



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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:**
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	Type	Range	Date Tested	Result	Details

Additional Information:

Case Sequenced to: 70947/2



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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	Type	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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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

Report Details:

Case Number: 82668	Seq: 1	Gender: F
Reported: 18/02/1993		Weight:
Hospitalisation:		Age:
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Polydactyly			

Medicine 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	Type	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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Public Case Detail

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:

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

Laboratory Investigations:

Date	Type	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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Public Case Detail

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

Report Details:

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:

Preferred Term	Severity	Report Description	Treatment
Hypertension			

Medicine Details:

CLONAZEPAM (Suspected)	Reason:
500.0 Microgram	As necessary
Batch:	Started: 09/11/1993 Stopped: CONTIN
PHENELZINE SULPHATE (Suspected)	Reason:
30.0 Milligram	Daily
Batch:	Started: Stopped: 02/11/1993
PHENELZINE SULPHATE (Suspected)	Reason:
30.0 Milligram	Daily
Batch:	Started: 16/11/1993 Stopped: CONTIN
PIMOZIDE (Suspected)	Reason:
2.0 Milligram	Daily
Batch:	Started: 03/11/1993 Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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

Report Details:

Case Number: 96926	Seq: 1	Gender: M
Reported: 07/11/1994		Weight:
Hospitalisation: Admitted to hospital		Age: 74Y
Onset Date: 05/10/1994		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Asthenia Dystonia Fatigue			Commenced cogentin.

Medicine Details:

ISOSORBIDE DINITRATE (Other drug)	Reason:
Tablet	30.0 Milligram
Batch:	Oral
Started:	Stopped: CONTIN
SIMVASTATIN (Other drug)	Reason:
Tablet	10.0 Milligram
Batch:	Daily
Started:	Stopped: CONTIN
VERAPAMIL HYDROCHLORIDE (Other drug)	Reason:
	240.0 Milligram
Batch:	Daily
Started:	Stopped: CONTIN
OXAZEPAM (Other drug)	Reason:
	15.0 Milligram
Batch:	Daily
Started:	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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

Report Details:

Case Number: 96926 **Seq:** 1 **Gender:** M
Reported: 07/11/1994 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 74Y
Onset Date: 05/10/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

ORAP (Suspected)	Reason:
Tablet	2.0 Milligram Daily Oral
Batch:	Started: 28/09/1994 Stopped: 05/10/1994

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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

Report Details:

Case Number: 97782

Seq: 1

Gender: M

Reported: 13/12/1994

Weight: 56.00

Hospitalisation:

Onset Date: 22/06/1994

Age: 49Y

Outcome: Recovered

DOB:

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)		Reason: Aids
Oral application	300.0 Milligram	Daily Oral
Batch:	Started: 27/05/1994	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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

Report Details:

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:

Medicine Details:

BENZYL PENICILLIN (Suspected)	Reason:
Injection	24.0 Million International Units Daily Intravenous
Batch:	Started: 13/06/1994 Stopped: 22/06/1994
PIMOZIDE (Suspected)	Reason: Unspecified psychosis
	4.0 Milligram Daily
Batch:	Started: 18/06/1994 Stopped: 22/06/1994

Laboratory Investigations:

Additional Information:



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Public Case Detail

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

Report Details:

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	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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

Report Details:

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:

Medicine Details:

PIMOZIDE (Suspected)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 20/10/1994	Stopped:	
THIORIDAZINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 07/12/1992	Stopped:	

Laboratory Investigations:

Additional Information:



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Public Case Detail

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:

AURORIX (Other drug)	Reason: Depression
Tablet	600.0 Milligram Daily Oral
Batch:	Started: 01/11/1996 Stopped:
ORAP (Suspected)	Reason: Hallucinations
Tablet	2.0 Dose Unspecified Daily Oral
Batch:	Started: 05/06/1997 Stopped: 19/06/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 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:

Onset Date: 31/07/1997

Age: 71Y

Outcome: Recovered

DOB:

Causality: Causality probable

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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

Report Details:

Case Number: 123039

Seq: 1

Gender: M

Reported: 03/12/1997

Weight:

Hospitalisation:

Age: 73Y

Onset Date: 25/09/1997

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination			Pimozide ceased, olanzapine started.

Medicine Details:

SINEMET (Other drug)	Reason:		
Tablet	5.5 Dose Unspecified Daily Oral		
Batch:	Started:	Stopped:	CONTIN
PIMOZIDE (Suspected)	Reason:		
	0.0		
Batch:	Started:	Stopped:	25/09/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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:

Preferred Term	Severity	Report Description	Treatment
Pain		Pubococcygeal pain	Quinine given & reduced pelvic floor exercises.
Muscle spasms			

Medicine Details:

EFEXOR (Other drug)	Reason: Depression	
375.0 Milligram	Daily	
Batch:	Started: 01/09/1998	Stopped: CONTIN
PINDOLOL (Other drug)		
10.0 Milligram	Daily	Oral
Batch:	Started: 01/09/1998	Stopped: CONTIN
ORAP (Suspected)		
4.0 Milligram	Daily	Oral
Batch:	Started: 01/09/1998	Stopped: 21/01/1999

Laboratory Investigations:

Date	Type	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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 78Y
Onset Date: 25/06/1999 **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	Type	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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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

Report Details:

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:

ZOLOFT (Suspected)	Reason:	
0.0		
Batch:	Started:	Stopped:
ORAP (Suspected)	Reason:	
0.0		
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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

Report Details:

Case Number: 188783
Reported: 24/07/2003

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 69
DOB: 05/10/1933
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Patient experienced extrapyramidal type symptoms including salivation, loss of facial expression, difficult waking and tremor.	Orap ceased.
Gait disturbance			
Salivary hypersecretion			
Tremor			

Medicine Details:

ORAP (Suspected)	Reason: Lichenifica&lich simplex chron
Tablet	2.0 Milligram Daily Oral
Batch:	Started: 15/06/2003 Stopped: 09/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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

Report Details:

Case Number: 196467

Seq: 1

Gender: M

Reported: 14/04/2004

Weight: 0.00

Hospitalisation:

Age: 22

Onset Date:

DOB:

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug interaction Death Drug toxicity Intentional overdose		Drug interaction, drug toxicity due to intentional overdose, death.	Given Charcoal.

Medicine Details:

MOCLOBEMIDE (Interaction)	Reason:	
Batch:	Started:	Stopped:
SERTRALINE HYDROCHLORIDE (Interaction)	Reason:	
Batch:	Started:	Stopped:
PIMOZIDE (Interaction)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/04/2004	Biochemistry				
14/04/2004	Haematology				
14/04/2004	Other data				

Additional Information:

J.Forensic Science 1997, 42(5): 951-953.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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

Report Details:

Case Number: 209819

Seq: 1

Gender: F

Reported: 13/07/2005

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Patient developed tardive dyskinesia.	Stopped Orap

Medicine Details:

ORAP (Suspected)	Reason:
Tablet	6.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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

Report Details:

Case Number: 212355 **Seq:** 1 **Gender:** F
Reported: 10/10/2005 **Weight:** 0.00
Hospitalisation: **Age:** 51
Onset Date: 15/09/2005 **DOB:** 30/05/1954
Outcome: Recovered 15/11/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast cyst		Patient developed breast cyst whilst on Orap.	

Medicine Details:

ORAP (Suspected)	Reason: Unspecified schizophrenia
Tablet	8.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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

Report Details:

Case Number: 221257

Seq: 1

Gender: F

Reported: 31/08/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depression	Incapacity/disability	Depression.	

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ORAP (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reporter indicated tha the patient has had a history of depression possibly caused by other medications.