:	Causality possible
ils:								
ed Term	S	everity		Repo	ort De	scription		Treatment
			Aspirati	on pneur	nonia			
			Inability	to swallo	w			
•			Mutism					
•	e incr							
abnormal								
			<u> </u>					
				Rea	son:			
		200.0	Milligram	ı	Daily			
	;	Started:				Stopped:		
ther drug)				Rea	son:			
		3.0	Milligram	I	Daily			
		Started:				Stopped:		
ATE (Other dru	g)				son:			
			Milligram	l	Daily			
		Started:						
ected)						Other&unspec		у
			Milligram	I	Daily		Oral	
	•	Started:				Stopped:		
nvestigatio	ns:							
Туре	Range	Date Tes	ted F	Result			Detail	S
formation:								
formation:								
formation:								
formation:								
	red Term chosphokinase abnormal tails: Other drug) OATE (Other drug) ected)	red Term S chosphokinase incr abnormal tails: Other drug) OATE (Other drug) ected)	tails: red Term Severity chosphokinase increation abnormal tails: Other drug) 200.0 Started: Other drug) 500.0 Started: ected) 500.0 Started: ected)	red Term Severity Aspiration Inability Mutism Started: Other drug) 200.0 Milligram Started: Other drug) 500.0 Milligram Started: Other drug)	tails: red Term Severity Report Aspiration pneur Inability to swalls Mutism thosphokinase increase abnormal Started: Other drug) Reast 3.0 Milligram Started: OATE (Other drug) Reast 500.0 Milligram Started: ected) Reast 50.0 Milligram Started:	Aspiration pneumonia Inability to swallow Mutism Aspiration pneumonia Inability to swallow Muti	red Term Severity Report Description Aspiration pneumonia Inability to swallow Mutism Aspiration pneumonia Inability to swallow Mutism Aspiration pneumonia Inability to swallow Mutism Phosphokinase increation abnormal Started: Reason: 200.0 Milligram Daily Started: Stopped: Reason: 3.0 Milligram Daily Started: Stopped: PATE (Other drug) Started: Stopped: Stopped: Reason: Other & Stopped: Stopped: Reason: Other & Stopped: Reason: Other & Stopped: Started: Stopped: Stopped: Reason: Other & Stopped: Stopped: Reason: Other & Stopped: Stopped: Stopped: Reason: Other & Stopped: Stopped: Stopped: Reason: Other & Stopped: Stopped: Stopped: Reason: Other & Stopped: Stopped: Stopped: Reason: Other & Stopped: Stopped: Stopped:	red Term Severity Report Description Aspiration pneumonia Inability to swallow Mutism Phosphokinase increation abnormal abnormal Phosphokinase increation abnormal abnormal abnormal abnormal abnormal abnormal abnormal abnorm

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:					
Case Number: 166463	Seq: 1			G	Gender: M
Reported: 16/07/2001	•			V	Veight:
lospitalisation: Admitted to hosp	ital				Age: 57Y
Onset Date:					DOB:
Outcome: Recovered				Cau	usality: Causality possible
eaction Details:					
Preferred Term	Severity		Report De	scription	Treatment
Neuroleptic malignant syndrome					Patient was hospitalised and treated with antibiotics (penicillin gentamicin and metronidazole. patient unresponsive and melleril discontinued.
Pyrexia					
Somnolence					
Tachycardia					
Tremor					
Medicine Details: LAMOTRIGINE (Other drug)		Milligram	Reason: Daily	Stornadi	
Batch: CLONAZEPAM (Other drug)	Started:		Reason:	Stopped:	
CLONAZEFAM (Other drug)	2.0	Milligram			
Batch:	Started:	Milligram	Daily	Stopped:	
SODIUM VALPROATE (Other drug)	- Claritour		Reason:	оторрош.	
ζ ζ,	500.0	Milligram	Daily		
Batch:	Started:	-		Stopped:	
MELLERIL (Suspected)			Reason:	Other&unspecifie	ed epilepsy
Tablet	50.0	Milligram	Daily	C	Oral
Batch:	Started:			Stopped:	
Laboratory Investigations:					
Additional Information:					

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Caso Number	ils:							
Case Nulliber	r: 167083	Seq:	1				Gende	er: M
Reported	i: 01/08/2001	l					Weigh	t:
ospitalisation	: Admitted to	o hospital					Ag	e: 51Y
Onset Date	20/06/2001	l					DO	B:
Outcome	: Recovered					С	ausalit	y: Causality possible
eaction Deta								
	rred Term	Se	verity	Rep	ort Desc	ription		Treatment
Confusional sta	ite							All psychotropic medications ceased. rehydration and admitted to hospital.
Drug level incre Tremor Vomiting	ased							
Medicine De				Pos	son:			
MELLEKIL (IIItei	action)		150.0 Millig		Daily			
Batch:		St	arted:	J. W	24,	Stopped:	20/06/2	001
SEROQUEL (Inte	eraction)			Rea	son:			
			200.0 Millio	gram	Daily			
Batch:		St	arted: 09/05/20	001		Stopped:	20/06/2	001
EPILIM (Interacti	ion)			Rea	son:			
			400.0 Millio	gram	Daily			
Batch:		St	arted: 13/06/20	001		Stopped:	20/06/2	001
LITHIUM CARBO	NATE (Interacti	ion)		Rea	son:			
			150.0 Millio	gram	Daily			
Batch:		Sta	arted:			Stopped:	20/06/2	001
_aboratory	Investigati	ons:						
	Туре	Range	Date Tested	Result			De	etails
Date	Type							

