

Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

**Report Details:** 

Case Number: 2623 Seq: 1 Gender: M

Reported: 22/05/1991 Weight:

Hospitalisation: Age: 59Y
Onset Date: 22/04/1991
DOB:

Onset Date: 22/04/1991

Outcome: Recovered

Causality: Causality probable

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

#### **Medicine Details:**

PIMOZIDE (Suspected) Reason: Unspecified psychosis

Tablet 2.0 Milligram Daily Oral

Batch: Started: 22/04/1991 Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Case Sequenced to: 70947/2

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Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

**Report Details:** 

Case Number: 70252 Seq: 1 Gender: F

Reported: 28/03/1991 Weight: 43.00 Hospitalisation: Age: 25

Onset Date: DOB: 23/02/1966

Outcome: Unknown Causality: Causality probable

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal			

#### **Medicine Details:**

PIMOZIDE (Suspected) Reason: Unspecified schizophrenia

4.0 Milligram Daily

**Batch: Started:** 01/11/1990 **Stopped:** 28/03/1991

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details
	Electrographics				19/3/91-sinus rhythm 100/min. st-t wave changes in inferior leads are abnormal. mild st segment depression in v3-v6 and lead i.

#### **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: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

Report Details.	Report	Details:
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Case Number:82668Seq:1Gender:FReported:18/02/1993Weight:Hospitalisation:Age:Onset Date:DOB:

Outcome: Not yet recovered Causality: Causality possible

#### Reaction Details:

•	<del></del>			
	Preferred Term	Severity	Report Description	Treatment
	Polydactyly			

#### Medicine Details:

vieuicine Details.		
MODECATE (Suspected)		Reason: Unspecified schizophrenia
	0.0	
Batch:	Started:	Stopped:
SERENACE (Suspected)		Reason: Unspecified schizophrenia
	0.0	
Batch:	Started:	Stopped:
PIMOZIDE (Suspected)		Reason: Unspecified schizophrenia
	0.0	
Batch:	Started:	Stopped:

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Bilateral bifid thumbs (complete polydactyly thumbs) of baby of mother with past history of schizophrenia on these medications prior to pregnancy. no treatment during pregnancy.

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Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

**Report Details:** 

Case Number: 91064 Seq: 1 Gender: F
Reported: 14/02/1994 Weight:
Hospitalisation: Age: 20Y

**Onset Date**: 29/01/1994 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Amenorrhoea			
Breast pain			
Galactorrhoea			
Hyperprolactinaemia			
Nausea			
Vertigo			
Vomiting			

# **Medicine Details:**

Γ	ORAP (Suspected)		Reason:	Unspecified neurosis
	Tablet	5.0 Milligram	Daily	Oral
	Batch:	Started:		Stopped:

**Laboratory Investigations:** 

ate	Туре	Range	Date Tested	Result	Details
	Prolactin	<500			739

# **Additional Information:**

Patient had been on orap 4mg daily for several months. symptoms began about 1 week after increasing the dose

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Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

Re	port	Detai	ls:
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Case Number: 93125 Seq: 1 Gender: F

Reported: 17/05/1994 Weight:
Hospitalisation: Age: 61

**Onset Date**: 18/11/1993 **DOB**: 02/10/1932

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

•	todotion Botanoi				
	Preferred Term	Severity	Report Description	Treatment	
	Hypertension				l

# **Medicine Details:**

CLONAZEPAM (Suspected)	F		
	500.0 Microgram	As necessary	
Batch:	Started: 09/11/1993	Stopped:	CONTIN
PHENELZINE SULPHATE (Suspected)	F	Reason:	
	30.0 Milligram	Daily	
Batch:	Started:	Stopped: 0	02/11/1993
PHENELZINE SULPHATE (Suspected)	F	Reason:	
	30.0 Milligram	Daily	
Batch:	Started: 16/11/1993	Stopped:	CONTIN
PIMOZIDE (Suspected)	F	Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 03/11/1993	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: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

