

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Re | port | Detai | ls: |
|----|------|-------|-----|
|----|------|-------|-----|

Case Number: 581 Seq: 1 Gender: M

 Reported:
 01/12/1989
 Weight:
 0.00

 Hospitalisation:
 Age:
 67Y

 Onset Date:
 31/12/1986
 DOB:

Outcome: Not yet recovered Causality: Causality possible

#### **Reaction Details:**

| Preferred Term          | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------|-----------|
| Extrapyramidal disorder |          |                    |           |

## **Medicine Details:**

| BENZHEXOL HYDROCHLORIDE (Suspected) |          |                  | son:  |          |  |
|-------------------------------------|----------|------------------|-------|----------|--|
|                                     | 0.0      |                  |       |          |  |
| Batch:                              | Started: |                  |       | Stopped: |  |
| BENZTROPINE MESYLATE (Suspected)    |          | Rea              | son:  |          |  |
|                                     | 0.0      |                  |       |          |  |
| Batch:                              | Started: |                  |       | Stopped: |  |
| STELAZINE (Suspected)               |          | Rea              | son:  |          |  |
|                                     | 4.0      | Dose Unspecified | Daily | Oral     |  |
| Batch:                              | Started: |                  |       | Stopped: |  |
| ROHYPNOL (Suspected)                |          | Rea              | son:  |          |  |
|                                     | 2.0      | Dose Unspecified | Daily |          |  |
| Batch:                              | Started: |                  |       | 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. Case Sequenced to: 26442/3. GP report

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report Deta  Case Numbe  Reporte  Iospitalisation  Onset Dat |            |                |                 |        |                                |                                 |
|--|------------|----------------|-----------------|--------|--------------------------------|---------------------------------|
| Reporte<br>ospitalisatio<br>Onset Dat                        | 3r. 7474   | 0              | 4               |        | O d                            | M                               |
| ospitalisatio<br>Onset Dat                                   |            | Seq            | j: 1            |        | Gende                          |                                 |
| Onset Dat  |            | 90             |                 |        | =                              | nt: 82.00                       |
|  |            |                |                 |        | _                              | e: 67Y                          |
| ( )IIITCAM   |            | _              |                 |        | DO                             |                                 |
|  | e: Unknowr | 1              |                 |        | Causain                        | ty: Causality possible          |
| eaction Det  | erred Term | S              | everity         | Rep    | ort Description                | Treatment                       |
| lallucination  |            |                | ,               |        |                                |                                 |
| -<br>Hepatomegaly  | /          |                |                 |        |                                |                                 |
|  |            |                |                 |        |                                |                                 |
| Medicine D   |            |                |                 | Rea    | son: Unspecified schizophre    | enia                            |
| (0)  |            |                | 0.0             |        |                                |                                 |
| Batch:   |            | ;              | Started:        |        | Stopped:                       |                                 |
| BENZHEXOL H  | YDROCHLORI | DE (Suspected) |                 | Rea    | son:                           |                                 |
| Batch:   |            | ;              | 0.0<br>Started: |        | Stopped:                       |                                 |
| BENZTROPINE  |            |                |                 | Rea    | ison:                          |                                 |
|  |            |                | 0.0             |        |                                |                                 |
| Batch:   |            |                | Started:        |        | Stopped:                       |                                 |
| _aboratory   | Type       | tions:         | Date Tested     | Result |                                | etails                          |
|  | adiololgy  |                |                 |        | Enlarged liver which was later | confirmed by isotope tomography |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 2511 Seq: 1 Gender: F

Reported: 09/11/1990 Weight: 70.00 Hospitalisation: Age: 37Y

**Onset Date**: 17/09/1990 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| Preferred Term          | Severity | Report Description | Treatment                               |
|-------------------------|----------|--------------------|---|
| Extrapyramidal disorder |          |                    | Decrease trifluoperazine to 20 mg daily |

## **Medicine Details:**

Batch:

PROZAC (Suspected)

Reason:

20.0 Milligram Daily

**Started:** 27/08/1990 **Stopped:** 03/10/1990

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason: Schizo-affective type psychos

25.0 Milligram Daily

Batch: Started: Stopped: 26/09/1990

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Case Sequenced to: 68362/2

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 2512 Seq: 1 Gender: F

 Reported:
 09/11/1990
 Weight:
 70.00

 Hospitalisation:
 Age:
 37Y

 Onset Date:
 26/09/1990
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| todotion Dotailoi  |          |                    |                               |
|--------------------|----------|--------------------|-------------------------------|
| Preferred Term     | Severity | Report Description | Treatment                     |
| Somnolence         |          |                    |                               |
| Visual disturbance |          |                    | Ceased prozac and benztropine |

#### **Medicine Details:**

| TRIFLUOPERAZINE HYDROCHLORIDE (S | Reason:             | Schizo-affective | ve type psychos |            |        |
|----------------------------------|---------------------|------------------|-----------------|------------|--------|
|                                  | 20.0 Milligram      | Daily            |                 |            |        |
| Batch:                           | Started: 26/09/1990 |                  | Stopped:        |            | CONTIN |
| BENZTROPINE MESYLATE (Suspected) |                     | Reason:          |                 |            |        |
|                                  | 2.0 Milligram       | Daily            |                 |            |        |
| Batch:                           | Started: 26/09/1990 |                  | Stopped:        | 03/10/1990 |        |
| PROZAC (Suspected)               |                     | Reason:          |                 |            |        |
|                                  | 20.0 Milligram      | Daily            |                 |            |        |
| Batch:                           | Started: 27/08/1990 |                  | Stopped:        | 03/10/1990 |        |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Case Sequenced to: 68362/3



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 2513 Seq: 1 Gender: F

 Reported:
 09/11/1990
 Weight:
 70.00

 Hospitalisation:
 Age:
 37Y

 Onset Date:
 06/10/1990
 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term | Severity | Report Description | Treatment         |
|----------------|----------|--------------------|-------------------|
| Somnolence     |          |                    | Ceased prozac 20. |

## **Medicine Details:**

PROZAC (Suspected)

Reason:

20.0 Milligram Total

**Batch: Started:** 06/10/1990 **Stopped:** 07/10/1990

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:

20.0 Milligram Daily

Batch: Started: 26/09/1990 Stopped: CONTIN

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Case Sequenced to: 68362/4

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 2536 Seq: 1 Gender: F

Reported: 03/01/1991 Weight: 0.00
Hospitalisation: Age: 86Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

|    | Preferred Term         | Severity | Report Description | Treatment               |
|----|------------------------|----------|--------------------|-------------------------|
| E: | ktrapyramidal disorder |          |                    | Bromocriptine increased |

## **Medicine Details:**

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:

1.0 Milligram Daily

Batch: Started: 20/07/1990 Stopped: 26/07/1990

**Laboratory Investigations:** 

| Date | Type | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Hospital report. Case Sequenced to: 68970/2



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

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

 Case Number:
 55239
 Seq: 1
 Gender: M

 Reported:
 11/07/1988
 Weight: 65.00

Hospitalisation: Age: 82Y
Onset Date: 07/07/1988
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| Preferred Term      | Severity | Report Description | Treatment                  |
|---------------------|----------|--------------------|----------------------------|
| Skin discolouration |          |                    | Rifadin and fucidin ceased |

## **Medicine Details:**

VELOSULIN (NORDISK) (Suspected) Reason: Diabetes mellitus

0.0

Batch: Started: Stopped:

INSULATARD (NORDISK) (Suspected) Reason: Diabetes mellitus

0.0

Batch: Started: Stopped:

RIFADIN (Suspected)

Oral application

Reason: Bacterial disease nec

**Batch: Started:** 05/07/1988 **Stopped:** 07/07/1988

FUCIDIN (Suspected) Reason: Bacterial disease nec

Tablet 1.5 Gram Daily Oral

**Batch: Started:** 05/07/1988 **Stopped:** 07/07/1988

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

## **Additional Information:**

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**Report Details:** 

Case Number: 55239

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

|  |                            |                  | Weight:                     |                    |
|--|----------------------------|------------------|-----------------------------|--------------------|
| ospitalisation:                          |                            |                  | Age:                        |                    |
| Onset Date: 07/07/1988                   |                            |                  | DOB:                        |                    |
| Outcome: Not yet recovered               |                            |                  | Causality:                  | Causality possible |
| action Details:                          |                            |                  |                             |                    |
|  |                            |                  |                             |                    |
|  |                            |                  |                             |                    |
|  |                            |                  |                             |                    |
|  |                            |                  |                             |                    |
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|  |                            |                  |                             |                    |
|  |                            |                  |                             |                    |
|  |                            |                  |                             |                    |
|  |                            |                  |                             |                    |
|  |                            |                  |                             |                    |
| edicine Details:                         |                            |                  |                             |                    |
| SEREPAX (Suspected)                      |                            | Reason:          | Specific disorders of sleep |                    |
| Tablet                                   | 15.0 Milligram             | Daily            | Oral                        |                    |
| Batch:                                   | <b>Started:</b> 30/06/1988 |                  | Stopped:                    |                    |
| HIAMINE (Suspected)                      |                            | Reason:          | Unspec vitamin deficien st  | ates               |
| Oral application                         | 200.0 Milligram            | Daily            | Oral                        |                    |
| Batch:                                   | Started: 30/06/1988        |                  | Stopped:                    |                    |
| Datcii.                                  |                            |                  | • •                         |                    |
|  |                            | Reason:          |                             |                    |
|  | 1.0 Milligram              | Reason:<br>Daily | Oral                        |                    |
| STELAZINE (Suspected)                    |                            |                  | Oral                        |                    |
| STELAZINE (Suspected) Tablet             | 1.0 Milligram              |                  |                             |                    |
| STELAZINE (Suspected) Tablet             | 1.0 Milligram              |                  | Oral                        |                    |
| STELAZINE (Suspected) Tablet             | 1.0 Milligram              |                  | Oral                        |                    |
| STELAZINE (Suspected)  Tablet  Batch:    | 1.0 Milligram              |                  | Oral                        |                    |
| STELAZINE (Suspected)  Tablet  Batch:    | 1.0 Milligram              |                  | Oral                        |                    |
| TELAZINE (Suspected) Tablet Batch:       | 1.0 Milligram              |                  | Oral                        |                    |
| TELAZINE (Suspected) Tablet Batch:       | 1.0 Milligram              |                  | Oral                        |                    |
| TELAZINE (Suspected) Tablet Batch:       | 1.0 Milligram              |                  | Oral                        |                    |
| STELAZINE (Suspected)  Tablet  Batch:    | 1.0 Milligram              |                  | Oral                        |                    |
| STELAZINE (Suspected)  Tablet  Batch:    | 1.0 Milligram              |                  | Oral                        |                    |
| STELAZINE (Suspected)  Tablet  Batch:    | 1.0 Milligram              |                  | Oral                        |                    |
| STELAZINE (Suspected)  Tablet  Batch:    | 1.0 Milligram              |                  | Oral                        |                    |
| Tablet Batch:  aboratory Investigations: | 1.0 Milligram              |                  | Oral                        |                    |
| Tablet Batch:  aboratory Investigations: | 1.0 Milligram              |                  | Oral                        |                    |
| Tablet Batch:  aboratory Investigations: | 1.0 Milligram              |                  | Oral                        |                    |
| Tablet Batch:  aboratory Investigations: | 1.0 Milligram              |                  | Oral                        |                    |
| STELAZINE (Suspected) Tablet             | 1.0 Milligram              |                  | Oral                        |                    |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 60372 Seq: 1 Gender: F

Reported: 05/05/1989 Weight: 60.00 Hospitalisation: Age: 65Y

**Onset Date**: 09/04/1989 **DOB**:

Outcome: Recovered Causality: Causality probable

Reaction Details:

| Neaction Details.                     |          |                    |                              |
|---------------------------------------|----------|--------------------|------------------------------|
| Preferred Term                        | Severity | Report Description | Treatment                    |
| Extrapyramidal disorder<br>Hypertonia |          |                    | Reducing dosage then ceased. |

#### **Medicine Details:**

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason: Manic-depression psycho,manic

0.0

**Batch**: **Started**: 30/03/1989 **Stopped**: 15/04/1989

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

See original report for other drugs. trifluoperazine 2mg tds prn and 4mg nocte reduced to 2mg nocte.

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| iber: 61088      | Seq:  | . 1                   |                           | Gend  |   |  |
|------------------|---|-----------------------|---------------------------|---|---|--|
| rted: 15/05/198  | 9   |                       | Weight:                   |   |   |  |
| tion:            |   |                       |                           | Ag  | e:  |  |
| Date:            |   |                       |                           | DC  | B:  |  |
| me: Unknown      |   |                       |                           | Causali   | ty: Causality possible  |  |
| <u> Details:</u> |   |                       |                           |   |   |  |
| eferred Term     | Se  | everity               | Repo                      | ort Description                                   | Treatment   |  |
| е                |   |                       |                           |   |   |  |
| <u> </u>         |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
| Details:         |   |                       |                           |   |   |  |
|                  |   |                       | Rea                       | son: Unspecified schizophre                       | enia  |  |
| ,                |   | 3.0 Dos               |                           | ·   |   |  |
| ch:              | S   |                       |                           |   |   |  |
|                  |   |                       |                           | 200   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
|                  |   |                       |                           |   |   |  |
| ry Investigat    |   | In                    |                           |   |   |  |
| ry Investigat    | <b>ions:</b><br>Range                           | Date Tested           | Result                    | D   | etails  |  |
|                  |   | Date Tested           | Result                    | D   | etails  |  |
|                  |   | Date Tested           | Result                    | D   | etails  |  |
|                  |   | Date Tested           | Result                    | D   | etails  |  |
|                  |   | Date Tested           | Result                    | D   | etails  |  |
|                  |   | Date Tested           | Result                    | D   | etails  |  |
|                  |   | Date Tested           | Result                    | D   | etails  |  |
|                  |   | Date Tested           | Result                    | D   | etails  |  |
| Туре             | Range   | Date Tested           | Result                    | D   | etails  |  |
|                  | Range   | Date Tested           | Result                    | D   | etails  |  |
| Туре             | Range   | Date Tested           | Result                    | D   | etails  |  |
| Туре             | Range   | Date Tested           | Result                    | D   | etails  |  |
| Туре             | Range   | Date Tested           | Result                    | D   | etails  |  |
| Туре             | Range   | Date Tested           | Result                    | D   | etails  |  |
| Туре             | Range   | Date Tested           | Result                    | D   | etails  |  |
|                  | tion: Date: Ome: Unknown Details: Deferred Term | Details:  (Suspected) | Details:  (Suspected)  20 | Details:  (Suspected)  Reas  3.0 Dose Unspecified | Details:  Details:  Severity Report Description  Reason: Unspecified schizophre |  |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 64765 Seq: 1 Gender: M

 Reported:
 16/03/1990
 Weight:
 70.00

 Hospitalisation:
 Age:
 38Y

 Onset Date:
 31/12/1983
 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term     | Severity | Report Description | Treatment  |
|--------------------|----------|--------------------|------------|
| Tardive dyskinesia |          |                    | Clonazepam |

#### Medicine Details:

| Medicine Details.                |                     |         |                           |  |
|----------------------------------|---------------------|---------|---------------------------|--|
| STELAZINE (Suspected)            |                     | Reason: | Unspecified schizophrenia |  |
| Tablet                           | 5.0 Milligram       | Daily   | Oral                      |  |
| Batch:                           | Started: 01/01/1983 |         | Stopped:                  |  |
| BENZTROPINE MESYLATE (Suspected) |                     | Reason: |                           |  |
| Tablet                           | 2.0 Milligram       | Daily   | Oral                      |  |
| Batch:                           | Started: 01/01/1983 |         | Stopped:                  |  |