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	167083	Seq: 1				Gender:	M
Reported:	01/08/2001					Weight:	
Hospitalisation:	Admitted to hospi	tal				Age:	51Y
Onset Date:	20/06/2001					DOB:	
Outcome:	Recovered					Causality:	Causality possible
Reaction Detai	ils:						
Medicine Deta	aile:						
GEMFIBROZIL (Ot					Reason:	Othr&unspec metabolic di	seases
(11	3,	1.3	2 Gram		Daily		
Batch:		Started: 1			- ,	Stopped:	
RANITIDINE (Othe	r drug)				Reason:		
,	.	300.) Millig	ram	Daily		
Batch:		Started:	J		•	Stopped:	
ACICLOVIR (Other	r drug)				Reason:		
		800.) Millig	ram	Daily		
Batch:		Started:				Stopped:	
l abayatamı lı							
Laboratory in	vestigations:						
Additional Inf	formation:						

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 167730
 Seq: 1
 Gender: M

 Reported:
 20/08/2001
 Weight:

Hospitalisation: Age: 59Y
Onset Date: DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
Anaemia			
Photosensitivity reaction			
Systemic lupus erythematosus			
Systemic lupus erythematosus ras			

Medicine Details:

Medicine Details.						
FLUPHENAZINE DECANOATE	(Suspected)		Reason:	Unspecifie	ed schizophrenia	
Injection	25.0	Milligram	Fortn	ightly	Intramuscular	
Batch:	Started:			Stopp	ed:	
THIORIDAZINE HYDROCHLOR	IDE (Suspected)		Reason:	Unspecifie	ed schizophrenia	
Tablet	50.0	Milligram	Daily		Oral	
Batch:	Started:			Stopp	ed:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Erythrocyte				Esr was 60mm/hr.
	Haemoglobin				Haemoglobin 11.4gm/dl.
	Immunology				Homogeneous antinuclear factor was positive (titer, 1:20,480).
	Lymphocytes				Lymphocytes 0.5 x 10/l.
	Platelets				Platelet count was normal.
	Rheumatoid factor				Rheumatoid factor was positive.
	Skin biopsy				Cutaneous lupus erythematosus, confirmed by skin biopsy.

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 167731 Reported: 20/08/2	_					_	
Ranorted 20/08/2		: 1				Gender:	M
	2001					Weight:	50)/
spitalisation:						Age:	
Onset Date:	and the decidence				,	DOB	
Outcome: Death,	maybe drug				,	Jausanty:	Causality possible
action Details: Preferred Term	S	everity	<u> </u>	Report De	scription		Treatment
neurysm			Aortic ane				
edicine Details:							
FLUPHENAZINE DECANOA	TE (Suspected)			Reason:	Unspecified s	chizophrenia	1
Injection		25.0	Milligram	Fortni	ghtly	Intramusc	ular
Batch:	5	Started:			Stopped:		
HIORIDAZINE HYDROCHL	ORIDE (Suspected			Reason:	Unspecified s		a
Tablet	_		Milligram	Daily		Oral	
Batch: PREDNISOLONE (Suspecte		Started:		Reason:	Stopped:		
REDNISOLONE (Suspecte	u)	10.0	Milligram	Daily			
Batch:	•	Started:	wiiiigram	Daily	Stopped:		
aboratory Investig	ations:	Date Test	ed Resi	ult		Deta	ils
		Date Test	ed Resi	Chest r	radiograph follo	owed by com	ils nputed tomographic scan of cular aneurysm of the arch o

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 169641 Seq: 1 Gender: F

Reported: 05/11/2001 Weight: 52.00 Hospitalisation: Age: 67

Onset Date: 28/09/2001 DOB: 16/06/1934

Outcome: Recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diplopia			Required a visit to doctor. date of recovery: 21/10/2001.