-		07/44/40/		4. '						Jer. IVI
senitalicati.		07/11/199							Weig	
-			to hospital							ge: 74Y
		05/10/199						_		OB:
		Recovere	∌d					С	ausal	ity: Causality possible
eaction Do					1					T + , ,
	eterre	ed Term	<del></del>	Severity	+	Кер	ort Desc	cription		Treatment
Asthenia										
Dystonia Fatigue										Commenced cogentin.
atigue										Commenced cogenium.
<i>l</i> ledicine l	Dots	aile:								
ISOSORBIDE			ner drug)			Rea	son:			
Table	t			30.0	Milligr	am			Oral	
Batch	h:			Started:	-			Stopped:		CONTIN
SIMVASTATIN	۱ (Otl	ner drug)				Rea	son:			
Table	t			10.0	Milligr	am	Daily		Oral	
Batch	h:			Started:				Stopped:		CONTIN
VERAPAMIL I	HYDF	OCHLORIE	DE (Other drug)	)		Rea	son:			
				240.0	Milligr	am	Daily			
Batch	h:			Started:				Stopped:		CONTIN
OXAZEPAM (	Othe	r drug)				Rea	son:			_
				15.0	Milligr	am	Daily			
D =4 - F	h:			Started:				Stopped:		CONTIN
Batch										
	v In	vaetina	tione:							
aborator		vestiga <sub>Type</sub>	tions: Range	Date Tes	ted	Result				Details

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

		Seq: 1		Gender:	
Reported:	07/11/1994			Weight:	
	Admitted to hospi	tal			74Y
Onset Date:	05/10/1994			DOB	
Outcome:	Recovered			Causality:	Causality possible
action Detail	s:				
ledicine Deta	ils:				
ORAP (Suspected)			Reason:		
Tablet		2.0 Milligram	Daily	Oral	
Batch:		Started: 28/09/1994	•	Stopped: 05/10/199	4
aboratory Inv	vestigations:				
aboratory In	vestigations:				
aboratory Inv	vestigations:				
aboratory In	vestigations:				
aboratory In	vestigations:				
aboratory Inv	vestigations:				
aboratory Inv	vestigations:				
aboratory In	vestigations:				
aboratory Inv					

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Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

Rei	port	Detail	ls:

Case Number: 97782 Seq: 1 Gender: M

Reported: 13/12/1994 Weight: 56.00 Hospitalisation: Age: 49Y

**Onset Date**: 22/06/1994 **DOB**:

Outcome: Recovered Causality: Causality possible

#### Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			

# **Medicine Details:**

DAPSONE (Other drug)		Reason: Aids	
Tablet	100.0 Milligram	Daily Oral	
Batch:	Started: 07/05/1994	Stopped:	
ZALCITABINE (Other drug)		Reason: Aids	
Tablet	2.2 Milligram	Daily Oral	
Batch:	Started:	Stopped:	
CLARITHROMYCIN (Other drug)		Reason: Aids	
Tablet	2.0 Gram	Daily Oral	
Batch:	Started: 26/05/1994	Stopped:	
RIFABUTIN (Other drug)		Danas Alala	
KIFABOTIN (Other drug)		Reason: Aids	
Oral application	300.0 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: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

Case Number:	97782	Seq: 1			Gender:	M
Reported:	13/12/1994				Weight:	56.00
Hospitalisation:					Age:	49Y
Onset Date:	22/06/1994				DOB:	
Outcome:	Recovered			С	ausality:	Causality possible
Reaction Detai	ils:					
<b>Medicine Det</b>	ails:					
BENZYLPENICILL			Reason:			
Injection		24.0 Million Intern	nation: Daily		Intravenous	S
Batch:		Started: 13/06/1994		Stopped:	22/06/1994	1
PIMOZIDE (Suspe	cted)		Reason:	Unspecified ps		
		4.0 Milligram	Daily			
Batch:		Started: 18/06/1994		Stopped:	22/06/1994	1
Laboratory In	vestigations:					
	_					
Additional In	formation:					
		hasa: nusima02	VDD600			Dono O of OO

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Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

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

 Case Number:
 100714
 Seq: 1
 Gender:
 F

 Reported:
 08/05/1995
 Weight:
 56.00

Hospitalisation:
Onset Date: 01/03/1995
Age: 21Y
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia			