**Laboratory Investigations:** 

| Date | Type | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### Additional Information:

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

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report Details:         |                 |                  |        |                               |   |  |
|-------------------------|-----------------|------------------|--------|-------------------------------|---|--|
| Case Number: 648        | 354 <b>Sec</b>  | <b>j</b> : 1     |        | Gen                           | der: M  |  |
| Reported: 23/           | 03/1990         |                  |        | Wei                           | ght:  |  |
| Hospitalisation:        |                 |                  |        | A                             | <b>.ge:</b> 31Y   |  |
| Onset Date: 15/         | 03/1990         |                  |        | D                             | OB:   |  |
| Outcome: Re             | covered         |                  |        | Causa                         | lity: Causality possible  |  |
| Reaction Details:       |                 |                  |        |                               |   |  |
| Preferred T             | erm S           | Severity         | Repo   | ort Description               | Treatment   |  |
| Blood creatine phosp    | hokinase incr   |                  |        |                               |   |  |
| Dehydration             |                 |                  |        |                               |   |  |
| Hyperhidrosis           |                 |                  |        |                               |   |  |
| Hypertonia              |                 |                  |        |                               |   |  |
| Neuroleptic malignar    | nt syndrome     |                  |        |                               | lv fluid, diazepam, withdrawal                                      |  |
|                         |                 |                  |        |                               | of n'lept (sic)   |  |
| Paralysis               |                 |                  |        |                               |   |  |
| Pyrexia                 |                 |                  |        |                               |   |  |
| Red blood cell sedim    | entation rate i |                  |        |                               |   |  |
| Tachycardia             |                 |                  |        |                               |   |  |
| Vomiting                |                 |                  |        |                               |   |  |
| Medicine Details        | <b>.</b> •      |                  |        |                               |   |  |
| COGENTIN (Other drug    |                 |                  | Rea    | son:                          |   |  |
|                         |                 | 4.0 Mill         | ligram | Daily                         |   |  |
| Batch:                  |                 | Started:         |        | Stopped:                      |   |  |
| STELAZINE (Suspected    | d)              |                  | Rea    | son: Otr spec symp psych      | opathol nec   |  |
| Tablet                  |                 | 0.0              |        | Oral                          |   |  |
| Batch:                  |                 | Started: 01/03/1 | 990    | <b>Stopped:</b> 12/03         | 3/1990  |  |
| Laboratory Inves        | stigations:     |                  |        |                               |   |  |
| Date Type               |                 | Date Tested      | Result |                               | Details   |  |
| Biochemist              | try             |                  |        | on arrival was 1275 u/l (20-2 | 0-11.0) with 83% neutrophils. (ck) 00). ck values peaked at 1665 on |  |
|                         |                 |                  |        | day 2 and settled to 80 on da | ay 12.  |  |
| Additional Information: |                 |                  |        |                               |   |  |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

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

Gender: F Case Number: 64990 Seq: 1

Reported: 04/04/1990 Weight: 57.00 **Hospitalisation:** Age: 71Y

Onset Date: 17/12/1989 DOB:

Outcome: Recovered Causality: Causality probable

#### **Reaction Details:**

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Hyperkinesia   |          |                    |           |

#### **Medicine Details:** SLOW-FE (Other drug)

| Tablet              | 1.0 Dose Unspecified Da    | aily Oral               |        |
|---------------------|----------------------------|-------------------------|--------|
| Batch:              | <b>Started:</b> 31/01/1985 | Stopped:                | CONTIN |
| NOCTEC (Other drug) | Reason                     | : Specific disorders of | sleep  |

Reason:

Iron deficiency anemias

500.0 Milligram Daily

Batch: Started: 31/01/1985 **Stopped:** 27/12/1989

STELAZINE (Suspected) Reason: Paranoia

> 3.0 Milligram Daily

Batch: Started: 24/01/1985 **Stopped:** 03/01/1990

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

ADRS004 Report Run: 06/06/2007 08:45AM Database: pusime02 Page 13 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Reported: 21/04/1990   | ase linininei | 65189      | Seq: | 1           |        |                 | Gende     | r: F                 |
|--|---------------|------------|------|-------------|--------|-----------------|-----------|----------------------|
| spitalisation: Onset Date: 21/04/1990 Outcome: Recovered Causality: Causality probable action Details: Preferred Term Severity Report Description Treatment aulogyration  Cogentin 2mg ivi  Predictine Details: TELAZINE (Suspected) Reason: 5.0 Milligram Total Batch: Started: 20/04/1990 Stopped: |               |            |      | -           |        |                 |           |                      |
| Onset Date: 21/04/1990 Outcome: Recovered Causality: Causality probable action Details:  Preferred Term Severity Report Description Treatment culogyration Cogentin 2mg ivi  Padicine Details:  TELAZINE (Suspected) Reason:  5.0 Milligram Total  Batch: Started: 20/04/1990 Stopped:               |               |            |      |             |        |                 | _         |                      |
| Preferred Term Severity Report Description Treatment Collogyration Cogentin 2mg ivi    Bedicine Details:  TELAZINE (Suspected)  Started: 20/04/1990 Stopped:  Paboratory Investigations:   | -             | 21/04/1990 |      |             |        |                 |           |                      |
| Preferred Term Severity Report Description Treatment Culogyration Cogentin 2mg ivi   edicine Details:  TELAZINE (Suspected) Reason: 5.0 Milligram Total Batch: Started: 20/04/1990 Stopped:  | Outcome:      | Recovered  |      |             |        |                 | Causality | : Causality probable |
| edicine Details:  TELAZINE (Suspected)  Started: 20/04/1990  Reason:  5.0 Milligram Total  Batch: Started: 20/04/1990 Stopped:   | action Detai  | ls:        |      |             |        |                 |           |                      |
| edicine Details:  Reason:  5.0 Milligram Total  Batch: Started: 20/04/1990 Stopped:  |               | ed Term    | Se   | verity      | Rep    | ort Description |           |                      |
| TELAZINE (Suspected)  5.0 Milligram Total  Batch: Started: 20/04/1990 Stopped:   | culogyration  |            |      |             |        |                 | C         | Cogentin 2mg ivi     |
| 5.0 Milligram Total  Batch: Started: 20/04/1990 Stopped:  aboratory Investigations:  |               |            |      |             |        |                 |           |                      |
| Batch: Started: 20/04/1990 Stopped:  |               |            |      |             |        |                 |           |                      |
| aboratory Investigations:  | Datah.        |            | 04   |             |        |                 | 1.        |                      |
|  |               |            |      |             |        |                 |           |                      |
|  | aborotory In  | westigatio |      |             |        |                 |           |                      |
|  |               |            |      | Date Tested | Result |                 | Det       | iails                |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 65617 Seq: 1 Gender: F

 Reported:
 23/05/1990
 Weight:
 50.00

 Hospitalisation:
 Age:
 59Y

Onset Date: 31/05/1990 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| • | todotion Botano. |          |                    |           |
|---|------------------|----------|--------------------|-----------|
|   | Preferred Term   | Severity | Report Description | Treatment |
|   | Hyperkinesia     |          |                    |           |
|   | Insomnia         |          |                    |           |

#### **Medicine Details:**

| PSEUDOEPHEDRINE HYDROCHLORID | E (Suspected)       | Reason: | Acute nasoph  | aryngitis,com cold |
|------------------------------|---------------------|---------|---------------|--------------------|
| Oral application             | 0.0                 |         |               | Oral               |
| Batch:                       | Started: 25/04/1990 |         | Stopped:      | 09/05/1990         |
| THYROXINE SODIUM (Suspected) |                     | Reason: | Myxedema      |                    |
|                              | 100.0 Microgram     | Daily   |               |                    |
| Batch:                       | Started: 01/01/1990 |         | Stopped:      | 09/05/1990         |
| STELAZINE (Suspected)        |                     | Reason: | Anxiety neuro | sis                |
| Oral application             | 10.0 Milligram      | Daily   |               | Oral               |
| Batch:                       | Started: 01/01/1990 |         | Stopped:      | 16/05/1990         |

**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. 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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 65933 Seq: 1 Gender: F

 Reported: 30/05/1990
 Weight: 51.00

 Hospitalisation:
 Age: 63Y

**Onset Date**: 15/01/1990 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

| <u> </u>       |          |                    |           |
|----------------|----------|--------------------|-----------|
| Preferred Term | Severity | Report Description | Treatment |
| Jaundice       |          |                    |           |
| Rash           |          |                    |           |

#### **Medicine Details:**

|                     | Reason:  | Otr loc skin&su  | ubcut tis infect  |
|---------------------|--|--|---|
| 2.0 Gram            | Daily  |  | Oral  |
| Started: 03/01/1990 |  | Stopped:   | 09/01/1990  |
|                     | Reason:  | Depression   |   |
| 10.0 Milligram      | Daily  |  | Oral  |
| Started:            |  | Stopped:   | 02/02/1990  |
|                     | Reason:  | Depression   |   |
| 75.0 Milligram      | Daily  |  | Oral  |
| Started:            |  | Stopped:   | 02/02/1990  |
|                     | Reason:  | Abnormal invo  | luntary movement  |
| 2.0 Milligram       | Daily  |  |   |
| Started:            |  | Stopped:   | 02/02/1990  |
|                     | Started: 03/01/1990  10.0 Milligram Started:  75.0 Milligram Started:  2.0 Milligram | 2.0 Gram Daily  Started: 03/01/1990  Reason: 10.0 Milligram Daily  Started:  Reason: 75.0 Milligram Daily  Started:  Reason: 2.0 Milligram Daily | 2.0 Gram Daily  Started: 03/01/1990 Stopped:  Reason: Depression  Daily  Started: Stopped:  Reason: Depression  Paily  Started: Stopped:  Reason: Depression  Paily  Started: Stopped:  Reason: Abnormal invo |

**Laboratory Investigations:** 

| Date | Туре         | Range | Date Tested | Result | Details   |
|------|--------------|-------|-------------|--------|---|
|      | Electrolytes |       |             |        | 30/1/90 2/2/90 13/2/90 23/5/90 14/6/90 ggt: 694 384<br>200 130 130 alk p: 360 358 287 156 195<br>bili: 136 148 101 7 4 ast: 97 45<br>31 |

#### **Additional Information:**

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 65979
 Seq: 1
 Gender: M

 Reported:
 11/06/1990
 Weight:

Hospitalisation: Age: 17Y

**Onset Date**: 31/03/1990 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

| • | teaction Betails. |          |                    |           |
|---|-------------------|----------|--------------------|-----------|
|   | Preferred Term    | Severity | Report Description | Treatment |
|   | Nausea            |          |                    | Tagamet.  |
|   | Vomiting          |          |                    |           |

#### **Medicine Details:**

STELAZINE (Suspected) Reason: Unspecified psychosis

7.0 Milligram Daily

Batch: Started: 01/04/1989 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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

|  | etails:  |                  |  |  |                                     |                   |                                  |                       |
|--|--|------------------|--|--|-------------------------------------|-------------------|----------------------------------|-----------------------|
| ase Nun  | nber: 67204  | Seq:             | : 1  |  |                                     |                   | Gende                            | r: F                  |
|  | rted: 10/08/19   | -                |  |  |                                     |                   | Weigh                            | t:                    |
| spitalisa  |  |                  |  |  |                                     |                   | _                                | e: 62Y                |
| -  | Date: 15/01/19   | 90               |  |  |                                     |                   | DO                               |                       |
| Outco  | ome: Recovere  | ed               |  |  |                                     | С                 | ausalit                          | y: Causality possible |
| action [   | Details:   |                  |  |  |                                     |                   |                                  |                       |
|  | referred Term  | Se               | everity  | Rep                                    | ort Descri                          | ption             |                                  | Treatment             |
| itigue   |  |                  |  |  |                                     |                   |                                  |                       |
| undice   |  |                  |  |  |                                     |                   |                                  |                       |
| ash  |  |                  |  |  |                                     |                   |                                  |                       |
| edicine  | Details:   |                  |  |  |                                     |                   |                                  |                       |
| LOPEN (S   |  |                  | 0.0  |  | ason:                               |                   |                                  |                       |
| Bat  | ch:  | s                | 0.0<br><b>started:</b> 03/01/1   | 1990                                   |                                     | Stopped:          | 15/01/19                         | 990                   |
| Bat  |  | s                | started: 03/01/1   | 1990<br><b>Re</b> a                    | ason:                               | Stopped:          | 15/01/19                         | 990                   |
| Bat<br>CARDIZEM  | ch:<br>(Suspected)   |                  | 120.0 Mill   | 1990<br><b>Re</b> a                    | ason:<br>Daily                      |                   |                                  |                       |
| Bat<br>CARDIZEM<br>Bat   | ch:<br>(Suspected)   |                  | started: 03/01/1   | 1990 <b>Re</b> a                       | ason:<br>Daily                      | Stopped:          |                                  |                       |
| Bat<br>CARDIZEM<br>Bat   | ch:<br>(Suspected)   |                  | 120.0 Mill   | 1990<br>Rea<br>ligram                  | ason:<br>Daily<br>ason:             |                   |                                  |                       |
| Bat<br>CARDIZEM<br>Bat   | (Suspected) cch: (Suspected)   | s                | 120.0 Mill   | 1990<br>Rea<br>ligram                  | ason: Daily ason: Daily             | Stopped:          | 02/02/19                         | 990                   |
| Bat<br>ARDIZEM<br>Bat<br>TELAZINE<br>Bat                       | ch: (Suspected) ch: (Suspected)  | s                | 120.0 Mill<br>tarted:<br>10.0 Mill                                     | 1990<br>Rea<br>ligram<br>Rea<br>ligram | ason: Daily ason: Daily             |                   | 02/02/19                         | 990                   |
| Bat<br>ARDIZEM<br>Bat<br>TELAZINE<br>Bat                       | (Suspected) cch: (Suspected)   | s                | 120.0 Mill<br>started:<br>10.0 Mill<br>started:                        | ligram Realigram Realigram             | ason: Daily ason: Daily             | Stopped:          | 02/02/19                         | 990                   |
| Bat<br>EARDIZEM<br>Bat<br>STELAZINE<br>Bat<br>PROTHIADE        | ch: (Suspected) ch: (Suspected)  | s                | 120.0 Mill<br>tarted:<br>10.0 Mill                                     | ligram Realigram Realigram             | ason: Daily ason: Daily ason: Daily | Stopped:          | 02/02/19                         | 990                   |
| Bat<br>CARDIZEM<br>Bat<br>CTELAZINE<br>Bat<br>PROTHIADE        | (Suspected)  (Ch: (Suspected)  (Ch: (Suspected)  (Ch: (Ch: (Suspected) | s<br>s           | 120.0 Mill<br>started:<br>10.0 Mill<br>started:<br>150.0 Mill          | ligram Realigram Realigram             | ason: Daily ason: Daily ason: Daily | Stopped:          | 02/02/19                         | 990                   |
| Bat<br>EARDIZEM<br>Bat<br>ETELAZINE<br>Bat<br>PROTHIADE<br>Bat | ch: (Suspected) ch: (Suspected) ch: EN (Suspected) ch:                 | s<br>s<br>tions: | 120.0 Mill<br>tarted:<br>10.0 Mill<br>tarted:<br>150.0 Mill<br>tarted: | ligram Realigram Realigram             | ason: Daily ason: Daily ason: Daily | Stopped:          | 02/02/19                         | 990                   |
| Bat<br>CARDIZEM<br>Bat<br>CTELAZINE<br>Bat<br>PROTHIADE        | (Suspected)  (Ch: (Suspected)  (Ch: (Suspected)  (Ch: (Ch: (Suspected) | s<br>s           | 120.0 Mill<br>started:<br>10.0 Mill<br>started:<br>150.0 Mill          | ligram Realigram Realigram             | ason: Daily ason: Daily ason: Daily | Stopped: Stopped: | 02/02/19<br>03/02/19<br>03/02/19 | 990                   |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report Details:  |                                 |                       |         |  |     |
|--|---------------------------------|-----------------------|---------|--|-----|
| Case Number: 67 Reported: 10 Hospitalisation: Onset Date: 15 Outcome: Re Reaction Details: | /08/1990<br>/01/1990<br>covered | 1                     |         | Gender:<br>Weight:<br>Age:<br>DOB:<br>Causality: | 62Y |
|  |                                 |                       |         |  |     |
| Medicine Details COGENTIN (Suspected   |                                 |                       | Reason: |  |     |
| Batch:   | St                              | 12.0 Milligram arted: | Daily   | <b>Stopped:</b> 03/02/1990                       |     |
|  |                                 |                       |         |  |     |
| Laboratory Inve  | stigations:                     |                       |         |  |     |
| Additional Infor   | mation:                         |                       |         |  |     |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 67824
 Seq: 1
 Gender:
 F