Medicine Details:

LIPEX (Other drug)		Reason: Othr&unspec metabolic diseases	
	20.0 Milligram	Daily	
Batch:	Started:	Stopped:	
HALCION (Other drug)		Reason: Specific disorders of sleep	
	125.0 Microgram	Daily	
Batch:	Started:	Stopped:	
MELLERIL (Suspected)		Reason: Unspecified psychosis	
	25.0 Milligram	Daily	
Batch:	Started: 01/01/1998	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has sulphur allergy. the dose start date for melleril is not accurate but indicates melleril was started sometime in the year.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	po	rt	De	tai	ls	:
----	----	----	----	-----	----	---

Case Number: 172442 Seq: 1 Gender: M

Reported: 06/02/2002 Weight: 0.00
Hospitalisation: Admitted to hospital Age: 99U
Onset Date: 28/12/2001
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

•	caction Betails.				
	Preferred Term	Severity	Report Description	Treatment	l
	Neuroleptic malignant syndrome				l

Medicine Details:

modionio Botano:			
MELLERIL (Interaction)		Reason: Unspecified schizophrenia	
	0.0	Oral	
Batch:	Started:	Stopped:	
OLANZAPINE (Interaction)		Reason:	
	0.0		
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

180454 is a duplicate.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 175204
 Seq: 1
 Gender:
 F

 Reported:
 06/05/2002
 Weight:

Hospitalisation: Age: 44

Onset Date: DOB: 28/04/1958

Outcome: Unknown Causality: Causality possible

Reaction Details:

104011011 20141101			
Preferred Term	Severity	Report Description	Treatment
Retinal disorder		Retinal toxicity, pigment epithelial atrophy.	Melleril was discontinued.

Medicine Details:

Medicine Details.				
MELLERIL (Suspected)		Reason:	Unspecified schizophreni	а
Tablet	0.0		Oral	
Batch:	Started: 01/01/1994		Stopped:	
CLOZAPINE (Suspected)		Reason:	Unspecified schizophreni	а
Tablet	450.0 Milligram	Daily	Oral	
Batch:	Started: 27/07/1994		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Electrographics				Erg (an electroretinogram) showed that the patient's retina was grossly abnormal and significantly extinguished.
	Other data			The reporter stated that the patient suffered from ex retinal pigment epithelial apathy.	

Additional Information:

The dose start date for melleril is not accurate but indicates the drug was started sometime in the year.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Rep	ort	Deta	ils:
-----	-----	------	------

Case Number: 175958 Seq: 1 Gender: F
Reported: 05/06/2002 Weight:
Hospitalisation: Admitted to hospital Age:

Onset Date: 18/05/2002 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

١,	teaction Details.				
	Preferred Term	Severity	Report Description	Treatment	
	Electrocardiogram QT prolonged			Patient hospitalised.	
	Electrocardiogram abnormal				

Medicine Details:

Medicine Details.				
MELLERIL (Suspected)		Reason:		
Tablet	0.0		Oral	
Batch:	Started:		Stopped:	
CLOZAPINE (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	400.0 N	Milligram Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Electrographics				Long circuit heart conduction and an increased qt interval.

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

 Case Number:
 177675
 Seq: 1
 Gender: M

 Reported:
 06/08/2002
 Weight:
 69.00

 Hospitalisation:
 Age: 45Y

Onset Date: 28/02/2001 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

reaction Details.	T	T	
Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Profound neurocognitive symptoms	Olanzapine, diazepam.
Anxiety			
Drug withdrawal syndrome			
Insomnia			
Neurosis			
Psychotic disorder			
Urinary incontinence			

Medicine Details:

MELLERIL (Suspected)	R	Reason:			
Tablet	250.0 Milligram	Daily	Oral		
Batch:	Started:	Stopped:	28/02/2001		

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. the dose stop date is not necessarily accurate but indicates melleril was stopped sometime in the month.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Re	oa	rt	De	tai	ls:
----	----	----	----	-----	-----

 Case Number:
 180056
 Seq: 1
 Gender: M

 Reported:
 28/10/2002
 Weight:

Hospitalisation: Age: 07Y
Onset Date: 01/10/2002 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

100000000000000000000000000000000000000		•	
Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			Required a visit to doctor. managed with insulin.

Medicine Details:

Medicine Details:				
ACTRAPID (Other drug)		Reaso	on: Diabetes mel	litus
	0.0			
Batch:	Started:	L TERM	Stopped:	CONTIN
MELLERIL (Suspected)		Reaso	on: Behavior disc	orders of childhod
Tablet	20.0	Milligram I	Daily	Oral
Batch:	Started: 01/	10/2002	Stopped:	CONTIN

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ		Serum glucose			Bgl stabe 4-10 - bgl increased to 18-20.	

Additional Information:

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Case Number: 180797

Reported: 18/12/2002

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Weight: 85.00

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Hospitalisation: Hospitalisation prolonged		Age : 73			
Onset Date: 16/10/2002		DOB : 02/02/1929			
Outcome: Unknown			Causali	ty: Causality possible	
action Details:	0	D	Na a a sha li a a	T t	
Preferred Term emor	Severity Severe	was previously on th	Nov 2001, ceased due	Treatment Thioridazine and Trifluoperazine ceased. Admitted to hospital.	
edicine Details:	DE (Suspected)	Reason:			
Tablet	,		Oral		
Batch:	Started:		Stopped:		
RIFLUOPERAZINE HYDROCHL	ORIDE (Suspected)	Reason:			
Batch:	Started:		Stopped:		
aboratory Investigation	ONS: Range Date Tes	ted Result	D	etails	
dditional Information	:				



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

D۵		Date	ila.
Κŧ	มบาเ	Deta	แเร.