# **Medicine Details:**

AROPAX (Suspected)		Reason: Dep	pression
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 13/01/1995		Stopped:
AROPAX (Suspected)		Reason: Dep	pression
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 01/03/1995		<b>Stopped:</b> 05/04/1995
COGENTIN (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 16/08/1994		Stopped:
LITHUM CADDONATE (Cuere esteet)		Danasani	
LITHIUM CARBONATE (Suspected)		Reason:	
Tablet	1.0 Gram	Reason: 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: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

THIORIDAZINE HYDROCHLORIDE (Suspecte	4.0 Milligram Started: 20/10/1994 ed)	Reason: Daily Reason:	Oral Stopped:	
Batch:	200.0 Milligram <b>Started:</b> 07/12/1992	Daily	Oral Stopped:	
aboratory Investigations:				
dditional Information:				

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Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

**Report Details:** 

 Case Number:
 119037
 Seq: 1
 Gender:
 F

 Reported:
 14/07/1997
 Weight:

Hospitalisation: Admitted to hospital Age: 93Y
Onset Date: 19/06/1997
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

#### Medicine Details:

Medicine Details.			
AURORIX (Other drug)	Reason	: Depression	
Tablet	600.0 Milligram Da	aily	Oral
Batch:	Started: 01/11/1996	Stopped:	
ORAP (Suspected)	Reasor	: Hallucinations	•
Tablet	2.0 Dose Unspecified Da	aily	Oral
Batch:	Started: 05/06/1997	Stopped:	19/06/1997

**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: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

**Report Details:** 

Case Number: 121288 Seq: 1 Gender: F

Reported: 02/10/1997 Weight: 70.00 Hospitalisation: Age: 71Y

Onset Date: 31/07/1997 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Marked parkinsonium side effects	

#### **Medicine Details:**

ATENOLOL (Other drug)		Reaso	n:	Essential benign hypertension	
Oral application	25.0	Milligram [	Daily	Oral	
Batch:	Started:			Stopped:	
APRINOX (Other drug)		Reaso	n:	Essential benign hypertension	
Tablet	5.0	Milligram [	Daily	Oral	
Batch:	Started:			Stopped:	
SLOW-K (Other drug)		Reaso	n:	Essential benign hypertension	
Tablet	1.0	Dose Unspecified [	Daily	Oral	
Batch:	Started:			Stopped:	
PIMOZIDE (Suspected)		Reaso	n:		
	2.0	Milligram [	Daily		
Batch:	Started:			Stopped:	

**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: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

Case Numb	<b>er</b> : 1	23039	Seq:	. 1				Gende		
_		3/12/199	7					Weight		
spitalisatio								_	: 73Y	
Onset Da			7					DOE		
		Jnknown					C	ausality	: Causality possi	ble
ction De										
	ferrec	d Term	Se	everity	Rep	ort Des	cription		Treatmen	
Illucination								P s <sup>i</sup>	imozide ceased, ola tarted.	anzapine
edicine <b>E</b>										
NEMET (Oth		g)		5.5 D		son:		01		
Tablet			c		se Unspecified	Daily	Ctonnod:	Oral	CONTINI	
Batch		o d\	5	tarted:	Doo		Stopped:		CONTIN	
IMOZIDE (Su	specie	∌u)		0.0	Rea	son:				
Batch	1:		s	tarted:			Stopped:	25/09/19	97	
		4.	i							
boratory Date		yestigati Type	Range	Date Tested	Result	<u> </u>		Det	ails	
Date		урс	range	Date rested	resuit			DC	ano	
						<u>.                                    </u>				
ditional	Info	rmatior	1:							
		-								
rt Run: 04/06	3/2007	12:07PM	Database: pı	usime02	A	ADRS004	ļ		Page 14	of 22



Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

**Report Details:** 

Case Number: 135192 Seq: 1 Gender: F

Reported: 18/01/1999 Weight: 82.00 Hospitalisation: Age: 38Y

**Onset Date**: 23/12/1998 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

•	toaction Botailei			
	Preferred Term	Severity	Report Description	Treatment
	Pain			Quinine given & reduced pelvic floor exercises.
	Muscle spasms			