 Reported:
 15/10/1990
 Weight:
 57.00

Hospitalisation:
Onset Date:

DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| reaction Details.                 |          |                    |                    |
|-----------------------------------|----------|--------------------|--------------------|
| Preferred Term                    | Severity | Report Description | Treatment          |
| Blood alkaline phosphatase increa |          |                    | Medication changed |
| Rash                              |          |                    |                    |
| Urticaria                         |          |                    |                    |

## **Medicine Details:**

STELAZINE (Suspected) Reason: Unspecified schizophrenia

Tablet 4.0 Milligram Daily Oral

**Batch: Started:** 01/01/1985 **Stopped:** 20/09/1990

**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.



Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detail | 30/10/1990<br>06/08/1990<br>Recovered | Seq: 1              |                        | c                   | Gender: M Weight: 80.00 Age: 47Y DOB: Causality: Causality possible  |
|--|---------------------------------------|---------------------|------------------------|---------------------|--|
| Preferre   |                                       | Severity            | Rep                    | ort Description     | Treatment  |
| Extrapyramidal di<br>Hypertension<br>Pyrexia<br>Salivary hypersec            |                                       |                     |                        | ·                   | Propranolol 40 mg tds from<br>03/09/90 to 05/09/90 with no<br>effect |
| Medicine Deta  |                                       | 0.0                 |                        | son: Unspecified so | chizophrenia   |
| Batch:   |                                       | Started:            |                        | Stopped:            |  |
| CHLORPROMAZIN  | E HYDROCHLOR                          |                     |                        | son: Unspecified so | chizophrenia   |
| Batch:   |                                       | Started: 17         | Milligram<br>7/07/1990 | Daily Stopped:      | 06/08/1990   |
| MODECATE (Suspe  | ected)                                |                     |                        | son: Unspecified so |  |
| Injection  |                                       | 50.0                | Milligram              | Alternate weeks     | Intramuscular  |
| Batch:   |                                       | Started: 09         | 9/07/1990              | Stopped:            | 17/08/1990   |
| Laboratory In  |                                       | S:<br>Range Date Te | sted Result            |                     | Details  |
| Additional Info  | ormation:                             |                     |                        |                     |  |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 68362 Seq: 1 Gender: F

 Reported: 09/11/1990
 Weight: 70.00

 Hospitalisation:
 Age: 37Y

 Onset Date: 31/01/1990
 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term   | Severity | Report Description | Treatment             |
|------------------|----------|--------------------|-----------------------|
| Weight increased |          |                    | Imiprimine was ceased |

#### **Medicine Details:**

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)

Reason: Schizo-affective type psychos

25.0 Milligram Daily

Batch: Started: Stopped: 26/09/1990

IMIPRAMINE HYDROCHLORIDE (Suspected) Reason: Schizo-affective type psychos

150.0 Milligram Daily

Batch: Started: Stopped: 27/08/1990

**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.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report Det      | tail        | s:     |          |              |         |          |                      |        |           |          |        |   |  |
|-----------------|-------------|--------|----------|--------------|---------|----------|----------------------|--------|-----------|----------|--------|---|--|
| Case Numb       | er:         | 693    | 94       |              | Seq:    | 1        |                      |        |           |          | Gend   | er: M   |  |
| Report          | ed:         | 01/0   | )2/1991  |              |         |          |                      |        |           |          | Weig   | ht:   |  |
| Hospitalisation | on:         |        |          |              |         |          |                      |        |           |          | Ą      | <b>je</b> : 49Y   |  |
| Onset Da        | ıte:        | 09/0   | 3/1990   | )            |         |          |                      |        |           |          | DC     | DB:   |  |
| Outcon          | ne:         | Rec    | overed   |              |         |          |                      |        |           | С        | ausali | ty: Causality possible                                      |  |
| Reaction De     |             |        |          |              |         |          |                      |        |           |          |        | T   |  |
|                 |             | ed Te  | erm      |              | Sev     | erity    |                      | Re     | port Des  | cription |        | Treatment   |  |
| Abdominal pa    | ain         |        |          |              |         |          |                      |        |           |          |        | ldc (drained 1.2l in 1 hr),<br>hydration. all drugs ceased. |  |
| Anuria          |             |        |          |              |         |          |                      |        |           |          |        | inyaration. all arago ocasca.                               |  |
| Constipation    |             |        |          |              |         |          |                      |        |           |          |        |   |  |
| Renal impairr   | nen         | t      |          |              |         |          |                      |        |           |          |        |   |  |
| Medicine [      | )eta        | ails:  |          |              |         |          |                      |        |           |          |        |   |  |
| LITHIUM CAR     |             |        |          | ted)         |         |          |                      | Re     | eason:    |          |        |   |  |
|                 |             |        |          |              |         | 1.0      | Gran                 | n      | Daily     |          |        |   |  |
| Batch           | :           |        |          |              | Sta     | rted:    |                      |        |           | Stopped: | 06/03/ | 1990  |  |
| DOXEPIN HYD     | RO          | CHLO   | RIDE (St | uspected     | d)      |          |                      | Re     | eason:    |          |        |   |  |
| Tablet          |             |        |          |              |         | 150.0    | 50.0 Milligram Daily |        |           |          | Oral   |   |  |
| Batch           |             |        |          |              |         | Started: |                      |        |           | Stopped: | 06/03/ | 1990  |  |
| TRIFLUOPER      |             | E HY   | DROCHL   | ORIDE (      | (Suspec |          | N ACUE               |        | eason:    |          | 01     |   |  |
| Tablet<br>Batch |             |        |          |              | Cto     | 5.0      | Millig               | gram   | Daily     | Stopped: | Oral   | 1000  |  |
| BENZTROPIN      |             | SYL A  | ATF (Sus | spected)     |         | iteu.    |                      | Re     | ason:     | Stoppeu. | 00/03/ | 1990  |  |
| Tablet          |             | -0,    | 11 (Out  | эрсокой      |         | 10.0     | Millio               |        | Daily     |          | Oral   |   |  |
| Batch           |             |        |          |              | Sta     | rted:    | ·                    | , -    | ,         | Stopped: |        | 1990  |  |
| l -l            | . 1         |        | 4! 4!    |              |         |          |                      |        |           |          |        |   |  |
| Laboratory      | <u>/ In</u> | Type   |          | ons:<br>Rang | ie l    | Date Tes | ted                  | Result |           |          | D      | etails  |  |
|                 | ioche       | emistr |          |              |         |          |                      |        | Creatinir | ne - 603 |        |   |  |
| Additional      | Inf         | orm    | nation   | :            |         |          |                      |        |           |          |        |   |  |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 69399
 Seq: 1
 Gender: M

 Reported:
 04/02/1991
 Weight:

Hospitalisation: Age: 62Y
Onset Date: 31/10/1990 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term   | Severity | Report Description | Treatment |
|------------------|----------|--------------------|-----------|
| Renal impairment |          |                    |           |

## **Medicine Details:**

| VALIUM (Suspected)            |                     | Reason:                                |  |
|-------------------------------|---------------------|--|--|
|                               | 5.0 Milligram       | As necessary                           |  |
| Batch:                        | Started: 03/10/1990 | <b>Stopped:</b> 04/10/1990             |  |
| HYPNOVEL (Suspected)          |                     | Reason:                                |  |
|                               | 5.0 Milligram       | As necessary                           |  |
| Batch:                        | Started: 03/10/1990 | <b>Stopped:</b> 04/10/1990             |  |
| STELAZINE (Suspected)         |                     | Reason: Otr spec symp psychopathol nec |  |
|                               | 6.0 Milligram       | Daily                                  |  |
| Batch:                        | Started: 03/10/1990 | <b>Stopped:</b> 04/10/1990             |  |
| CEFOTAXIME SODIUM (Suspected) |                     | Reason:                                |  |
| Injection                     | 4.0 Gram            | Daily Intravenous                      |  |
| Batch:                        | Started: 03/10/1990 | <b>Stopped:</b> 04/10/1990             |  |

**Laboratory Investigations:** 

| Date | Туре         | Range | Date Tested | Result | Details  |
|------|--------------|-------|-------------|--------|--|
|      | Biochemistry |       |             |        | 04/10, 05/10, 06/10, 07/10, 08/10, 09/10, 11/10 15/10 creatinine 69 56 270 442 443 203 82 74 urea 3.4 3.5 8.3 13.0 9.1 6.2 2.7 |

#### **Additional Information:**

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

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 24 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 69399
 Seq: 1
 Gender: M

 Reported:
 04/02/1991
 Weight:

Hospitalisation: Age: 62Y
Onset Date: 31/10/1990
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

| CEFOTAXIME SODIUM (Suspected)   |                     | Reason: |          |             |
|---------------------------------|---------------------|---------|----------|-------------|
| Injection                       | 6.0 Gram            | Daily   |          | Intravenous |
| Batch:                          | Started: 04/10/1990 |         | Stopped: | 06/10/1990  |
| CEFOTAXIME SODIUM (Suspected)   |                     | Reason: |          |             |
| Injection                       | 1.5 Gram            | Daily   |          | Intravenous |
| Batch:                          | Started: 07/10/1990 |         | Stopped: | 12/10/1990  |
| RANITIDINE (Suspected)          |                     | Reason: |          |             |
|                                 | 150.0 Milligram     | Daily   |          |             |
| Batch:                          | Started: 04/10/1990 |         | Stopped: | 09/10/1990  |
| GENTAMICIN SULPHATE (Suspected) |                     | Reason: |          |             |
|                                 |                     |         |          |             |
|                                 | 240.0 Milligram     | Daily   |          |             |

## **Laboratory Investigations:**

#### **Additional Information:**

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

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 25 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Report Details: | Report Detai | ls: |
|-----------------|--------------|-----|
|-----------------|--------------|-----|

 Case Number:
 69399
 Seq: 1
 Gender: M

 Reported:
 04/02/1991
 Weight:

Hospitalisation: Age: 62Y
Onset Date: 31/10/1990
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

| ACICLOVIR (Suspected) |                             | Reason:  |             |
|-----------------------|-----------------------------|----------|-------------|
| Injection             | 1.2 Gram                    | Daily    | Intravenous |
| Batch:                | <b>Started:</b> 03/10/1990  | Stopped: | 04/10/1990  |
| FLAGYL (Suspected)    |                             | Reason:  |             |
| Injection             | 1.5 Gram                    | Daily    | Intravenous |
| Batch:                | <b>Started</b> : 04/10/1990 | Stopped: | 10/10/1990  |

# **Laboratory Investigations:**

#### **Additional Information:**

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

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 26 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 69871 Seq: 1 Gender: M

Reported: 23/08/1990 Weight: 103.00 Hospitalisation: Age: 41Y

Onset Date: 19/08/1990 DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

| Preferred Term      | Severity | Report Description | Treatment |
|---------------------|----------|--------------------|-----------|
| Rash maculo-papular |          |                    |           |

#### **Medicine Details:**

STELAZINE (Suspected) Reason: Unspecified schizophrenia

5.0 Milligram Daily

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.

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 27 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| ospitalisatio        |   |              |                   |           |        |       |                            |                                    |                    |
|----------------------|---|--------------|-------------------|-----------|--------|-------|----------------------------|------------------------------------|--------------------|
|                      | red: 21/03/199<br>on:<br>ate: 11/03/199 | 1            | : 1               |           |        |       |                            | Gender:<br>Weight:<br>Age:<br>DOB: | 65Y                |
| Outcon<br>eaction De | ne: Not yet red                         | covered      |                   |           |        |       | C:                         | ausanty:                           | Causality possible |
|                      | ferred Term                             | S            | everity           |           | Repo   | rt De | scription                  |                                    | Treatment          |
| Nopecia              |   |              | •                 |           |        |       | ·                          |                                    |                    |
| /ledicine [          | Details:                                |              |                   |           |        |       |                            |                                    |                    |
|                      | NE (Suspected)                          |              |                   |           | Reas   |       | Other rheumat              |                                    |                    |
| Tablet               |   | _            |                   | Milligram |        | Daily | 04                         | Oral                               |                    |
| Batch                | 1:<br>AZINE HYDROCH                     |              | Started: 28/      | u2/1991   | Reas   | on:   | Stopped:<br>Unspecified sc |                                    |                    |
| Tablet               |   | LONIDE (JUSP |                   | Milligram |        | Daily | onspecified SC             | Oral                               |                    |
| Batch                |   | 5            | Started:          | 914111    |        |       | Stopped:                   | - · <del>- ·</del> ·               |                    |
| RANITIDINE (         | Suspected)                              |              |                   |           | Reas   |       | Chronic ulcer of           | of skin                            |                    |
| Batch                | ۱۰                                      | •            | 300.0<br>Started: | Milligram |        | Daily | Stopped:                   |                                    |                    |
|                      | OL (Suspected)                          | •            | rtartea.          |           | Reas   | on:   | otopped.                   |                                    |                    |
|                      | ,                                       |              | 4.0               | Gram      |        | Daily |                            |                                    |                    |
| Batch                | 1:                                      |              | Started:          |           |        |       | Stopped:                   |                                    |                    |
|                      | v Invosticati                           | ione:        |                   |           |        |       |                            |                                    |                    |
| ahorator             | , ilivestigati                          |              | Data Tasi         |           |        |       |                            |                                    |                    |
| aboratory Date       | Туре                                    | Range        | Date Test         | ted   F   | Result |       |                            | Detai                              | ls                 |