Gender: M Case Number: 181463 Seq: 1 Reported: 13/01/2003 Weight: 0.00 Hospitalisation: Admitted to hospital **Age:** 38Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
		Hepatic Function Abnormal and Hyperkalaemia	
		haemorrhage	Fluids and insulin were administered, Thioridazine was discontinued.
	Caused or prolonged inpatient hospitalisation		

Medicine Details:

THIORIDAZINE HYDROCHLORI	DE (Suspected)	Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
13/01/2003	ALT = SGPT	(>30)			
13/01/2003	Creatinine	(rr0.06-0.12)			
13/01/2003	GGT = SGGT =	(>35)			
13/01/2003	Immunology				
13/01/2003	Potassium	(RR 3-5-5.0)			
13/01/2003	SAP = ALP	(30-100)			
13/01/2003	Serum glucose				

Additional Information:

Blood osmolarity increased. History diabetes mellitus non-insulin-dependent.

The patient recommenced thiaridazine from his own supply with recourrence of the vasculitis rash 24 hours later.

24D. Report Source Literature

Journal: British Journal of Dermatology
Author: Greenfield JR, McGrath M, Kossard S, Charlesworth JA, Campbell LV. Title: ANCA-postive vasculitis induced by thioridazine: confirmed by rechallenge.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 181463 Reported: 13/01/2003 Hospitalisation: Admitted to hospi Onset Date:			1		Gender: M Weight: 0.00 Age: 38Y DOB:		
Outco	me: Unknown					ty: Causality certain	
Reaction D							
Preferred Term			verity	Repoi	t Description	Treatment	
Gastrointes	tinal haemorrha	prolon inpatie	ged				
Hyperglycae	emia	Cause prolon inpatie hospit	ged				
Hyperkalaei	mia	Cause prolon inpatie hospit	ged				
Medicine THIORIDAZI	Details: NE HYDROCHLOR	RIDE (Suspected)	Reas	on:		
Bate	ch:	St	arted:		Stopped:		
Laborato	ry Investigat	ions:					
Date	Туре	Range	Date Tested	Result	D	etails	
13/01/2003	Sodium	(137-146)					
13/01/2003	Urea	(3.0-8.5)					
	Urine osmolality	(RR 275-295)					
13/01/2003	White blood cells						

Additional Information:

Blood osmolarity increased. History diabetes mellitus non-insulin-dependent.

The patient recommenced thiaridazine from his own supply with recourrence of the vasculitis rash 24 hours later.

24D. Report Source Literature
Journal:British Journal of Dermatology
Author: Greenfield JR, McGrath M, Kossard S, Charlesworth JA, Campbell LV. Title: ANCA-postive vasculitis induced by thioridazine: confirmed by rechallenge.

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 181463	Seq: 1	Gen	der: M		
Reported: 13/01/2003		Weig	ght: 0.00		
Hospitalisation: Admitted to h	nospital	A	Age: 38Y		
Onset Date:		D	DOB:		
Outcome: Unknown		Causa	lity: Causality certain		
leaction Details:					
Preferred Term	Severity	Report Description	Treatment		
Ketoacidosis	Caused or prolonged inpatient hospitalisation				
Leukocytoclastic vasculitis	Caused or prolonged inpatient hospitalisation				
Leukocytosis	Caused or prolonged inpatient hospitalisation				
Medicine Details: THIORIDAZINE HYDROCHLORIDE	(Suspected)	Reason:			
Batch:	Started:	Stopped:			
Laboratory Investigation	15:				

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Blood osmolarity increased. History diabetes mellitus non-insulin-dependent. The patient recommenced thiaridazine from his own supply with reccurrence of the vasculitis rash 24 hours later.

24D. Report Source Literature
Journal:British Journal of Dermatology
Author: Greenfield JR, McGrath M, Kossard S, Charlesworth JA, Campbell LV.
Title: ANCA-postive vasculitis induced by thioridazine: confirmed by rechallenge.



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

ospital	Gender: M Weight: 0.00 Age: 38Y DOB: Causality: Causality certain		
Severity	Report Description	Treatment	
Caused or prolonged inpatient hospitalisation	Report Description	rreaument	
Caused or prolonged inpatient hospitalisation			
Suspected)	Reason:		
Started:	Stopped:		
٥٠			
s:			
	Severity Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation	Severity Report Description Caused or prolonged inpatient hospitalisation Caused or prolonged inpatient hospitalisation Suspected) Reason: Started: Stopped:	

Additional Information:

Blood osmolarity increased. History diabetes mellitus non-insulin-dependent.

The patient recommenced thiaridazine from his own supply with recourrence of the vasculitis rash 24 hours later.