#### **Medicine Details:**

EFEXOR (Other drug)	1	Reason: Depre	ession		
	375.0 Milligram	Daily			
Batch:	<b>Started:</b> 01/09/1998	S	topped:	CONTIN	
PINDOLOL (Other drug)	· ·	Reason:			
Tablet	10.0 Milligram	Daily	Ora	al	
Batch:	<b>Started:</b> 01/09/1998	S	topped:	CONTIN	
ORAP (Suspected)	ı	Reason:			
Tablet	4.0 Milligram	Daily	Ora	al	
Batch:	Started: 01/09/1998	S	topped: 21	/01/1999	

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

Orap reducing because of recovery from psychotic features. story fits a cramping muscle pain from psychotropic. 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: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

**Report Details:** 

Case Number: 143317 Seq: 1 Gender: F

Reported: 31/08/1999

Hospitalisation: Admitted to hospital
Onset Date: 25/06/1999

Weight:
Age: 78Y
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope		Recurrent falls right knee pain	Ceased orap.

#### **Medicine Details:**

ORAP (Suspected) Reason:

2.0 Milligram Daily

**Batch: Started:** 01/03/1999 **Stopped:** 26/06/1999

**Laboratory Investigations:** 

Date	Туре	Range	Date Tested	Result	Details

#### **Additional Information:**

See original report for details of other drugs: timolol, inderal, xalaten. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

Report Details:	etails:
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 Case Number:
 165977
 Seq: 1
 Gender:
 F

 Reported:
 18/06/2001
 Weight:
 3.00

 Hospitalisation:
 Age: AD

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

#### **Reaction Details:**

Preferred Term	Severity	Report Description	Treatment
Congenital hand malformation			

#### **Medicine Details:**

Medicine Details.			
ZOLOFT (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ORAP (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	

#### **Laboratory Investigations:**

<u> </u>	i ji iii tootiga				
Date	Туре	Range	Date Tested	Result	Details
	Other data				Absent middle and ring fingers, hypoplastic index finger, hypoplastic little finger and possibly mildly small thumb.

#### **Additional Information:**

Other drugs prescribed: 'antibiotics'& steroids 2 weeks early trimester one. teratogenic effect right hand - absent middle and ring fingers, hypoplastic index finger, hypoplastic little finger and possibly mildly small thumb.

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

Case Number: 188783 Reported: 24/07/2003 Hospitalisation: Onset Date: Outcome: Recovered Reaction Details:	Seq: 1		١		0.00
Preferred Term	Severity	Repo	rt Description		Treatment
Extrapyramidal disorder		Patient experiend	ced extrapyramidal ty ing salivation, loss o , difficult waking and	f l	ap ceased.
Gait disturbance Salivary hypersecretion Tremor					
Medicine Details:  ORAP (Suspected)		Reas	on: Lichenifica&lich	simplex ch	nron
Tablet	2.0	Milligram		Oral	
Batch:	Started: 15/0		Stopped:		3
Laboratory Investigations					
Date Type Ra	ange Date Test	ed Result		Detai	ls
Additional Information:					

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Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