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 28 of 197



Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number:                 |                             | Seq: 1      |                  |                | Gender:      | F                  |   |
|------------------------------|-----------------------------|-------------|------------------|----------------|--------------|--------------------|---|
|                              | 21/03/1991                  |             |                  |                | Weight:      | SEV                |   |
| Hospitalisation: Onset Date: | 11/03/1001                  |             |                  |                | Age:<br>DOB: |                    |   |
|                              | Not yet recovered           |             |                  |                |              | Causality possible |   |
| Reaction Detai               |                             |             |                  |                |              | caacamy pecchan    |   |
|                              |                             |             |                  |                |              |                    |   |
|                              |                             |             |                  |                |              |                    |   |
|                              |                             |             |                  |                |              |                    |   |
|                              |                             |             |                  |                |              |                    |   |
|                              |                             |             |                  |                |              |                    |   |
|                              |                             |             |                  |                |              |                    |   |
|                              |                             |             |                  |                |              |                    |   |
|                              |                             |             |                  |                |              |                    |   |
|                              |                             |             |                  |                |              |                    |   |
|                              |                             |             |                  |                |              |                    |   |
|                              |                             |             |                  |                |              |                    |   |
| Medicine Deta                |                             |             | Po               | ason:          |              |                    | 1 |
| COLOXIL (Suspec              | steu)                       | 1.0         | Dose Unspecified |                |              |                    |   |
| Batch:                       |                             | Started:    | Dood Griopodino  | Dany           | Stopped:     |                    |   |
| METOCI OPPAMIC               | - IIV - DO - O III - O DIDE | · · · · ·   |                  |                |              |                    |   |
| WEIGCLOPKAWIL                | E HYDROCHLORIDE             | (Suspected) | Re               | ason:          |              |                    |   |
| WETOCLOPRAMIL                | DE HYDROCHLORIDE            |             | Re<br>Milligram  | ason:<br>Daily |              |                    |   |
| Batch:                       | DE HYDROCHLORIDE            |             |                  |                | Stopped:     |                    | • |
|                              | DE HYDROCHLORIDE            | 30.0        |                  |                | Stopped:     |                    |   |
|                              | DE HYDROGHLORIDE            | 30.0        |                  |                | Stopped:     |                    |   |
|                              | DE HYDROCHLORIDE            | 30.0        |                  |                | Stopped:     |                    |   |
|                              | DE HYDROGHLORIDE            | 30.0        |                  |                | Stopped:     |                    |   |
|                              | DE HYDROCHLORIDE            | 30.0        |                  |                | Stopped:     |                    |   |
| Batch:                       |                             | 30.0        |                  |                | Stopped:     |                    |   |
|                              |                             | 30.0        |                  |                | Stopped:     |                    |   |
| Batch:                       |                             | 30.0        |                  |                | Stopped:     |                    |   |
| Batch:                       |                             | 30.0        |                  |                | Stopped:     |                    |   |
| Batch:                       |                             | 30.0        |                  |                | Stopped:     |                    |   |
| Batch:                       |                             | 30.0        |                  |                | Stopped:     |                    |   |
| Batch:                       |                             | 30.0        |                  |                | Stopped:     |                    |   |
| Batch:                       |                             | 30.0        |                  |                | Stopped:     |                    |   |
| Batch:                       | vestigations:               | 30.0        |                  |                | Stopped:     |                    |   |
| Batch:                       | vestigations:               | 30.0        |                  |                | Stopped:     |                    |   |
| Batch:                       | vestigations:               | 30.0        |                  |                | Stopped:     |                    |   |
| Batch:                       | vestigations:               | 30.0        |                  |                | Stopped:     |                    |   |
| Batch:                       | vestigations:               | 30.0        |                  |                | Stopped:     |                    |   |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Report | <b>Details:</b> |
|--------|-----------------|
|--------|-----------------|

Case Number: 70181 Seq: 1 Gender: M
Reported: 08/03/1991 Weight:
Hospitalisation: Age: 52Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

#### **Reaction Details:**

| Preferred Term                 | Severity | Report Description | Treatment |
|--------------------------------|----------|--------------------|-----------|
| Neuroleptic malignant syndrome |          |                    | Valium    |

## **Medicine Details:**

| MODECATE (Suspected)  |                     | Reason: | Unspecified psychosis       |  |
|-----------------------|---------------------|---------|-----------------------------|--|
| Injection             | 25.0 Milligram      | Daily   | Intramuscular               |  |
| Batch:                | Started: 15/02/1991 |         | <b>Stopped:</b> 15/02/1991  |  |
| STELAZINE (Suspected) |                     | Reason: | Unspecified psychosis       |  |
| Oral application      | 20.0 Milligram      | Daily   | Oral                        |  |
| Batch:                | Started: 20/02/1991 |         | Stopped: 22/02/1991         |  |
| LARGACTIL (Suspected) |                     | Reason: | Unspecified psychosis       |  |
| Oral application      | 800.0 Milligram     | Daily   | Oral                        |  |
| Batch:                | Started: 21/02/1991 |         | <b>Stopped:</b> 22/02/1991  |  |
| COGENTIN (Suspected)  |                     | Reason: | Unspecified psychosis       |  |
| Tablet                | 2.0 Milligram       | Daily   | Oral                        |  |
| Batch:                | Started: 20/02/1991 |         | <b>Stopped</b> : 22/02/1991 |  |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 30 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 70633
 Seq: 1
 Gender:
 F

 Reported:
 22/04/1991
 Weight:

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

Outcome: Recovered Causality: Causality possible

Reaction Details:

| Preferred Term          | Severity | Report Description | Treatment    |
|-------------------------|----------|--------------------|--------------|
| Extrapyramidal disorder |          |                    | Benztropine. |

## **Medicine Details:**

**DYAZIDE (Other drug)**Reason: Congestive heart failure

1.0 Dose Unspecified Daily

Batch: Started: Stopped:

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason: Other paranoid states

Oral application 5.0 Milligram Daily Oral

**Batch: Started: Stopped:** 25/10/1990

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason: Other paranoid states

Oral application 10.0 Milligram Daily Oral

Batch: Started: 26/10/1990 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.

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 31 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report D        | etails:          |               |           |                |                       |                    |
|-----------------|------------------|---------------|-----------|----------------|-----------------------|--------------------|
| Case Num        | nber: 70781      | Seq: 1        |           |                | Gender:               | F                  |
|                 | rted: 13/05/1991 |               |           |                | Weight:               |                    |
| ospitalisat     |                  |               |           |                | Age:                  | 53Y                |
| -               | Date: 25/02/1991 |               |           |                | DOB:                  |                    |
| Outco           | ome: Recovered   |               |           | С              | ausality:             | Causality probable |
| eaction E       | Details:         |               |           |                |                       |                    |
| Pr              | referred Term    | Severity      | Repo      | rt Description |                       | Treatment          |
| leuroleptic     | malignant syndro | ome           |           |                | Hyd                   | ration.            |
| <b>Medicine</b> |                  |               |           |                |                       |                    |
| STELAZINE       | (Suspected)      |               | Reas      |                | ea no heart ir        | ivolv              |
|                 |                  | 30.0          | Milligram | Daily          |                       |                    |
| Bate            |                  | C444- 00/0    | 1/1001    |                | 07/00/4004            |                    |
|                 | ch:              | Started: 29/0 | 1/1991    |                | 27/02/1991            |                    |
| _aborato        | ry Investigatio  | ons:          |           |                |                       |                    |
|                 |                  |               |           |                | 27/02/1991<br>Details |                    |

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 32 of 197



Report Details:

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| ase Number:       | 71619      | Seq            | : 1        |           |       |       |                | Gend   | er: F                |   |          |
|-------------------|------------|----------------|------------|-----------|-------|-------|----------------|--------|----------------------|---|----------|
| Reported          | : 08/04/1  | 991            |            |           |       |       |                | Weig   | <b>ht:</b> 58.0      | 0   |          |
| spitalisation:    |            |                |            |           |       |       |                | Ą      | <b>ge:</b> 51Y       |   |          |
| Onset Date        | : 27/12/1  | 990            |            |           |       |       |                | DO     | DB:                  |   |          |
| Outcome:          | Recove     | red            |            |           |       |       | С              | ausali | ty: Cau              | sality poss   | sible    |
| action Deta       |            |                |            |           |       |       |                |        |                      |   |          |
|                   | red Term   | S              | everity    |           | Repor | t De  | scription      |        |                      | Treatme   |          |
| abetes insipid    | us         |                |            |           |       |       |                |        | including<br>hyperna | eplacement<br>g d5w 100m<br>traemic cor<br>v kci/day. | ıl/h for |
|                   |            |                |            |           |       |       |                |        |                      |   |          |
| edicine De        | tails:     |                |            |           |       |       |                |        |                      |   |          |
| ITAMINS (Other    |            |                |            |           | Reaso | n:    |                |        |                      |   |          |
|                   |            |                | 0.0        |           |       |       |                |        |                      |   |          |
| Batch:            |            |                | Started:   |           |       |       | Stopped:       |        |                      |   |          |
| HYROXINE SOD      | IUM (Other | drug)          |            |           | Reaso | on:   | Myxedema       |        |                      |   |          |
| Tablet            |            |                | 150.0      | Microgram | I     | Daily |                | Oral   |                      |   |          |
| Batch:            |            | (              | Started:   |           |       |       | Stopped:       |        |                      |   |          |
| RIADEL (Suspe     | cted)      |                |            |           | Reaso |       | Unspecified so |        | enia                 |   |          |
| Tablet            |            |                |            | Milligram | I     | Daily |                | Oral   |                      |   |          |
| Batch:            |            |                | Started:   |           |       |       | Stopped:       |        |                      | 07Y   |          |
| TELAZINE (Sus     | pected)    |                |            |           | Reaso |       | Unspecified so |        | enia                 |   |          |
| Tablet            |            |                |            | Milligram | ſ     | Daily |                | Oral   |                      |   |          |
| Batch:            |            |                | Started:   |           |       |       | Stopped:       |        |                      | 07Y   |          |
| boratory I        | nvestig    | ations:        |            |           |       |       |                |        |                      |   |          |
| Date              | Туре       | Range          | Date Teste | ed Res    | ult   |       |                | D      | etails               |   |          |
| dditional In      | ıformati   | ion:           | 1          |           |       |       |                |        |                      |   |          |
| ort Run: 06/06/20 | 007 08:45  | AM Database: p | ousime02   |           | AD    | )RS00 | )4             |        |                      | Page 33   | of 19    |



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

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

 Case Number:
 72321
 Seq: 1
 Gender:
 F

 Reported:
 10/09/1991
 Weight:
 60.00

 Hospitalisation:
 Age: 35Y

Onset Date: 09/09/1991 DOB:

Outcome: Not yet recovered Causality: Causality possible

#### Reaction Details:

| todotion Botano. |          |                    |   |
|------------------|----------|--------------------|---|
| Preferred Term   | Severity | Report Description | Treatment   |
| Face oedema      |          | Facial swelling    |   |
| Urticaria        |          |                    | Phenergan 25mg and symptometic measures for itch. |

#### **Medicine Details:**

| PROZAC (Suspected)    |              | Reas             | on:   | Depression     |              |
|-----------------------|--------------|------------------|-------|----------------|--------------|
| Tablet                | 1.0          | Dose Unspecified | Daily |                | Oral         |
| Batch:                | Started: 09/ | 08/1991          |       | Stopped:       | 10/09/1991   |
| STELAZINE (Suspected) |              | Reas             | on:   | Paranoia       |              |
| Oral application      | 25.0         | Milligram        | Daily |                | Oral         |
| Batch:                | Started:     | L TERM           |       | Stopped:       |              |
| COGENTIN (Suspected)  |              | Reas             | on:   | Disturbance of | coordination |
|                       | 1.0          | Dose Unspecified | Daily |                |              |
| Batch:                | Started:     | L TERM           |       | Stopped:       |              |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Case Numb   | <b>er</b> : 73189                                  | Seq:   | : 1                                      |            |             | G                    | ender:   | F       |             |
|---|--|--------|--|------------|-------------|----------------------|----------|---------|-------------|
| _   | ted: 02/10/1991                                    |        |  |            |             | V                    | /eight:  |         |             |
| ospitalisati  |  |        |  |            |             |                      | Age:     |         |             |
| Onset Da  |  |        |  |            |             |                      | DOB:     |         |             |
|   | ne: Unknown  |        |  |            |             | Cai                  | usality: | Causali | ty possible |
| eaction Do  |  | - 1 -  | 1  |            |             |                      |          |         |             |
| Pre<br>Confusional :  | ferred Term  | Se     | everity                                  | Repo       | ort Descrip | otion                |          | Tr      | reatment    |
|   |  |        |  |            |             |                      |          |         |             |
|   |  |        |  |            |             |                      |          |         |             |
| Medicine I  |  |        |  | Rea        | son:        |                      |          |         |             |
| ZANTAC (Oth   | er drug)   |        | 0.0                                      | Rea        |             |                      |          |         |             |
| ZANTAC (Oth<br>Batch  | er drug)<br>n:                                     | s      | 0.0<br>started:                          |            | ;           | Stopped:             |          |         |             |
| ZANTAC (Oth   | er drug)<br>n:                                     | s      | tarted:                                  |            |             | Stopped:             |          |         |             |
| ZANTAC (Oth<br>Batch<br>MYLANTA (O  | er drug)<br>n:<br>ther drug)                       |        | tarted:<br>0.0                           |            | son:        |                      |          |         |             |
| ZANTAC (Oth  Batch  MYLANTA (Oth  Batch   | er drug)<br>n:<br>ther drug)<br>n:                 |        | tarted:                                  | Rea        | son:        | Stopped:<br>Stopped: |          |         |             |
| ZANTAC (Oth<br>Batch<br>MYLANTA (O  | er drug)<br>n:<br>ther drug)<br>n:                 |        | 0.0                                      | Rea        | son:        |                      |          |         |             |
| ZANTAC (Oth  Batch  MYLANTA (Oth  Batch   | er drug) n: ther drug) n: other drug)              | s      | tarted:<br>0.0                           | Rea        | son:        |                      |          |         |             |
| ZANTAC (Oth<br>Batch<br>MYLANTA (Or<br>Batch<br>TIMOPTOL (O                     | er drug) n: ther drug) n: Other drug)              | s      | 0.0 started:                             | Rea<br>Rea | son:        | Stopped:             |          |         |             |
| ZANTAC (Oth<br>Batch<br>MYLANTA (Oth<br>Batch<br>TIMOPTOL (Oth<br>Batch         | er drug) n: ther drug) n: Other drug)              | s      | 0.0 started:                             | Rea<br>Rea | son:        | Stopped:             |          |         |             |
| ZANTAC (Oth<br>Batch<br>MYLANTA (Oth<br>Batch<br>TIMOPTOL (Oth<br>Batch         | er drug) n: ther drug) n: Other drug) n: her drug) | s      | 0.0 started:  0.0 started:  0.0 started: | Rea<br>Rea | son:        | Stopped:             |          |         |             |
| ZANTAC (Oth  Batch MYLANTA (Oth  Batch TIMOPTOL (Oth  Batch PROPINE (Oth  Batch | er drug) n: ther drug) n: other drug) n: her drug) | s<br>s | 0.0 started: 0.0 started: 0.0 started:   | Rea<br>Rea | son:        | Stopped:<br>Stopped: |          |         |             |
| ZANTAC (Oth  Batch MYLANTA (Oth  Batch TIMOPTOL (Oth  Batch PROPINE (Oth  Batch | er drug) n: ther drug) n: Other drug) n: her drug) | s<br>s | 0.0 started: 0.0 started: 0.0 started:   | Rea<br>Rea | son:        | Stopped:<br>Stopped: | Detail   | ls      |             |