24D. Report Source Literature
Journal:British Journal of Dermatology
Author: Greenfield JR, McGrath M, Kossard S, Charlesworth JA, Campbell LV. Title: ANCA-postive vasculitis induced by thioridazine: confirmed by rechallenge.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report D	Details:
----------	----------

 Case Number:
 181670
 Seq: 1
 Gender:
 F

 Reported:
 15/01/2003
 Weight:
 0.00

 Hospitalisation:
 Age: 72

Onset Date: 11/12/2002 **DOB**: 01/11/1930

Outcome: Unknown Causality: Causality possible

Reaction Details:

todotion Botano.			
Preferred Term	Severity	Report Description	Treatment
Renal impairment		Renal function medically significant abnormal, hypotensive	
Hypotension			

Medicine Details:

Medicine Details:			
SODIUM VALPROATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
MELLERIL (Suspected)		Reason:	
Tablet	275.0 Milligram	Daily Oral	
Batch:	Started: 23/10/2002	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/01/2003	Creatinine				
15/01/2003	Urea		11/12/2002	20.4	
15/01/2003	Urea		11/12/2002	0.23	

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 182478 Seq: 1 Gender: F

Reported: 06/02/2003 Weight: 0.00 Hospitalisation: Age: 22Y

Onset Date: 17/04/2000 DOB:

Outcome: Death Causality: Causality possible

Reaction Details:

teaction Betails.			
Preferred Term	Severity	Report Description	Treatment
Arrhythmia		_ ,	Post mortem conducted on 18/04/2000
Death		Arrhythmia, ventricular fibrilation, drug toxicity, and death.	Post mortem conducted on 18/04/2000
Ventricular fibrillation	Life threatening		

Medicine Details:

THIORIDAZINE HYDROCHLOR	RIDE (Suspected)		Reason:	
Tablet	300.0	Milligram	Daily	Oral
Batch:	Started:			Stopped:

Laboratory Investigations:

	. <u>,</u>				
Date	Туре	Range	Date Tested	Result	Details
06/02/2003	Creatine	(0.05 - 5mg/L)	18/04/2000	1.5	
06/02/2003	Creatine	(0.05 - 5mg/L)	18/04/2000	2.3	
06/02/2003	Creatine	(0.05 - 5mg/L)	18/04/2000	0.1	

Additional Information:

There were no suspicious circumstances. The coroner's formal finding on 04/02/03 stated the sole cause of death as 'toxic effects of Thioridazine'. Other drugs - Sertraline, Diazepam, Nystatin, Clotrimazole, Clonazepam, Paracetamol and Chlorpromazine. The patient experienced cardiac arrythmia and then ventricular fibrillation on 17/04/03 and the outcome was death. The dose of thioridazine was not inappropriate or excessive.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:		
Case Number: 194448	Seq: 1	Gender: F
Reported: 09/02/2004		Weight: 0.00

Hospitalisation: Age: 37Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Visual acuity reduced	Coverny	Impaired driving ability,	riodanone
Retinopathy		Retinopathy, Vitreous floaters, acquired night blindness, visual acuity reduced, retinal depigmentation, chorioretinal atrophy, pupillary reflex impaired.	
Chorioretinal atrophy Night blindness Pupillary reflex impaired Retinal depigmentation Vitreous floaters			

Medicine Details:

CARBAMAZEPINE (Other dru	g)		Reason:		
Batch:	Started:			Stopped:	
THIORIDAZINE HYDROCHLO	RIDE (Suspected)		Reason:		
Tablet	900.0	Milligram	Daily	Oral	
Batch:	Started:			Stopped:	4 months

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
09/02/2004	Other data				

Additional Information:

Four months later her vision had improved sufficiently to allow her to drive again. Unfortunately, she remains visually disabled at night. Clinical and Experimental Ophthalmology 2003; 31: 533-544.

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Case Number: 195845

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

	: 23/03/2004					_	t: 0.00	
lospitalisation			Age : 69Y					
Onset Date			DOB:					
	Recovered		Causality: Causality possible					
eaction Deta	a with .	Don	ant Daganint	I	Tractment			
	red Term	Se	verity		ort Descript		Treatment	
Akathisia Medication erro	kathisia			Moderate akathisia, medication error.				
Madiaina Da	toilo:							
Medicine De MELLERIL (Susp				Rea	son:			
Tablet	,		Dose Unspecified Oral					
Batch:		Sf	tarted:	L TERM	Si	topped:	8 years	
Laboratory I		O NS: Range	Date Tested	Result		D/	etails	
Date	Туре	Range	Date Testeu	Result		De	talls	
Additional Ir	nformation	:						
eport Run: 01/06/2	007 02:47PM	Database: pu	usime02	P	ADRS004		Page 381 of 393	