Onset Date: DoB: Outcome: Death Causality: Causality possible	Report D	etails:				
Hospitalisation: Age: 22 Onset Date: DOB: Outcome: Death Causality: Causality possible  Reaction Details:  Preferred Term Severity Report Description Treatment Drug interaction Drug interaction, drug toxicity due to intentional overdose, death.  Death Drug toxicity Intentional overdose  Medicine Details:  MOCLOBEMIDE (Interaction) Reason:  Batch: Started: Stopped:  SERTRALINE HYDROCHLORIDE (Interaction) Reason:  Batch: Started: Stopped:  PIMOZIDE (Interaction) Reason:  Batch: Started: Stopped:  PIMOZIDE (Interaction) Reason:  Batch: Started: Stopped:  Details Stopped:  Laboratory Investigations:  Date Type Range Date Tested Result Details	Case Nun	nber: 196467	Seq: 1		Gen	der: M
Hospitalisation: Age: 22    Onset Date: DOB:    Outcome: Death Causality: Causality possible  Reaction Details:  Preferred Term Severity Report Description Treatment Drug interaction Drug interaction, drug toxicity due to intentional overdose, death.  Death Drug toxicity Intentional overdose  Medicine Details:  MOCLOBEMIDE (Interaction) Reason:  Batch: Started: Stopped:  SERTRALINE HYDROCHLORIDE (Interaction) Reason:  Batch: Started: Stopped:  PIMOZIDE (Interaction) Reason:  Batch: Started: Stopped:  PIMOZIDE (Interaction) Reason:  Batch: Started: Stopped:  Details Stopped:  Laboratory Investigations:  Date Type Range Date Tested Result Details	Repo	orted: 14/04/2004	-		Weig	ght: 0.00
Onset Date: Outcome: Death  Reaction Details:  Preferred Term Severity Report Description Treatment  Drug interaction  Drug interaction, drug toxicity due to intentional overdose, death.  Drug toxicity Intentional overdose  Medicine Details:  MocLobemide (interaction)  Batch: Started: Stopped:  Batch: Started: Stopped:  PIMOZIDE (interaction)  Reason:  Batch: Started: Stopped:  PIMOZIDE (interaction)  Reason:  Batch: Started: Stopped:  Date Type Range Date Tested Result Details  Laboratory Investigations:  Date Type Range Date Tested Result Details	-					
Reaction Details: Preferred Term Severity Report Description Treatment Drug interaction Drug interaction Drug interaction, drug toxicity due to intentional overdose, death.  Drug toxicity Intentional overdose  Medicine Details:  MOCLOBEMIDE (interaction) Reason: Batch: Started: Stopped:  SERTRALINE HYDROCHLORIDE (interaction) Reason: Batch: Started: Stopped:  PIMOZIDE (interaction) Reason:  Batch: Started: Stopped:  PIMOZIDE (interaction) Reason:  Batch: Started: Stopped:  Date Type Range Date Tested Result Details	-					_
Reaction Details: Preferred Term Severity Report Description Treatment Drug interaction Drug interaction, drug toxicity due to intentional overdose, death.  Drug toxicity Intentional overdose  Medicine Details:  MOCLOBEMIDE (interaction) Batch: Started: Stopped:  SERTRALINE HYDROCHLORIDE (interaction) Reason: Batch: Started: Stopped:  PIMOZIDE (interaction) Reason:  Batch: Started: Stopped:  PIMOZIDE (interaction) Reason:  Batch: Started: Stopped:  Date Type Range Date Tested Result Details	Outco	ome: Death				
Drug interaction Death Drug toxicity Intentional overdose    Medicine Details:	Reaction I	Details:				
Intentional overdose, death.   Death   Drug toxicity   Intentional overdose   Death   Drug toxicity   Intentional overdose   Death   Death	Р	referred Term	Severity	Repo	ort Description	Treatment
Death Drug toxicity Intentional overdose    Medicine Details:	Drug intera	ction		Drug interaction,	drug toxicity due to	Given Charcoal.
Drug toxicity Intentional overdose  Medicine Details:  MOCLOBEMIDE (Interaction)  Batch: Started: Stopped:  SERTRALINE HYDROCHLORIDE (Interaction)  Batch: Started: Stopped:  PIMOZIDE (Interaction)  Reason:  Batch: Started: Stopped:  PIMOZIDE (Interaction)  Reason:  Batch: Started: Stopped:  Date Type Range Date Tested Result Details				intentional overd	ose, death.	
Medicine Details:  MOCLOBEMIDE (Interaction)  Batch: Started: Stopped:  SERTRALINE HYDROCHLORIDE (Interaction)  Batch: Started: Stopped:  PIMOZIDE (Interaction)  Batch: Started: Stopped:  PIMOZIDE (Interaction)  Batch: Started: Stopped:  Laboratory Investigations:  Date Type Range Date Tested Result Details  14/04/2004 Biochemistry 14/04/2004 Haematology		L .				
Medicine Details:  MOCLOBEMIDE (Interaction) Reason:  Batch: Started: Stopped:  SERTRALINE HYDROCHLORIDE (Interaction) Reason:  Batch: Started: Stopped:  PIMOZIDE (Interaction) Reason:  Batch: Started: Stopped:  Batch: Started: Stopped:	_	-				
Batch: Started: Stopped:	intentional	overdose				
Batch: Started: Stopped:   SERTRALINE HYDROCHLORIDE (Interaction)   Reason:   Batch: Started: Stopped:						
Batch: Started: Stopped:						
Batch: Started: Stopped:						
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Laboratory Investigations:  Date Type Range Date Tested Result Details  14/04/2004 Biochemistry Haematology Haematology	PIMOZIDE (	Interaction)		Rea	son:	
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14/04/2004 Haematology				sted Result		Details
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14/04/2004 Other data						
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	Addition	al Information	n:			
Additional Information:	J.Forensic S	science 1997, 42(5)	): 951-953.			
Additional Information: J.Forensic Science 1997, 42(5): 951-953.						