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number:<br>Reported:<br>Hospitalisation:<br>Onset Date:<br>Outcome:<br>Reaction Detai | 02/10/1991<br>Unknown | Seq: 1                     |         |                 | Gender:<br>Weight:<br>Age:<br>DOB:<br>ausality: |        |
|--|-----------------------|----------------------------|---------|-----------------|---|--------|
|  |                       |                            |         |                 |   |        |
|  |                       |                            |         |                 |   |        |
| Medicine Deta  |                       |                            | D       | Ohman in the li |   |        |
| TRENTAL 400 (Sus   | spected)              | 0.0                        | Reason: | Chron isch hea  | art dis no hyp                                  | per    |
|  |                       | 0.0                        | Daily   | O: .            | 00/00/400                                       |        |
| Batch:   |                       | <b>Started:</b> 06/09/1991 | _       |                 | 20/09/1991                                      |        |
| COGENTIN (Suspe  | ected)                |                            | Reason: | Otr spec symp   | psychopath                                      | ol nec |
|  |                       | 0.0                        | Daily   |                 |   |        |
| Batch:   |                       | Started:                   | _       |                 | 20/09/1991                                      |        |
| STELAZINE (Susp  | ected)                |                            | Reason: | Explosive pers  | onality disor                                   | der    |
|  |                       | 0.0                        | Daily   |                 |   |        |
| Batch:   |                       | Started:                   |         | Stopped:        | 20/09/1991                                      |        |
| Laboratory In  | vestigations:         |                            |         |                 |   |        |
| Additional Inf   | ormation:             |                            |         |                 |   |        |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 75652
 Seq: 1
 Gender:
 F

 Reported:
 19/02/1992
 Weight:

Hospitalisation: Age: AD
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

| cuotion betails.                  |          |                    |           |  |  |  |  |  |
|-----------------------------------|----------|--------------------|-----------|--|--|--|--|--|
| Preferred Term                    | Severity | Report Description | Treatment |  |  |  |  |  |
| Blood alkaline phosphatase increa |          |                    |           |  |  |  |  |  |
| Rash                              |          |                    |           |  |  |  |  |  |
| Urticaria                         |          |                    |           |  |  |  |  |  |

### **Medicine Details:**

STELAZINE (Suspected) Reason: Paranoid type schizophrenia

4.0 Milligram Daily

**Batch: Started:** 01/01/1973 **Stopped:** 28/09/1990

COGENTIN (Suspected) Reason:

Tablet 500.0 Microgram 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 stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 77010
 Seq:
 1
 Gender:
 F

 Reported:
 14/05/1992
 Weight:
 80.00

 Hospitalisation:
 Age:
 49Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

| Preferred Term                         | Severity | Report Description                             | Treatment |
|--|----------|--|-----------|
| Hypertriglyceridaemia                  |          | Amazing jump in cholesterol and triglycerides. |           |
| Drug ineffective Hypercholesterolaemia |          |  |           |

### **Medicine Details:**

| ATROMID-S (Other drug) |                     | Reason: |                         |             |
|------------------------|---------------------|---------|-------------------------|-------------|
|                        | 1.5 Gram            | Daily   |                         |             |
| Batch:                 | Started: 22/02/1989 |         | <b>Stopped:</b> 30/12/  | 1991        |
| STELAZINE (Suspected)  |                     | Reason: | Unspecifid affective ps | sychosis    |
|                        | 0.0                 |         |                         |             |
| Batch:                 | Started: 01/01/1985 |         | Stopped:                |             |
| LOPID (Suspected)      |                     | Reason: | Othr&unspec metaboli    | ic diseases |
|                        | 120.0 Milligram     | Daily   |                         |             |
| Batch:                 | Started: 30/12/1991 |         | <b>Stopped:</b> 14/05/  | 1992        |
| ASPIRIN (Suspected)    |                     | Reason: |                         |             |
|                        | 150.0 Milligram     | Daily   |                         |             |
| Batch:                 | Started: 01/01/1990 |         | Stopped:                | CONTIN      |

**Laboratory Investigations:** 

| Date | Туре         | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|---------|
|      | Cholesterol  |       | 22/02/1989  | 8      |         |
|      | Cholesterol  |       | 29/05/1990  | 9.9    |         |
|      | Cholesterol  |       | 10/09/1990  | 9.1    |         |
|      | Cholesterol  |       | 06/01/1991  | 5.5    |         |
|      | Cholesterol  |       | 13/04/1992  | 15     |         |
|      | Cholesterol  |       | 27/04/1992  | 19     |         |
|      | Triglyceride |       | 22/02/1989  | 4      |         |

#### **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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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 77010 Seq: 1 Gender: F

Reported: 14/05/1992 Weight: 80.00
Hospitalisation: Age: 49Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

### **Medicine Details:**

| CAPOTEN (Suspected)   |                            | Reason:      | Essential benign hypertension  |  |
|-----------------------|----------------------------|--------------|--------------------------------|--|
|                       | 50.0 Milligram             | Daily        |                                |  |
| Batch:                | Started: 04/10/1991        |              | Stopped:                       |  |
| TRYPTANOL (Suspected) |                            | Reason:      | Unspecifid affective psychosis |  |
|                       | 75.0 Milligram             | Daily        |                                |  |
| Batch:                | Started: 01/01/1985        |              | Stopped:                       |  |
| BETALOC (Suspected)   |                            | Reason:      | Essential benign hypertension  |  |
|                       | 50.0 Milligram             | Daily        |                                |  |
| Batch:                | Started: 28/08/1990        |              | Stopped:                       |  |
| PROGYNOVA (Suspected) |                            | Reason:      |                                |  |
|                       | 2.0 Dose Unspe             | cified Daily |                                |  |
| Batch:                | <b>Started:</b> 13/11/1990 |              | Stopped:                       |  |

**Laboratory Investigations:** 

| Date | Туре         | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|---------|
|      | Triglyceride |       | 29/05/1990  | -      |         |
|      | Triglyceride |       | 10/09/1990  | 6.3    |         |
|      | Triglyceride |       | 06/01/1991  | 3.4    |         |
|      | Triglyceride |       | 13/04/1992  | 23     |         |
|      | Triglyceride |       | 27/04/1992  | 31     |         |

#### **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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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

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

Case Number: 80349 Seq: 1 Gender: M

Reported: 18/09/1992 Weight: 65.00 Hospitalisation: Age: 79

**Onset Date**: 21/07/1992 **DOB**: 07/09/1912

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term          | Severity | Report Description | Treatment            |
|-------------------------|----------|--------------------|----------------------|
| Extrapyramidal disorder |          |                    | Mianserin, cogentin. |

### **Medicine Details:**

STELAZINE (Suspected) Reason: Depression

2.0 Milligram Daily

**Batch**: **Started**: 01/06/1992 **Stopped**: 21/07/1992

STEMETIL (Suspected) Reason:

15.0 Milligram Daily

**Batch: Started:** 30/05/1992 **Stopped:** 21/07/1992

**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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Reporte                           |                | Seq     |                    |                  |         | C                | ender: F      |                    |
|-----------------------------------|----------------|---------|--------------------|------------------|---------|------------------|---------------|--------------------|
|                                   | ed: 10/12/199  | 2       |                    |                  |         | ٧                | Veight:       |                    |
| spitalisatio                      |                |         |                    |                  |         |                  | Age: 7        |                    |
|                                   | te: 09/12/199  |         |                    |                  |         |                  |               | 0/06/1914          |
|                                   | e: Not yet red | covered |                    |                  |         | Ca               | usality: C    | Causality possible |
| action De                         |                |         | 1                  |                  |         |                  | <u> </u>      |                    |
|                                   | erred Term     | Se      | everity            | Rep              | ort Des | cription         |               | Treatment          |
| ruritus                           |                |         |                    |                  |         |                  |               |                    |
| ash                               |                |         |                    |                  |         |                  |               |                    |
|                                   |                |         |                    |                  |         |                  |               |                    |
|                                   |                |         |                    |                  |         |                  |               |                    |
|                                   |                |         |                    |                  |         |                  |               |                    |
|                                   |                |         |                    |                  |         |                  |               |                    |
|                                   |                |         |                    |                  |         |                  |               |                    |
| ledicine D                        |                |         |                    | Dan              |         |                  |               |                    |
| VALIUM (Susp                      | ectea)         |         | 20                 |                  | son:    | accany           |               |                    |
| Batch:                            |                | <       | 2.0  <br>Started:  | Milligram        | As nec  | essary Stopped:  |               |                    |
| PANADOL (Sus                      |                |         | raiteu.            | Rea              | son:    | Gloppeu.         |               |                    |
|                                   | opolou/        |         | 2.0                | Dose Unspecified |         | essarv           |               |                    |
| Batch:                            | :              | \$      | Started:           |                  |         | Stopped:         |               |                    |
| NORFLOXACIN                       |                |         |                    | Rea              | son:    | Othr diseases of | urinary tract | <u> </u>           |
| Tablet                            |                |         | 800.0              | Milligram        | Daily   | (                | Oral          |                    |
|                                   | <u> </u>       |         | Started: 08/1      | 2/1992           |         | Stopped: 1       | 0/12/1992     |                    |
| Batch:                            |                |         |                    | Rea              | son:    |                  |               |                    |
| Batch:<br>STELAZINE (S            | uspected)      |         |                    |                  | Daily   | ,                | S1            |                    |
|                                   | uspected)      |         | 10.0               | Milligram        | Dally   | ,                | Oral          |                    |
| STELAZINE (S                      |                | s       | 10.0  <br>Started: | Milligram        | Daily   | Stopped:         | orai          |                    |
| Tablet  Batch:                    | :              |         |                    | Milligram        | Daily   |                  | orai          |                    |
| STELAZINE (Se<br>Tablet<br>Batch: |                |         |                    |                  | Daily   |                  | Details       |                    |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 82379 Seq: 1 Gender: F

Reported: 19/01/1993 Weight:
Hospitalisation: Age:
Onset Date: 04/01/1993 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| todotion botano. |          |                    |           |  |  |  |  |  |
|------------------|----------|--------------------|-----------|--|--|--|--|--|
| Preferred Term   | Severity | Report Description | Treatment |  |  |  |  |  |
| Mouth ulceration |          |                    |           |  |  |  |  |  |
| Neutropenia      |          |                    |           |  |  |  |  |  |

#### **Medicine Details:**

| COGENTIN (Other drug) |                            | Reason: |            |            |
|-----------------------|----------------------------|---------|------------|------------|
| ooonin (onor arag)    | 500.0 Microgram            | Daily   |            |            |
| Batch:                | <b>Started:</b> 18/07/1992 |         | Stopped:   | CONTIN     |
| STELAZINE (Suspected) |                            | Reason: | Depression |            |
|                       | 40.0 Milligram             | Daily   |            |            |
| Batch:                | Started: 24/06/1992        |         | Stopped:   | 05/01/1993 |
| NORTAB (Suspected)    |                            | Reason: |            |            |
|                       | 25.0 Milligram             | Daily   |            |            |
| Batch:                | Started: 22/12/1992        |         | Stopped:   | 05/01/1993 |

**Laboratory Investigations:** 

| Date | Туре              | Range   | Date Tested | Result | Details |
|------|-------------------|---------|-------------|--------|---------|
|      | Neutrophils       | 2.0 - 8 | 04/01/1993  | 1.8    |         |
|      | White blood cells |         | 04/01/1993  | 4.0    |         |

### **Additional Information:**

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 83150 Seq: 1 Gender: M

Reported: 15/03/1993 Weight: 76.00 Hospitalisation: Age: 41Y

**Onset Date**: 25/10/1992 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term | Severity | Report Description | Treatment       |
|----------------|----------|--------------------|-----------------|
| Anaemia        |          |                    | Iron supplement |

### **Medicine Details:**

STELAZINE (Suspected)

4.0 Milligram Daily

Batch: Started: 01/01/1985 Stopped:

**Laboratory Investigations:** 

|   | Date | Туре        | Range | Date Tested | Result    | Details |
|---|------|-------------|-------|-------------|-----------|---------|
| Ī |      | Haemoglobin |       | 01/11/1992  | 12.6 G/DL |         |

#### **Additional Information:**

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

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 84373 Seq: 1 Gender: M
Reported: 04/05/1993 Weight:
Hospitalisation: Age: 83Y

**Onset Date**: 24/04/1993 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| Preferred Term             | Severity | Report Description     | Treatment  |
|----------------------------|----------|------------------------|--|
| Glossitis                  |          | Desquamation of tongue |  |
| Conjunctivitis             |          | -                      | Eye ointments, tpn.  |
| Dermatitis bullous         |          |                        |  |
| Mouth ulceration           |          |                        |  |
| Oedema peripheral          |          |                        |  |
| Rash maculo-papular        |          |                        |  |
| Toxic epidermal necrolysis |          |                        | Iv cyclophosphamide x 5days, iv hydrocortisone iv, antibiotics, eye oint &tpn. |

### **Medicine Details:**

| SERENACE (Suspected)  | Reas                       | on: Unspecified psychosis         |
|-----------------------|----------------------------|-----------------------------------|
| Injection             | 5.0 Dose Unspecified       | Total Intramuscular               |
| Batch:                | Started:                   | <b>Stopped:</b> 24/04/1993        |
| BISALAX (Suspected)   | Reas                       | on: Constipation                  |
| Tablet                | 5.0 Milligram              | As necessary Oral                 |
| Batch:                | Started:                   | <b>Stopped:</b> 24/04/1993        |
| STELAZINE (Suspected) | Reas                       | son:                              |
| Tablet                | 1.0 Dose Unspecified       | Daily Oral                        |
| Batch:                | <b>Started:</b> 16/04/1993 | <b>Stopped:</b> 24/04/1993        |
| TENORMIN (Suspected)  | Reas                       | on: Essential benign hypertension |
| Tablet                | 50.0 Milligram             | Daily Oral                        |
| Batch:                | Started: L TERM            | <b>Stopped:</b> 24/04/1993        |

**Laboratory Investigations:** 

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

### **Additional Information:**

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 44 of 197



Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number:     |                   | Seq: 1   |              |          |       |          | Gender:    | M                  |   |
|------------------|-------------------|----------|--------------|----------|-------|----------|------------|--------------------|---|
| Reported:        | 04/05/1993        |          |              |          |       |          | Weight:    |                    |   |
| Hospitalisation: | 0.4.0.4.4.000     |          |              |          |       |          | Age:       |                    |   |
| Onset Date:      |                   |          |              |          |       | C        | DOB:       | Causality possible | 2 |
| Reaction Detail  | Not yet recovered |          |              |          |       | C        | ausanty.   | Causality possible | 3 |
| Neaction Detail  | <b>5.</b>         |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
| Medicine Deta    |                   |          |              |          |       |          |            |                    |   |
| ZYLOPRIM (Suspec | eted)             | 300      | 0 Milliaron  | Reas     |       | Gout     | Oral       |                    |   |
| Batch:           |                   | Started: | .0 Milligran | L TERM   | Daily | Stonned: | 24/04/1993 | 3                  |   |
| Daten.           |                   | Starteu. |              | LILIXIVI |       | эторрец. | 24/04/1993 | ,                  |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
| Laboratory Inv   | estigations:      |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
| Additional Info  | ormation:         |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |
|                  |                   |          |              |          |       |          |            |                    |   |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Re | port | Detail | ls: |
|----|------|--------|-----|
|----|------|--------|-----|

Case Number: 85885 Seq: 1 Gender: M

Reported: 06/07/1993 Weight:
Hospitalisation: Age: 17Y

**Onset Date**: 12/06/1993 **DOB**:

Outcome: Recovered Causality: Causality possible

### **Reaction Details:**

| Preferred Term | Severity | Report Description                      | Treatment         |
|----------------|----------|---|-------------------|
| Dystonia       |          | Dystonic reaction affecting jaw & neck. | 4mg cogentin imi. |