Case Number: 196864

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Reported: 29/04	./2004			Weigl	nt: 0.00		
lospitalisation:				Ag	je : 46		
Onset Date:		DOB : 17/12/1957					
Outcome: Not y	et recovered		Causality: Causality possible				
eaction Details:							
Preferred Ter	m S	everity		Description	Treatment		
Tardive dyskinesia		Tai	rdive dyskinesia				
Medicine Details:							
MELLERIL (Suspected)			Reaso	·			
			se Unspecified	Oral			
Batch:		Started:		Stopped:			
Laboratory Invest	igations:						
Date Type	Range	Date Tested	Result	D	etails		
Additional Informa	ation:						
eport Run: 01/06/2007 02	:47PM Database: p	usime02	ADF	RS004	Page 382 of 393		



Case Number: 202679

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Seq: 1

Reported: 18/11/20	04		Weight: 0.00			
Hospitalisation: Admitted	I to hospital	Age : 48				
Onset Date:		DOB:				
Outcome: Unrelate	d death	Ca	ausality: Causality possible			
teaction Details:						
Preferred Term	Severity	Report Description	Treatment			
Bronchopneumonia	Caused or prolonged inpatient hospitalisation	Patient died of bronchopneumonia.				
Medicine Details:						
THIORIDAZINE HYDROCHLO	RIDE (Suspected)	Reason:				
Tablet			Oral			
Batch:	Started:	Stopped:				
Laboratory Investiga						
Date Type	Range Date Teste	ed Result	Details			
Additional Information	on:					
eport Run: 01/06/2007 02:47F	M Database: pusime02	ADRS004	Page 383 of 393			



Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Danart Data:				
Report Detail	s:			
Case Number:	207600	Seq: 1	Gende	er: F
Reported:	04/05/2005		Weigh	t : 0.00
ospitalisation:			Ag	e: 0
Onset Date:	01/08/2002		DO	B : 01/05/2002
Outcome:	Death, maybe dr	ug	01/08/2002 Causalit	y: Causality possible
eaction Detai	ils:			
Preferre	ed Term	Severity	Report Description	Treatment
Orug exposure d	uring pregnancy	Death	Sudden infant death syndrome, mother on Thioridazine for schizophrenia.	
Sudden infant de	ath syndrome	Death		
Medicine Det	ails:			
	DROCHLORIDE (Sus	spected)	Reason: Unspecified schizophre	nia
Tablet			Oral	
Batch:		Started:	Stopped:	
Laboratory In	nvestigations: Type Rar	ige Date Test	ed Result De	etails

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 207812 Seq: 1 Gender: M

Reported: 13/05/2005 Weight: 0.00 Hospitalisation: Age: 27Y

Onset Date: 29/09/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

100.00.00.			
Preferred Term	Severity	Report Description	Treatment
Akathisia		The patient experienced akathisia and anxiety.	Risperidone ceased.
Anxiety			
Therapy regimen changed			

Medicine Details:

TEMAZEPAM (Other drug)		Reason:	
	20.0 Milligram	Daily	Oral
Batch:	Started: 29/09/1998	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified so	chizophrenia
	500.0 Microgram	Daily	Oral
Batch:	Started: 04/09/1998	Stopped:	06/10/1998
THIORIDAZINE HYDROCHLORIDE (Suspect	ted)	Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 29/09/1998	Stopped:	0
PROCYCLIDINE HYDROCHLORIDE (Suspec	cted)	Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 29/09/1998	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Clinical Trial RODOS WAVEI: RODOS Report 207816 is the second sequence to this report. Patient on variable dose of Risperdal from 0.5 mg to 6 mg

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:

Case Number: 207816 Seq: 1 Gender: M

Reported: 13/05/2005 Weight: 0.00 Hospitalisation: Age: 25Y

Onset Date: 23/11/1996 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

reaction Details.			
Preferred Term	Severity	Report Description	Treatment
	Caused or prolonged inpatient hospitalisation		Given Cogentin 4mg daily.

Medicine Details:

DIAZEPAM (Other drug) Reason:

15.0 Milligram

Batch: Started: 23/11/1996 Stopped:

THIORIDAZINE HYDROCHLORIDE (Suspected)

Tablet

Batch: Started: Stopped: Contin

Reason:

Oral

RISPERDAL (Suspected) Reason: Unspecified schizophrenia

Tablet 12.0 Milligram Daily Oral

Batch: Started: Stopped: 0

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Clinical Trial RODOS WAVE I: RODOS Report 207812 is the first sequence to this report.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