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# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

Laboratory Investigation  Date Type  Additional Information:	S: Range Date Tes	sted Result		Details
		sted Result		Details
		stad Rasult	T	Details
Batch:	Started:		Stopped:	
Tablet	6.0	Milligram		ral
Medicine Details: ORAP (Suspected)		D.	pason:	
Tardive dyskinesia		Patient develo	ped tardive dyskinesia.	Stopped Orap
Preferred Term	Severity		port Description	Treatment
action Details:			Cau	sality: Causality possible
			0	DOB:
Outcome: Unknown				
				'eight: 0.00 Age: 99U



Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

eport Details:				
ase Number: 212355	Seq: 1		Gender:	F
Reported: 10/10/2005	•		Weight:	0.00
spitalisation:			Age:	
Onset Date: 15/09/2005			_	30/05/1954
Outcome: Recovered		15/11/2005		Causality possible
ction Details:			•	, ,
Preferred Term	Severity	Report De	escription	Treatment
east cyst		Patient developed bre Orap.	ast cyst whilst on	
edicine Details:  RAP (Suspected)	9.0	Reason:	Unspecified schizophrenia	1
Tablet  Batch:	8.0 Started:	Milligram Daily		
	<u> </u>	L TERM	Stopped:	
	Junious	LIERM	Stopped:	
aboratory Investigations:  Date Type Ran			Stopped:  Detai	ls

Report Run: 04/06/2007 12:07PM Database: pusime02 ADRS004 Page 21 of 22



Date Range: 28 Mar 1991 To 18 Jul 2007 Unclear causality excluded GM medicines Only Tradenames: ORAP,PIMOZIDE

Despitalisation: Onset Date: Outcome: action Deta Preferr epression    Deta	: 31/08/2006 : : : : : : : : : : : : : : : : : :	ability	Repo	ort Descrip	Weig Aç D0 Causali	ht: 0.00 ge: 99u OB: ity: Causality possible  Treatment
Outcome: action Deta Preferr epression  edicine Det METFORMIN HYD Batch:	Unknown  ills: red Term  tails:	Incapacity/dis ability		ort Descrip	Causali	ity: Causality possible
ledicine Det METFORMIN HYD Batch:	red Term	Incapacity/dis ability		ort Descrip	tion	Treatment
epression  ledicine Det	tails:	Incapacity/dis ability		ort Descrip	tion	Treatment
ledicine Det METFORMIN HYD Batch:		ability	Depression.			
METFORMIN HYD Batch:						
		ier arug)	Rea	ıson:		
ORAP (Suspected		Started:		s	topped:	
(	d)		Rea	ison:		
Tablet		2.0	Milligram	Daily	Oral	
Batch:		Started:		s	topped:	
aborato <u>ry</u> Ir	nvestigațions					
Date	Type R	ange Date Test	ed Result		D	Details

Report Run: 04/06/2007 12:07PM Database: pusime02 ADRS004 Page 22 of 22