#### **Medicine Details:**

| Medicine Details.     |                     |                               |  |
|-----------------------|---------------------|-------------------------------|--|
| SERENACE (Suspected)  |                     | Reason: Unspecified psychosis |  |
| Oral application      | 15.0 Milligram      | Daily Oral                    |  |
| Batch:                | Started: 09/06/1993 | <b>Stopped:</b> 10/06/1993    |  |
| STELAZINE (Suspected) |                     | Reason: Unspecified psychosis |  |
| Oral application      | 20.0 Milligram      | Daily Oral                    |  |
| Batch:                | Started: 10/06/1993 | <b>Stopped</b> : 14/06/1993   |  |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 86192 Seq: 1 Gender: F

 Reported: 23/07/1993
 Weight: 53.00

 Hospitalisation:
 Age: 53Y

 Onset Date: 15/11/1992
 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term     | Severity | Report Description | Treatment |
|--------------------|----------|--------------------|-----------|
| Anaemia macrocytic |          |                    |           |
| Arthralgia         |          |                    |           |
| Chills             |          |                    |           |
| Hepatitis          |          |                    |           |
| Hepatomegaly       |          |                    |           |
| Neutropenia        |          |                    |           |
| Oedema             |          |                    |           |
| Pyrexia            |          |                    |           |
| Rash               |          |                    |           |
| Thrombocythaemia   |          |                    |           |
| Weight decreased   |          |                    |           |

#### **Medicine Details:**

| Medicine Details.                |                     |                                   |  |
|----------------------------------|---------------------|-----------------------------------|--|
| BENZTROPINE MESYLATE (Suspected) |                     | Reason: Unspecified schizophrenia |  |
| Oral application                 | 2.0 Milligram       | Daily Oral                        |  |
| Batch:                           | Started: 01/01/1981 | <b>Stopped:</b> 16/06/1993        |  |
| STELAZINE (Suspected)            |                     | Reason: Unspecified schizophrenia |  |
|                                  | 1.0 Milligram       | Daily                             |  |
| Batch:                           | Started: 01/01/1981 | <b>Stopped:</b> 16/06/1993        |  |

**Laboratory Investigations:** 

| Date | Туре         | Range | Date Tested | Result | Details   |
|------|--------------|-------|-------------|--------|---|
|      | Immunology   |       |             |        | Anti-smooth muscle antibody positive  |
|      | Liver biopsy |       |             |        | Liver biopsy = epitheliod granulenas and a prominent eosinophil infiltrate= "suggestive of hypersensitivity reaction to drugs". |
|      | SAP = ALP    |       | 15/11/1992  | 429    |   |

### **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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 87514 Seq: 1 Gender: F
Reported: 06/09/1993 Weight: 53.00
Hospitalisation: Admitted to hospital Age: 46Y

**Onset Date**: 15/11/1992 **DOB**:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

| iteaction betails. |          |                    |           |
|--------------------|----------|--------------------|-----------|
| Preferred Term     | Severity | Report Description | Treatment |
| Arthralgia         |          |                    |           |
| Chills             |          |                    |           |
| Hepatitis          |          |                    |           |
| Oedema peripheral  |          |                    |           |
| Pruritus           |          |                    |           |
| Rash               |          |                    |           |
| Weight decreased   |          |                    |           |

#### **Medicine Details:**

| FELODIPINE (Other drug)           |                     | Reason: |              |                 |
|-----------------------------------|---------------------|---------|--------------|-----------------|
|                                   | 5.0 Milligram       | Daily   |              |                 |
| Batch:                            | Started: 01/08/1992 |         | Stopped:     | 28/02/1993      |
| BENZTROPINE MESYLATE (Suspected)  |                     | Reason: | Other&unspec | cified epilepsy |
| Tablet                            | 2.0 Milligram       | Daily   |              | Oral            |
| Batch:                            | Started: 01/01/1981 |         | Stopped:     | 16/06/1993      |
| TRIFLUOPERAZINE HYDROCHLORIDE (Se | uspected)           | Reason: | Other&unspec | cified epilepsy |
| Tablet                            | 7.0 Milligram       | Daily   |              | Oral            |
| Batch:                            | Started: 01/01/1981 |         | Stopped:     | 16/06/1993      |

**Laboratory Investigations:** 

| Date | Туре         | Range | Date Tested | Result | Details  |
|------|--------------|-------|-------------|--------|--|
|      | Albumin      | G/L   | 15/11/1992  | 29     |  |
|      | Liver biopsy |       |             |        | Liver biopsy which showed granolomatous hepatitis with a prominent eosinophi lic infiltrate suggestive of a drug reaction. |
|      | SAP = ALP    | U/L   | 15/11/1992  | 429    |  |

#### **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 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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 87597 Seq: 1 Gender: M

**Reported:** 10/09/1993 **Weight:** 105.00

Hospitalisation: Age: 26Y

Onset Date: 27/07/1993

Outcome: Recovered

Causality: Causality possible

Reaction Details:

| todotion Botano: |                          |          |                    |           |  |  |  |  |
|------------------|--------------------------|----------|--------------------|-----------|--|--|--|--|
|                  | Preferred Term           | Severity | Report Description | Treatment |  |  |  |  |
|                  | Agitation                |          |                    |           |  |  |  |  |
|                  | Disturbance in attention |          |                    |           |  |  |  |  |

### **Medicine Details:**

STELAZINE (Suspected) Reason: Unspecified schizophrenia

Oral application 10.0 Milligram Daily Oral

**Batch: Started:** 01/01/1992 **Stopped:** 20/08/1993

AURORIX (Suspected) Reason: Unspecified schizophrenia

Tablet 2.0 Dose Unspecified Daily Oral

**Batch: Started:** 27/07/1993 **Stopped:** 20/08/1993

# **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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

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

Case Number: 87945 Seq: 1 Gender: M

**Reported:** 28/09/1993 **Weight:** 

Hospitalisation: Age: 33Y
Onset Date: 28/06/1993
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term | Severity | Report Description      | Treatment               |
|----------------|----------|-------------------------|-------------------------|
| Rash           |          | Rash on arms and trunk. | 25mg promethazine stat. |

### **Medicine Details:**

STELAZINE (Suspected) Reason: Unspecified psychosis

Oral application 7.0 Milligram Daily Oral

**Batch: Started:** 24/06/1993 **Stopped:** 28/06/1993

## **Laboratory Investigations:**

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 88459 Seq: 1 Gender: M
Reported: 13/10/1993 Weight:
Hospitalisation: Age: 58Y

**Onset Date**: 31/10/1992 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| reaction Betails: |                  |          |                    |           |  |  |  |  |
|-------------------|------------------|----------|--------------------|-----------|--|--|--|--|
|                   | Preferred Term   | Severity | Report Description | Treatment |  |  |  |  |
|                   | Haematuria       |          |                    |           |  |  |  |  |
|                   | Renal impairment |          |                    |           |  |  |  |  |

#### **Medicine Details:**

| Wedicine Details.             |          |           |         |                         |        |
|-------------------------------|----------|-----------|---------|-------------------------|--------|
| LITHIUM CARBONATE (Suspected) |          |           | Reason: |                         |        |
| Tablet                        | 1.5      | Gram      | Daily   | Oral                    |        |
| Batch:                        | Started: |           | L TERM  | Stopped:                | CONTIN |
| PROPRANOLOL HYDROCHLORIDE (Su | spected) |           | Reason: | Abnormal involuntary mo | vement |
| Tablet                        | 80.0     | Milligram | Daily   | Oral                    |        |
| Batch:                        | Started: |           |         | Stopped:                |        |
| STELAZINE (Suspected)         |          |           | Reason: |                         |        |
| Tablet                        | 5.0      | Milligram | Daily   | Oral                    |        |
| Batch:                        | Started: |           |         | Stopped:                |        |
| LARGACTIL (Suspected)         |          |           | Reason: |                         |        |
| Tablet                        | 100.0    | Milligram | Daily   | Oral                    |        |
| Batch:                        | Started: |           |         | Stopped:                |        |

**Laboratory Investigations:** 

| ı | Date | Type           | Range    | Date Tested | Result | Details  |
|---|------|----------------|----------|-------------|--------|--|
| ĺ |      | Creatinine     | (50-120) | 01/10/1992  | 146    |  |
|   |      | Renal biopsy = |          |             |        | Renal biopsy(4/12/92)=moderate interstitial fibrosis and tubular atrophy consistent with chronic lithium toxicity. |

#### **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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report Details:                        |  |                    |            |                    |  |  |
|--|--|--------------------|------------|--------------------|--|--|
| Case Number: 88465                     | Seq: 1   |                    | Gender:    | F                  |  |  |
| Reported: 14/10/1993                   |  |                    | Weight:    | 40) (              |  |  |
| ospitalisation:                        |  |                    | Age:       |                    |  |  |
| Onset Date: 05/05/1993                 |  |                    | DOB:       |                    |  |  |
| Outcome: Recovered                     |  |                    | Causality: | Causality probable |  |  |
| eaction Details:                       | 1 0 " 1  | D 15 : "           | ī          | <del> </del>       |  |  |
| Preferred Term  Dystonia               | Severity   | Report Description |            | Treatment gentin   |  |  |
|  |  |                    |            |                    |  |  |
|  |  |                    |            |                    |  |  |
| Medicine Details:                      |  |                    |            |                    |  |  |
| STELAZINE (Suspected)                  | Reason: Nausea and vomiting                        |                    |            |                    |  |  |
| Batch:                                 | 4.0 Milligram 1 time  Started: 05/05/1993 Stopped: |                    |            |                    |  |  |
|  |  |                    |            |                    |  |  |
|  |  |                    |            |                    |  |  |
|  |  | Popult             | Dotoi      | le.                |  |  |
| Laboratory Investigations  Date Type R | ange Date Tested                                   | Result             | Detai      | ls                 |  |  |
|  |  | Result             | Detai      | İs                 |  |  |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 89602 Seq: 1 Gender: F

Reported: 01/12/1993 Weight:
Hospitalisation: Age: 63Y

Onset Date: 28/10/1993 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term  | Severity | Report Description | Treatment |
|-----------------|----------|--------------------|-----------|
| Agranulocytosis |          |                    |           |

### **Medicine Details:**

PARACETAMOL (Other drug)

| Oral application                   | 1.0            | Gram Da | ily        | Oral       |
|------------------------------------|----------------|---------|------------|------------|
| Batch:                             | Started: 22/10 | 0/1993  | Stopped:   | 24/11/1993 |
| MIANSERIN HYDROCHLORIDE (Suspected | )              | Reason  | Depression |            |
| <b>—</b>                           |                |         |            |            |

Reason:

Pain

 Tablet
 80.0 Milligram
 Daily
 Oral

 Batch:
 Started: 30/09/1993
 Stopped: 02/11/1993

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason: Depression

15.0 Milligram Daily

Batch: Started: Stopped: 02/11/1993

**Laboratory Investigations:** 

| Date | Туре        | Range | Date Tested | Result | Details  |
|------|-------------|-------|-------------|--------|--|
|      | Bone marrow |       |             |        | Maturation arrest of granulocytes at the promyelocyte stage. |

#### **Additional Information:**

Chronic schizophrenia on mianserin

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 53 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 91019 Seq: 1 Gender: M

Reported: 11/02/1994 Weight: 55.00 Hospitalisation: Age: 52

**Onset Date**: 21/01/1994 **DOB**: 31/08/1941

Outcome: Recovered Causality: Causality possible

Reaction Details:

| Preferred Term            | Severity | Report Description | Treatment    |
|---------------------------|----------|--------------------|--------------|
| Hepatic function abnormal |          |                    | Benztroprine |
| Pyrexia                   |          |                    |              |

### **Medicine Details:**

MOCLOBEMIDE (Other drug) Reason: Depression

900.0 Milligram Daily

**Batch: Started:** 29/09/1993 **Stopped:** 23/01/1994

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

80.0 Milligram Daily

Batch: Started: 06/01/1994 Stopped: 19/01/1994

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason: Depression

10.0 Milligram Daily

**Batch: Started:** 09/12/1993 **Stopped:** 20/01/1994

METHOHEXITONE SODIUM (Suspected) Reason: Other disturbance of sensation

Injection 70.0 Milligram Alternate days Intravenous

Batch: Started: 17/01/1994 Stopped: 07/02/1994

**Laboratory Investigations:** 

| Date | Type       | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|---------|
|      | ALT = SGPT |       | 21/01/1994  | 20     |         |
|      | ALT = SGPT |       | 23/01/1994  | 195    |         |
|      | ALT = SGPT |       | 25/01/1994  | 273    |         |
|      | ALT = SGPT |       | 08/02/1994  | 19     |         |
|      | ALT = SGPT |       | 01/03/1994  | 25     |         |
|      | ALT = SGPT |       | 31/01/1994  | 116    |         |
|      | ALT = SGPT |       | 27/01/1994  | 228    |         |

#### Additional Information:

Moclobemide has been restarted at 300mg/bd without recurrence of adverse reaction .

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 91019 Seq: 1 Gender: M

Reported: 11/02/1994 Weight: 55.00 Hospitalisation: Age: 52

**Onset Date**: 21/01/1994 **DOB**: 31/08/1941

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

### **Medicine Details:**

SUXAMETHONIUM NOS (Suspected) Reason: Other disturbance of sensation

Injection 40.0 Milligram Alternate days Intravenous

Batch: Started: 17/01/1994 Stopped: 07/04/1994

**Laboratory Investigations:** 

|      | <del>,</del> |       |             |        |         |
|------|--------------|-------|-------------|--------|---------|
| Date | Туре         | Range | Date Tested | Result | Details |
|      | AST = SGOT   |       | 21/01/1994  | 13     |         |
|      | AST = SGOT   |       | 23/01/1994  | 212    |         |
|      | AST = SGOT   |       | 25/01/1994  | 128    |         |
|      | AST = SGOT   |       | 31/01/1994  | 33     |         |
|      | AST = SGOT   |       | 01/03/1994  | 16     |         |
|      | AST = SGOT   |       | 08/02/1994  | 10     |         |
|      | AST = SGOT   |       | 27/01/1994  | 71     |         |

#### **Additional Information:**

Moclobemide has been restarted at 300mg/bd without recurrence of adverse reaction .

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 55 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 91019 Seq: 1 Gender: M

Reported: 11/02/1994 Weight: 55.00 Hospitalisation: Age: 52

**Onset Date:** 21/01/1994 **DOB:** 31/08/1941

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

**Medicine Details:** 

MOCLOBEMIDE (Other drug) Reason: Depression

900.0 Milligram Daily

**Batch: Started:** 29/09/1993 **Stopped:** 23/01/1994

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

80.0 Milligram Daily

Batch: Started: 06/01/1994 Stopped: 19/01/1994

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason: Depression

10.0 Milligram Daily

**Batch: Started:** 09/12/1993 **Stopped:** 20/01/1994

METHOHEXITONE SODIUM (Suspected) Reason: Other disturbance of sensation

Injection 70.0 Milligram Alternate days Intravenous

Batch: Started: 17/01/1994 Stopped: 07/02/1994

**Laboratory Investigations:** 

| Date | Type      | Range | Date Tested | Result | Details |
|------|-----------|-------|-------------|--------|---------|
|      | Bilirubin |       | 21/01/1994  | 9      |         |
|      | Bilirubin |       | 23/01/1994  | 10     |         |
|      | Bilirubin |       | 25/01/1994  | 14     |         |
|      | Bilirubin |       | 31/01/1994  | 10     |         |
|      | Bilirubin |       | 01/03/1994  | 21     |         |
|      | Bilirubin |       | 08/02/1994  | 22     |         |
|      | Bilirubin |       | 27/01/1994  | 10     |         |

#### **Additional Information:**

Moclobemide has been restarted at 300mg/bd without recurrence of adverse reaction .