0 N	etails:					
		Seq:	1			t: 63.00 e: 21Y
Outco	ome: Death, may	ybe drug			Causalit	y: Causality possible
eaction E						
	referred Term		verity	•	ort Description	Treatment
Completed	suicide	Death	Co	mpleted suic	ide, overdose, drug toxicity.	
Orug toxicit	у	Death Death				
<u>/ledicine</u> AROPAX (S	Details:			Ros	ason:	
ANOFAX (3	uspecieu)			Nec	Oral	
Bat	ch:	Sta	arted:		Stopped:	
	EDINE (O					
CARBAMAZ	ZEPINE (Suspected)			Rea	ason:	
		01		Rea	ason:	
Bat	ch:		arted:		oral Stopped:	
Bat	ch: INE HYDROCHLORII				ason:	
Bat THIORIDAZI	ch: INE HYDROCHLORII	DE (Suspected)			Stopped:	
Bat THIORIDAZI Tabl	ch: INE HYDROCHLORII let ch:	DE (Suspected)		Rea	Stopped: Oral Stopped: Oral	
Bat THIORIDAZI Tabl Bat ALCOHOL (ch: INE HYDROCHLORII let ch:	DE (Suspected)		Rea	Stopped: Oral Stopped: Oral Stopped:	
Bat THIORIDAZI Tabl Bat ALCOHOL (ch: INE HYDROCHLORII let ch: Suspected) I Liquid	DE (Suspected) Sta		Rea	Stopped: Oral Stopped: Oral Stopped:	0
Bat THIORIDAZI Tabl Bat ALCOHOL (Oral Bat	ch: INE HYDROCHLORII let ch: Suspected) I Liquid ch:	DE (Suspected) Sta	arted:	Rea	Stopped: Oral Stopped: Oral Stopped: Oral Oral Oral Oral	0
Bat THIORIDAZI Tabl Bat ALCOHOL (Oral Bat	ch: INE HYDROCHLORII let ch: Suspected) I Liquid	DE (Suspected) Sta Sta	arted:	Rea	Stopped: Oral Stopped: Oral Stopped: Oral Stopped: Oral Stopped:	ıtails

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Detail	s:						
Case Number:	208539	Seq: 1				Gender	F
Reported:	07/06/2005	•				Weight:	63.00
Hospitalisation:						_	21Y
Onset Date:						DOB	:
Outcome:	Death, maybe dru	ıg				Causality	Causality possible
Reaction Detai	ils:						
Medicine Det							
LAMICTAL (Suspe	ected)			Reas		Other&unspecified epilep	sy
Tablet			0 Milligram		Daily	Oral	
Batch:		Started:		L TERM		Stopped:	0
Laboratory In	vestigations:						
	gao						
A 1 1141							
Additional Int		o for over the	o vooro co	d was tal	ina c	docada of 600ma/days	at the time of death layered
of Forensic Science Drummer, Ken Op	r been on lamounging res - Postmortem Inv	o ioi over tille	e years an	u was lak	my a	uusaye oi buumg/day a	t the time of death. Journal
		estigation of t	₋amotrigine	e Concen	tration	ıs, Maria G. Pricone, Cl	nristopher V. King, Olaf H.

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:					
Case Number: 209810 Reported: 13/07/2005	Seq: 1		_	nt: 0.00	
Hospitalisation: Onset Date: 21/04/2005	:		je: 29 DB: 26/03/1976		
Outcome: Recovered				ty: Causality possible	
Reaction Details:				ty. Caddanty possible	
Preferred Term	Severity	Repo	ort Description	Treatment	
Drug withdrawal syndrome	ability www.s	hich included h vithdrawn form I peech and com eteriorated grea	ced withdrawal symptoms allucinations after being Meleril. 28/04/2005. Her muniction skills had atly, she found difficulty word and tended to stutter	Seroquel	
Regressive behaviour	ability was	She went from a very competnet person with good life skills to a child of approximate 4 years of age. She experienced loss of social skills and confidence.27/06/2005.			
Medicine Details: SERENACE (Other drug)		Reas	con		
SERENACE (Other drug)		Reas	son:		
Batch:	Started:		Stopped:		
TEGRETOL (Other drug)		Reas	son:		
Batch:	Started:		Stopped:		
EPILIM (Other drug)		Reas	son:		
Batch:	Started:		Stopped:		
MELLERIL (Suspected)		Reas			
Tablet			Oral		
Batch:	Started:		Stopped : 15/05/2	2005 0	
Laboratory Investigation	ons:				
Date Type	Range Date Tested	Result	D	etails	
Additional Information PMHx: congenital central nervo					

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 209810 Reported: 13/07/200 Hospitalisation: Onset Date: 21/04/200 Outcome: Recovered Reaction Details:	05		Gender: F Weight: 0.00 Age: 29 DOB: 26/03/1 Causality: Causal	
Preferred Term	Severity	Report Description	T	reatment
Anxiety	Incapacity/dis ability			
Disturbance in attention	Incapacity/dis ability			
Hallucination				
Speech disorder	Incapacity/dis ability			
Weight decreased	Incapacity/dis ability			
Medicine Details: SERENACE (Other drug)		Reason:		
Batch:	Started:	Stopped	:	
TEGRETOL (Other drug)		Reason:		
Batch:	Started:	Stopped	:	
EPILIM (Other drug)		Reason:		
Batch:	Started:	Stopped	:	
MELLERIL (Suspected)		Reason:		
Tablet			Oral	
Batch:	Started:	Stopped	: 15/05/2005 0	
Laboratory Investiga	tions:			
Additional Information PMHx: congenital central ner				

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Report Details:	
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Case Number: 211188 Seq: 1 Gender: M
Reported: 30/08/2005 Weight: 0.00

