



# 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:

<b>PIMOZIDE (Suspected)</b>	<b>Reason:</b> Unspecified psychosis
Tablet	2.0 Milligram                      Daily                      Oral
<b>Batch:</b>	<b>Started:</b> 22/04/1991 <b>Stopped:</b>

## 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:

<b>PIMOZIDE (Suspected)</b>	<b>Reason:</b> Unspecified schizophrenia
4.0 Milligram	Daily
<b>Batch:</b>	<b>Started:</b> 01/11/1990
	<b>Stopped:</b> 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:

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

### Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Polydactyly			

### Medicine Details:

<b>MODECATE (Suspected)</b>	<b>Reason:</b> Unspecified schizophrenia
0.0	
<b>Batch:</b>	<b>Started:</b>
	<b>Stopped:</b>
<b>SERENACE (Suspected)</b>	<b>Reason:</b> Unspecified schizophrenia
0.0	
<b>Batch:</b>	<b>Started:</b>
	<b>Stopped:</b>
<b>PIMOZIDE (Suspected)</b>	<b>Reason:</b> Unspecified schizophrenia
0.0	
<b>Batch:</b>	<b>Started:</b>
	<b>Stopped:</b>

### 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.



# 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:** 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:

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

### 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



# 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:** 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:

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

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

### Reaction Details:

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

### Medicine Details:

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

<b>ORAP (Suspected)</b>	<b>Reason:</b>
Tablet	2.0 Milligram Daily Oral
<b>Batch:</b>	<b>Started:</b> 28/09/1994 <b>Stopped:</b> 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:

<b>DAPSONE (Other drug)</b>		<b>Reason:</b> Aids
Tablet	100.0 Milligram	Daily Oral
<b>Batch:</b>	<b>Started:</b> 07/05/1994	<b>Stopped:</b>
<b>ZALCITABINE (Other drug)</b>		<b>Reason:</b> Aids
Tablet	2.2 Milligram	Daily Oral
<b>Batch:</b>	<b>Started:</b>	<b>Stopped:</b>
<b>CLARITHROMYCIN (Other drug)</b>		<b>Reason:</b> Aids
Tablet	2.0 Gram	Daily Oral
<b>Batch:</b>	<b>Started:</b> 26/05/1994	<b>Stopped:</b>
<b>RIFABUTIN (Other drug)</b>		<b>Reason:</b> Aids
Oral application	300.0 Milligram	Daily Oral
<b>Batch:</b>	<b>Started:</b> 27/05/1994	<b>Stopped:</b>

### 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:

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

### 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:** 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:

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

### 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:

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

### 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:** 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:

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

<b>Case Number:</b> 121288	<b>Seq:</b> 1	<b>Gender:</b> F
<b>Reported:</b> 02/10/1997		<b>Weight:</b> 70.00
<b>Hospitalisation:</b>		<b>Age:</b> 71Y
<b>Onset Date:</b> 31/07/1997		<b>DOB:</b>
<b>Outcome:</b> Recovered		<b>Causality:</b> Causality probable

### Reaction Details:

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

### Medicine Details:

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

### 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:

<b>SINEMET (Other drug)</b>	<b>Reason:</b>
Tablet	5.5 Dose Unspecified Daily Oral
<b>Batch:</b>	<b>Started:</b> <b>Stopped:</b> CONTIN
<b>PIMOZIDE (Suspected)</b>	<b>Reason:</b>
	0.0
<b>Batch:</b>	<b>Started:</b> <b>Stopped:</b> 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:

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

<b>ORAP (Suspected)</b>	<b>Reason:</b>
	2.0 Milligram Daily
<b>Batch:</b>	<b>Started:</b> 01/03/1999 <b>Stopped:</b> 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:

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

<b>ORAP (Suspected)</b>	<b>Reason:</b>
Tablet	6.0 Milligram Daily Oral
<b>Batch:</b>	<b>Started:</b> <b>Stopped:</b>

### 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:

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

### 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.