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 56 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 91019 Seq: 1 Gender: M

Reported: 11/02/1994 Weight: 55.00 Hospitalisation: Age: 52

Onset Date: 21/01/1994 DOB: 31/08/1941

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

### **Medicine Details:**

SUXAMETHONIUM NOS (Suspected) Reason: Other disturbance of sensation

Injection 40.0 Milligram Alternate days Intravenous

Batch: Started: 17/01/1994 Stopped: 07/04/1994

**Laboratory Investigations:** 

| <u> </u> | <del>,</del> |       |             |        |  |
|----------|--------------|-------|-------------|--------|--|
| Date     | Туре         | Range | Date Tested | Result | Details  |
|          | Biochemistry |       |             |        | Increased lfts's including rise in alk phos, ggt, ast & alt also increased ldh |
|          | GGT = SGGT = |       | 21/01/1994  | 33     |  |
|          | GGT = SGGT = |       | 23/01/1994  | 169    |  |
|          | GGT = SGGT = |       | 27/01/1994  | 533    |  |
|          | GGT = SGGT = |       | 01/03/1994  | 58     |  |
|          | GGT = SGGT = |       | 08/02/1994  | 152    |  |

#### **Additional Information:**

Moclobemide has been restarted at 300mg/bd without recurrence of adverse reaction .

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 91019 Seq: 1 Gender: M

Reported: 11/02/1994 Weight: 55.00 Hospitalisation: Age: 52

**Onset Date**: 21/01/1994 **DOB**: 31/08/1941

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

**Medicine Details:** 

MOCLOBEMIDE (Other drug) Reason: Depression

900.0 Milligram Daily

**Batch: Started:** 29/09/1993 **Stopped:** 23/01/1994

MIANSERIN HYDROCHLORIDE (Suspected) Reason: Depression

80.0 Milligram Daily

Batch: Started: 06/01/1994 Stopped: 19/01/1994

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason: Depression

10.0 Milligram Daily

**Batch: Started:** 09/12/1993 **Stopped:** 20/01/1994

METHOHEXITONE SODIUM (Suspected) Reason: Other disturbance of sensation

Injection 70.0 Milligram Alternate days Intravenous

Batch: Started: 17/01/1994 Stopped: 07/02/1994

**Laboratory Investigations:** 

| Date | Type         | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|---------|
|      | GGT = SGGT = |       | 31/01/1994  | 340    |         |
|      | GGT = SGGT = |       | 25/01/1994  | 405    |         |
|      | SAP = ALP    |       | 21/01/1994  | 63     |         |
|      | SAP = ALP    |       | 23/01/1994  | 154    |         |
|      | SAP = ALP    |       | 25/01/1994  | 378    |         |
|      | SAP = ALP    |       | 27/01/1994  | 548    |         |
|      | SAP = ALP    |       | 31/01/1994  | 331    |         |

#### **Additional Information:**

Moclobemide has been restarted at 300mg/bd without recurrence of adverse reaction .

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 58 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 91019 Seq: 1 Gender: M

Reported: 11/02/1994 Weight: 55.00 Hospitalisation: Age: 52

**Onset Date**: 21/01/1994 **DOB**: 31/08/1941

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

### **Medicine Details:**

SUXAMETHONIUM NOS (Suspected) Reason: Other disturbance of sensation

Injection 40.0 Milligram Alternate days Intravenous

Batch: Started: 17/01/1994 Stopped: 07/04/1994

**Laboratory Investigations:** 

| Date | Туре      | Range | Date Tested | Result | Details |
|------|-----------|-------|-------------|--------|---------|
|      | SAP = ALP |       | 08/02/1994  | 140    |         |
|      | SAP = ALP |       | 10/02/1994  | 80     |         |

#### **Additional Information:**

Moclobemide has been restarted at 300mg/bd without recurrence of adverse reaction .

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 91223 Seq: 1 Gender: M

Reported: 23/02/1994 Weight: 75.00 Hospitalisation: Age: A7

Onset Date: 19/02/1994 DOB:
Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| Preferred Term            | Severity | Report Description        | Treatment |
|---------------------------|----------|---------------------------|-----------|
| Photosensitivity reaction | Severe   | Sunburn on legs and face. |           |

### **Medicine Details:**

| STELAZINE (Suspected) |                     | Reason:                       |        |
|-----------------------|---------------------|-------------------------------|--------|
|                       | 2.0 Milligram       | Daily                         |        |
| Batch:                | Started: 01/11/1992 | Stopped:                      | CONTIN |
| ENDEP (Suspected)     |                     | Reason:                       |        |
|                       | 50.0 Milligram      | Daily                         |        |
| Batch:                | Started: 01/11/1992 | Stopped:                      | CONTIN |
| FELDENE (Suspected)   |                     | Reason: Unspecified arthritis |        |
|                       | 20.0 Milligram      | Daily                         |        |
| Batch:                | Started: 01/11/1992 | Stopped:                      |        |
| KALURIL (Suspected)   |                     | Reason:                       |        |
|                       | 5.0 Milligram       | Daily                         |        |
| Batch:                | Started: 01/11/1992 | Stopped:                      | CONTIN |

**Laboratory Investigations:** 

| Date | Type | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### Additional Information:

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

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 60 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report Detail | ls: |
|---------------|-----|
|---------------|-----|

Case Number: 91223 Seq: 1 Gender: M

 Reported: 23/02/1994
 Weight: 75.00

 Hospitalisation:
 Age: A7

 Onset Date: 19/02/1994
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

ECOTRIN (Suspected) Reason: Unspecified arthritis

1.0 Dose Unspecified Daily

Batch: Started: 01/11/1992 Stopped: CONTIN

LASIX (Suspected) Reason:

1.0 Dose Unspecified Daily

Batch: Started: 01/11/1992 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 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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 91378 Seq: 1 Gender: F

Reported: 02/03/1994 Weight: 45.00 Hospitalisation: Age: 20Y

**Onset Date**: 25/01/1994 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term | Severity | Report Description                 | Treatment |
|----------------|----------|------------------------------------|-----------|
| Urticaria      |          | Itchy rash on upper arms and chest |           |

#### Medicine Details:

| COGENTIN (Other drug) |                            | Reason:       |                       |  |
|-----------------------|----------------------------|---------------|-----------------------|--|
| COGENTIN (Other drug) | 4.O. Milliana              |               |                       |  |
|                       | 1.0 Milligram              | Daily         |                       |  |
| Batch:                | <b>Started:</b> 13/01/1994 | St            | opped:                |  |
| STELAZINE (Suspected) |                            | Reason: Unspe | ecified psychosis     |  |
| Oral application      | 20.0 Milligram             | Daily         | Oral                  |  |
| Batch:                | Started: 16/01/1994        | St            | opped: 18/01/1994     |  |
| STELAZINE (Suspected) |                            | Reason: Unspe | ecified schizophrenia |  |
| Oral application      | 40.0 Milligram             | Daily         | Oral                  |  |
| Batch:                | Started: 18/01/1994        | St            | opped: 27/01/1994     |  |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

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

Case Number: 91856 Seq: 1 Gender: F

Reported: 25/03/1994 Weight: 45.00 Hospitalisation: Age: 20Y

**Onset Date**: 18/03/1994 **DOB**:

Outcome: Recovered Causality: Causality possible

Reaction Details:

| <del></del>    |          |                    |  |
|----------------|----------|--------------------|--|
| Preferred Term | Severity | Report Description | Treatment  |
| Dystonia       |          |                    | Given 2 gm oral cogentin, 20 mins later given 1 mg im. |

#### **Medicine Details:**

| Modifile Botalie:      |             |                  |       |               |            |
|------------------------|-------------|------------------|-------|---------------|------------|
| TRIPHASIL (Other drug) |             | Rea              | son:  | Contraception |            |
| Tablet                 | 1.0         | Dose Unspecified | Daily |               | Oral       |
| Batch:                 | Started:    |                  |       | Stopped:      |            |
| STELAZINE (Suspected)  |             | Rea              | son:  |               |            |
| Tablet                 | 10.0        | Milligram        | Daily |               | Oral       |
| Batch:                 | Started: 17 | /03/1994         |       | Stopped:      | 18/03/1994 |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 92419 Gender: F Seq: 1

Reported: 26/04/1994 Weight: Hospitalisation: Age: 45Y Onset Date: 22/07/1993 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term                 | Severity | Report Description | Treatment |
|--------------------------------|----------|--------------------|-----------|
| Neuroleptic malignant syndrome |          |                    |           |

### **Medicine Details:**

| DIAZEPAM (Other drug) |                     | Reason: Unspecified schizophrenia |
|-----------------------|---------------------|-----------------------------------|
| Tablet                | 5.0 Milligram       | As necessary Oral                 |
| Batch:                | Started: 07/07/1993 | Stopped:                          |

PARACETAMOL (Other drug) Reason: Pyrexia of unknown origin

Oral application 3.0 Dose Unspecified Daily Oral Batch: Started: 07/07/1993 Stopped:

**SEPTRIN FORTE (Other drug)** Reason: Othr diseases of urinary tract

Oral application 2.0 Dose Unspecified Daily Oral Batch: Started: 07/07/1993 Stopped:

CHLORPROMAZINE HYDROCHLORIDE (Suspected) Reason: Unspecified schizophrenia

Oral application 100.0 Milligram As necessary Oral Batch: Started: 07/07/1993 Stopped:

**Laboratory Investigations:** 

| Date | Туре            | Range        | Date Tested | Result | Details         |
|------|-----------------|--------------|-------------|--------|-----------------|
|      | Biochemistry    | < 0.06 MG/L  | 22/07/1993  | 107.00 | Myoglobin       |
|      | Biochemistry    | < 0.06 MG/L  | 22/07/1993  | 34.80  | Myoglobin       |
|      | Biochemistry    | < 0.38 MG/L  | 22/07/1993  | 3180   | Urine myoglobin |
|      | Creatine kinase | < 10U/L      | 22/07/1993  | 517    |                 |
|      | Creatine        | 25 - 200 U/L | 22/07/1993  | 23690  |                 |
|      | Creatine        | 25 - 200 U/L | 22/07/1993  | 139178 |                 |
|      | Creatine        | 25 - 200 U/L | 23/07/1993  | 98778  |                 |

### **Additional Information:**

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Re | port | Detail | ls: |
|----|------|--------|-----|
|----|------|--------|-----|

 Case Number:
 92419
 Seq: 1
 Gender:
 F

 Reported:
 26/04/1994
 Weight:

Hospitalisation: Age: 45Y
Onset Date: 22/07/1993
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

| MODECATE (Suspected)       |                     | Reason: Unspeci- | fied schizophrenia |  |
|----------------------------|---------------------|------------------|--------------------|--|
| Injection                  | 50.0 Milligram      | Fortnightly      | Intramuscular      |  |
| Batch:                     | Started:            | Stop             | ped: 14/07/1993    |  |
| TRIFLUOPERAZINE HYDROCHLO  | RIDE (Suspected)    | Reason: Unspeci  | fied schizophrenia |  |
| Oral application           | 30.0 Milligram      | Daily            | Oral               |  |
| Batch:                     | Started:            | Stop             | ped:               |  |
| AMITRIPTYLINE HYDROCHLORID | E (Suspected)       | Reason:          |                    |  |
| Tablet                     | 150.0 Milligram     | Daily            | Oral               |  |
| Batch:                     | Started: 21/07/1993 | Stop             | ped:               |  |

**Laboratory Investigations:** 

| Date | Type     | Range        | Date Tested | Result | Details |
|------|----------|--------------|-------------|--------|---------|
|      | Creatine | 25 - 200 U/L | 24/07/1993  | 42708  |         |
|      | Creatine | 25 - 200 U/L | 25/07/1993  | 16831  |         |
|      | Creatine | 25 - 200 U/L | 27/07/1993  | 3731   |         |

### **Additional Information:**

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

|                        | 1 - •1 -          |                                |            |                |            |                    |
|------------------------|-------------------|--------------------------------|------------|----------------|------------|--------------------|
| Report Det             | tails:            |                                |            |                |            |                    |
| Case Numb              | <b>er</b> : 93741 | Seq: 1                         |            |                | Gender:    | F                  |
| Reporte                | ed: 17/06/1994    |                                |            |                | Weight:    |                    |
| lospitalisatio         | on:               |                                |            |                | Age:       | 19Y                |
| Onset Da               | ite: 08/07/1993   |                                |            |                | DOB:       |                    |
| Outcom                 | ne: Recovered     |                                |            | С              | ausality:  | Causality possible |
| eaction De             | etails:           |                                |            |                |            |                    |
| Pref                   | ferred Term       | Severity                       | Repo       | rt Description |            | Treatment          |
| Hyperkinesia           |                   |                                |            |                | Ben        | ztropine.          |
| Hypertonia             |                   |                                |            |                |            |                    |
|                        |                   |                                |            |                |            |                    |
| Medicine E             |                   |                                | Reas       | on:            |            |                    |
| Oral a                 | pplication        | 15.0 N                         | /lilligram | Daily          | Oral       |                    |
| Batch                  | :                 | <b>Started</b> : 07/07         | 7/1993     | Stopped:       | 14/07/1993 |                    |
| CHLORPROM              | AZINE HYDROCHL    | ORIDE (Suspected)              | Reas       | on:            |            |                    |
| Oral a                 | pplication        | 150.0 M                        | /lilligram | Daily          | Oral       |                    |
| Batch                  | :                 | Started: 28/06                 | 6/1993     | Stopped:       | 07/07/1993 |                    |
|                        |                   |                                |            |                |            |                    |
|                        | / Investigatio    |                                | d Doguit T |                | Dotoile    |                    |
| <b>Laboratory</b> Date | / Investigatio    | O <b>ns:</b> Range Date Tested | d Result   |                | Details    |                    |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 94667 Seq: 1 Gender: F

Reported: 28/07/1994 Weight: 56.00 Hospitalisation: Age: 66

**Onset Date**: 31/03/1993 **DOB**: 28/07/1926

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| Preferred Term        | Severity | Report Description | Treatment |
|-----------------------|----------|--------------------|-----------|
| Neuropathy peripheral |          |                    |           |

#### **Medicine Details:**

| IMIGRAN (Suspected)    |                     | Reason: Mic | ıraine   |
|------------------------|---------------------|-------------|----------|
| ` ' '                  |                     | •           |          |
| Tablet                 | 400.0 Milligram     | Monthly     | Oral     |
| Batch:                 | Started: 01/01/1992 |             | Stopped: |
| STELAZINE (Suspected)  |                     | Reason:     |          |
|                        | 10.0 Milligram      | Daily       |          |
| Batch:                 | Started: 01/01/1991 |             | Stopped: |
| FOLIC ACID (Suspected) |                     | Reason:     |          |
|                        | 5.0 Milligram       | Daily       |          |
| Batch:                 | Started: 01/01/1992 |             | Stopped: |
| EUHYPNOS (Suspected)   |                     | Reason:     |          |
|                        | 10.0 Milligram      | Daily       |          |
| Batch:                 | Started: 01/01/1992 |             | Stopped: |