Age: 18

Hospitalisation: Age: 18

Onset Date: 30/06/2000 DOB: 28/05/1982
Outcome: Recovered Causality: Causality probable

Reaction Details:

Cachon Details.			
Preferred Term	Severity	Report Description	Treatment
Ophthalmoplegia		Patient developed muscular stiffness, particularly of the jaw, rigidity, drooling, inability to speak, frozen stiff, even frozen eye balls 6 hours after the 3rd dose.	
Drooling			
Joint stiffness			
Muscle rigidity			
Musculoskeletal stiffness			

Medicine Details:

THIORIDAZINE HYDROCHLORIDE	(Suspected)	Reason:	Unspecified schizophrenia	
Tablet	600.0 Milligram	Daily	Oral	
Batch:	Started: 28/06/2000		Stopped: 30/06/2000	0

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
ĺ						

Additional Information:

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Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number: 212	ノロんン	Sea. 1			(₇ Dnn	or. E
Reported: 28/		Seq: 1	Gender: F Weight: 70.00			
ospitalisation:	03/2003				•	ge: 56
Onset Date: 01/	09/2005					DB : 29/01/1949
Outcome: Not		ed	Ca			ity: Causality possible
eaction Details:	.,	-			- 0.0.0 0	
	Preferred Term Severity		Repo	ort Description		Treatment
/lusculoskeletal stiffr	ness				Ceased all medication, ICU.	
Agitation						
Clonus						
lyperhidrosis						
Hypertonia						
Serotonin syndrome						
Medicine Details OLANZAPINE (Suspect			Rea	son: Manic-depres	ssion psy	cho,manic
ledicine Details		Started: 18		son: Manic-depres		
Medicine Details OLANZAPINE (Suspec	ted)			Stopped		
fledicine Details OLANZAPINE (Suspect	ted)		/08/2005	Stopped	08/09/2	2005
Medicine Details OLANZAPINE (Suspect Batch: DOXEPIN HYDROCHLO	ted) ORIDE (Suspect	ed) Started:	/08/2005	Stopped:	08/09/2	2005
Medicine Details OLANZAPINE (Suspect Batch: DOXEPIN HYDROCHLO Batch: AMITRIPTYLINE HYDR	DRIDE (Suspect	ed) Started:	//08/2005 Rea Rea	Stopped: Stopped: Stopped: Stopped:	08/09/2	2005
Medicine Details OLANZAPINE (Suspect Batch: DOXEPIN HYDROCHLO Batch: AMITRIPTYLINE HYDR	DRIDE (Suspect	ed) Started: uspected)	/08/2005 Rea	Stopped: Stopped: Stopped: Stopped:	08/09/2	2005
Medicine Details OLANZAPINE (Suspect Batch: DOXEPIN HYDROCHLO Batch: AMITRIPTYLINE HYDR	DRIDE (Suspect	ed) Started: uspected)	//08/2005 Rea Rea	Stopped: Stopped: Stopped: Stopped:	08/09/2 08/09/2 08/09/2	2005 2005 2005
Medicine Details OLANZAPINE (Suspect Batch: DOXEPIN HYDROCHLO Batch: AMITRIPTYLINE HYDR Batch: MELLERIL (Suspected)	ORIDE (Suspect	Started: uspected) Started: Started:	//08/2005 Rea Rea	Stopped: Stopped: Stopped: Stopped:	08/09/2 08/09/2 08/09/2	2005 2005 2005
Medicine Details OLANZAPINE (Suspect Batch: DOXEPIN HYDROCHLO Batch: AMITRIPTYLINE HYDR Batch: MELLERIL (Suspected)	ORIDE (Suspect	Started: uspected) Started: Started:	Rea	Stopped: Stopped: Stopped: Stopped:	08/09/2 08/09/2 08/09/2	2005 2005 2005

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 14 Jun 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: ALDAZINE,MELLERIL,THIORIDAZINE HYDROCHLORIDE

Case Number:	212062	Seq: 1		Gender:	F
Reported:	28/09/2005			Weight:	70.00
Hospitalisation:				Age:	
Onset Date:	01/09/2005			DOB:	29/01/1949
Outcome:	Not yet recovered	I		Causality:	Causality possible
Reaction Detai	ls:				
Medicine Deta	ails:				
RISPERIDONE (Su			Reason:	Otr spec symp psychopati	nol nec
,					
Batch:		Started: 28/08/2005		Stopped: 08/09/2009	5
LITHIUM CARBON	ATE (Suspected)		Reason:	Manic-depression psycho	manic
Tablet		1.0 Gram	Daily	Oral	
Batch:		Started: 18/08/2005		Stopped: 08/09/2009	5 0
Laboratory In	vestigations:				
•	3				
Additional las	iormation:				
Additional Inf	ormation:				
Additional Inf	ormation:				
Additional Inf	ormation:				
Additional Inf	formation:				
Additional Inf	ormation:				

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