**Laboratory Investigations:** 

| Date | Туре            | Range | Date Tested | Result | Details  |
|------|-----------------|-------|-------------|--------|--|
|      | Electrographics |       |             |        | Migraine and myeloproliferative disorder. slowly pregressive peripheral neuropathy motor and sensory. nerve conduction studies reveal moderate slowing. may relate to myeloproliferative disorder. |

#### **Additional Information:**

Report Run: 06/06/2007 08:45AM Database: pusime02 ADRS004 Page 67 of 197

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



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

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

Case Number: 94667 Seq: 1 Gender: F

Reported: 28/07/1994 Weight: 56.00 Hospitalisation: Age: 66

**Onset Date:** 31/03/1993 **DOB:** 28/07/1926

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

#### **Medicine Details:**

| Medicine Details.       |                     |         |          |  |
|-------------------------|---------------------|---------|----------|--|
| TRYPTANOL (Suspected)   |                     |         |          |  |
|                         | 50.0 Milligram      | Daily   |          |  |
| Batch:                  | Started: 01/01/1992 |         | Stopped: |  |
| SANDOMIGRAN (Suspected) |                     | Reason: |          |  |
|                         | 5.0 Milligram       | Daily   |          |  |
| Batch:                  | Started: 01/01/1991 |         | Stopped: |  |

# **Laboratory Investigations:**

#### **Additional Information:**

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

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 94744
 Seq: 1
 Gender: M

 Reported:
 01/08/1994
 Weight:

Hospitalisation: Admitted to hospital Age: 20Y
Onset Date: 08/07/1994
DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term        | Severity | Report Description | Treatment |
|-----------------------|----------|--------------------|-----------|
| Hepatitis cholestatic |          |                    |           |

### **Medicine Details:**

| STELAZINE (Suspected)            |                     | Reason: Unspecified psychosis          |
|----------------------------------|---------------------|--|
|                                  | 20.0 Milligram      | Daily                                  |
| Batch:                           | Started: 29/06/1994 | <b>Stopped</b> : 14/07/1994            |
| LARGACTIL (Suspected)            |                     | Reason: Unspecified psychosis          |
|                                  | 800.0 Milligram     | Daily                                  |
| Batch:                           | Started: 29/06/1994 | <b>Stopped:</b> 14/07/1994             |
| BENZTROPINE MESYLATE (Suspected) |                     | Reason: Hered dystonia musculor deform |
|                                  | 4.0 Milligram       | Daily                                  |
| Batch:                           | Started: 29/06/1994 | <b>Stopped:</b> 14/07/1994             |

Laboratory Investigations:

| Laborato | ry mroonga |          |             |        |         |
|----------|------------|----------|-------------|--------|---------|
| Date     | Туре       | Range    | Date Tested | Result | Details |
|          | ALT = SGPT | < 40     | 07/07/1994  | 98     |         |
|          | ALT = SGPT | < 40     | 08/07/1994  | 98     |         |
|          | ALT = SGPT | < 40     | 28/07/1994  | 16     |         |
|          | Bilirubin  | (3-20)   | 07/07/1994  | 32     |         |
|          | Bilirubin  | (3-20)   | 08/07/1994  | 32     |         |
|          | Bilirubin  | (3-20)   | 28/07/1994  | 26     |         |
|          | SAP = ALP  | (35-135) | 07/07/1994  | 126    |         |

### **Additional Information:**

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 94744
 Seq: 1
 Gender: M

 Reported:
 01/08/1994
 Weight:

Hospitalisation: Admitted to hospital Age: 20Y
Onset Date: 08/07/1994
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

### **Medicine Details:**

| STELAZINE (Suspected)            |                     | Reason: Unspecified psychosis          |
|----------------------------------|---------------------|--|
|                                  | 20.0 Milligram      | Daily                                  |
| Batch:                           | Started: 29/06/1994 | <b>Stopped:</b> 14/07/1994             |
| LARGACTIL (Suspected)            |                     | Reason: Unspecified psychosis          |
|                                  | 800.0 Milligram     | Daily                                  |
| Batch:                           | Started: 29/06/1994 | Stopped: 14/07/1994                    |
| BENZTROPINE MESYLATE (Suspected) |                     | Reason: Hered dystonia musculor deform |
|                                  | 4.0 Milligram       | Daily                                  |
| Batch:                           | Started: 29/06/1994 | Stopped: 14/07/1994                    |

**Laboratory Investigations:** 

| Date | Туре      | Range    | Date Tested | Result | Details |
|------|-----------|----------|-------------|--------|---------|
|      | SAP = ALP | (35-135) | 08/07/1994  | 126    |         |
|      | SAP = ALP | (35-135) | 28/07/1994  | 101    |         |

### **Additional Information:**

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Cooo Nussal  | 04947  | 0            | . 1  |                    |                         | ^        | ender:       | Е                  |
|--|--|--------------|--|--------------------|-------------------------|----------|--------------|--------------------|
|  | oer: 94817   | Seq          | j <b>.</b> 1                                 |                    |                         |          |              |                    |
| _  | ted: 03/08/199                                       | 94           |  |                    |                         | VV       | _            | 60.00              |
| ospitalisati   | on:<br>ate: 28/06/199                                | 24           |  |                    |                         |          | Age:<br>DOB: |                    |
|  |  |              | Nac  |                    |                         | Cau      |              | Causality probable |
| eaction D  | me: Recovere   | a with seque | iae  |                    |                         | Cau      | isaiity.     | Causality probable |
|  | eferred Term   | S            | everity                                      | Ren                | ort Desc                | rintion  |              | Treatment          |
|  |  |              | ovonty                                       | ТОР                | 011 2000                | приот    |              | Hodanone           |
|  |  |              |  |                    |                         |          |              |                    |
|  |  |              |  |                    |                         |          |              |                    |
|  |  |              |  |                    |                         |          |              |                    |
|  |  |              |  |                    |                         |          |              |                    |
|  |  |              |  |                    |                         |          |              |                    |
|  |  |              |  |                    |                         |          |              |                    |
|  |  |              |  |                    |                         |          |              |                    |
|  |  |              |  |                    |                         |          |              |                    |
|  |  |              |  |                    |                         |          |              |                    |
|  |  |              |  |                    |                         |          |              |                    |
| <i>l</i> ledicine                                    | Details:   |              |  |                    |                         |          |              |                    |
|  |  |              |  | Rea                | ıson:                   |          |              |                    |
|  |  |              | 0.0  | Rea                | son:                    |          |              |                    |
|  | Other drug)  | •            | 0.0<br>Started:                              | Rea                | ıson:                   | Stopped: |              |                    |
| SINEQUAN (   | Other drug)<br>h:                                    | •            | Started:                                     |                    | son:                    | Stopped: |              |                    |
| SINEQUAN (( Batc                                     | Other drug)<br>h:<br>Other drug)                     | •            |  |                    |                         |          |              |                    |
| NITRADISC (  | Other drug)<br>h:<br>Other drug)<br>h:               |              | Started:                                     | Rea                | ison:                   | Stopped: |              |                    |
| SINEQUAN ((  Batc                                    | Other drug)<br>h:<br>Other drug)<br>h:               |              | 0.0<br>Started:                              | Rea<br>Rea         | ison:                   |          |              |                    |
| SINEQUAN (  Batc  NITRADISC (  Batc  ADALAT (Oti     | Other drug) h: Other drug) h: ner drug)              | \$           | 0.0 Started: 20.0 Milli                      | Rea<br>Rea         | ison:                   | Stopped: |              |                    |
| Batc NITRADISC (  Batc ADALAT (Oth                   | Other drug) h: Other drug) h: ner drug)              | \$           | 0.0<br>Started:                              | Rea<br>Rea<br>gram | ison:<br>ison:<br>Daily |          |              |                    |
| Batc NITRADISC (  Batc ADALAT (Oti                   | Other drug) h: Other drug) h: ner drug)              | \$           | 0.0 Started: 20.0 Milli Started:             | Rea<br>Rea<br>gram | ison: Daily             | Stopped: |              |                    |
| Batc NITRADISC (  Batc ADALAT (Oth  Batc BRUFEN (Oth | Other drug) h: Other drug) h: ner drug) h: ner drug) | •            | 0.0 Started: 20.0 Milli Started: 400.0 Milli | Rea<br>Rea<br>gram | ison:<br>ison:<br>Daily | Stopped: |              |                    |
| Batc NITRADISC (  Batc ADALAT (Oth                   | Other drug) h: Other drug) h: ner drug) h: ner drug) | •            | 0.0 Started: 20.0 Milli Started:             | Rea<br>Rea<br>gram | ison: Daily             | Stopped: |              |                    |
| Batc NITRADISC (  Batc ADALAT (Ott  Batc BRUFEN (Ott | Other drug) h: Other drug) h: ner drug) h: ner drug) | 9            | 0.0 Started: 20.0 Milli Started: 400.0 Milli | Rea<br>Rea<br>gram | ison: Daily             | Stopped: |              |                    |
| Batc NITRADISC (  Batc ADALAT (Ott  Batc BRUFEN (Ott | Other drug) h: Other drug) h: ner drug) h: ner drug) | 9            | 0.0 Started: 20.0 Milli Started: 400.0 Milli | Rea<br>Rea<br>gram | ison: Daily             | Stopped: | Detai        | ils                |

#### **Additional Information:**

Sequelae - intermittent hypotension.

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| oase Hullibel.            | 94817        | Seq: 1       |      |           |                       |               |          | Gender:    | ⊢       |              |          |
|---------------------------|--------------|--------------|------|-----------|-----------------------|---------------|----------|------------|---------|--------------|----------|
|                           | 03/08/1994   | •            |      |           |                       |               |          | Weight:    |         |              |          |
| ospitalisation:           |              |              |      |           |                       |               |          | Age:       |         |              |          |
| Onset Date:               | 28/06/1994   |              |      |           |                       |               |          | DOB:       |         |              |          |
| Outcome:                  | Recovered wi | ith sequelae |      |           |                       |               | C        | ausality:  | Causali | ity probable | <b>:</b> |
| action Detai              | ls:          |              |      |           |                       |               |          |            |         |              |          |
|                           |              |              |      |           |                       |               |          |            |         |              |          |
|                           |              |              |      |           |                       |               |          |            |         |              |          |
|                           |              |              |      |           |                       |               |          |            |         |              |          |
|                           |              |              |      |           |                       |               |          |            |         |              |          |
|                           |              |              |      |           |                       |               |          |            |         |              |          |
|                           |              |              |      |           |                       |               |          |            |         |              |          |
|                           |              |              |      |           |                       |               |          |            |         |              |          |
|                           |              |              |      |           |                       |               |          |            |         |              |          |
|                           |              |              |      |           |                       |               |          |            |         |              |          |
|                           |              |              |      |           |                       |               |          |            |         |              |          |
|                           |              |              |      |           |                       |               |          |            |         |              |          |
|                           |              |              |      |           |                       |               |          |            |         |              |          |
| ledicine Det              |              |              |      |           | Reas                  | on:           |          |            |         |              |          |
| PARLODEL (Other           | uruy)        |              | 3.0  | Dose Unsp |                       |               |          |            |         |              |          |
| Batch:                    |              | Star         |      | Dose Onst | Jecilieu              | Dally         | Stopped: |            |         |              |          |
| Daten.                    |              |              |      |           |                       |               |          |            |         |              |          |
|                           | acted)       | - Ciai       | ieu. |           | Ross                  | on:           |          |            |         |              |          |
|                           | ected)       |              |      | Milligram | Reas                  |               | Paranoia |            |         |              |          |
| STELAZINE (Susp           | ected)       |              | 4.0  | Milligram |                       | son:<br>Daily | Paranoia | 30/06/1994 | ı       |              |          |
|                           | ected)       | Star         | 4.0  |           | <b>Reas</b><br>L TERM |               | Paranoia | 30/06/1994 | ı       |              |          |
| STELAZINE (Susp           | ected)       |              | 4.0  |           |                       |               | Paranoia | 30/06/1994 | ı       |              |          |
| STELAZINE (Susp           | ected)       |              | 4.0  |           |                       |               | Paranoia | 30/06/1994 | ļ       |              |          |
| STELAZINE (Susp           | ected)       |              | 4.0  |           |                       |               | Paranoia | 30/06/1994 | i.      |              |          |
| STELAZINE (Susp           | ected)       |              | 4.0  |           |                       |               | Paranoia | 30/06/1994 | ı       |              |          |
| STELAZINE (Susp           | ected)       |              | 4.0  |           |                       |               | Paranoia | 30/06/1994 | ı       |              |          |
| STELAZINE (Susp           | ected)       |              | 4.0  |           |                       |               | Paranoia | 30/06/1994 | ı       |              |          |
| STELAZINE (Susp<br>Batch: |              | Star         | 4.0  |           |                       |               | Paranoia | 30/06/1994 | ı       |              |          |
| STELAZINE (Susp<br>Batch: |              | Star         | 4.0  |           |                       |               | Paranoia | 30/06/1994 | ı       |              |          |
| STELAZINE (Susp<br>Batch: |              | Star         | 4.0  |           |                       |               | Paranoia | 30/06/1994 | ı       |              |          |
| STELAZINE (Susp<br>Batch: |              | Star         | 4.0  |           |                       |               | Paranoia | 30/06/1994 |         |              |          |
| STELAZINE (Susp<br>Batch: |              | Star         | 4.0  |           |                       |               | Paranoia | 30/06/1994 | ı       |              |          |
| STELAZINE (Susp<br>Batch: |              | Star         | 4.0  |           |                       |               | Paranoia | 30/06/1994 |         |              |          |
| STELAZINE (Susp<br>Batch: |              | Star         | 4.0  |           |                       |               | Paranoia | 30/06/1994 |         |              |          |
| STELAZINE (Susp<br>Batch: |              | Star         | 4.0  |           |                       |               | Paranoia | 30/06/1994 |         |              |          |
| STELAZINE (Susp           |              | Star         | 4.0  |           |                       |               | Paranoia | 30/06/1994 | ı       |              |          |
| Batch:  Batch:            | vestigation  | Star         | 4.0  |           |                       |               | Paranoia | 30/06/1994 |         |              |          |
| Batch:  aboratory In      | vestigation  | Star         | 4.0  |           |                       |               | Paranoia | 30/06/1994 |         |              |          |
| STELAZINE (Susp<br>Batch: | vestigation  | Star         | 4.0  |           |                       |               | Paranoia | 30/06/1994 |         |              |          |
| Batch:  Batch:            | vestigation  | Star         | 4.0  |           |                       |               | Paranoia | 30/06/1994 |         |              |          |

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Case Number: 94819

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Repor         | ted: 03/08/1994 |              |             |             |          | We       | <b>ight</b> : 70            | .00              |  |
|---------------|-----------------|--------------|-------------|-------------|----------|----------|-----------------------------|------------------|--|
| spitalisati   |                 |              |             |             |          |          | <b>Age</b> : 76             | Υ                |  |
|               | ate: 27/07/1994 |              |             |             |          |          | DOB:                        |                  |  |
|               | me: Not yet rec | overed       |             |             |          | Caus     | usality: Causality possible |                  |  |
| action D      |                 | <del></del>  | ., I        |             |          |          | 1                           | <del>-</del> , . |  |
|               | eferred Term    | Se           | everity     | Rep         | ort Desc | ription  |                             | Treatment        |  |
| /pothermia    | 1               |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
| edicine       | Details:        |              |             |             |          |          |                             |                  |  |
| BENZHEXOL     | HYDROCHLORIDE   | (Other drug) |             |             | ason:    |          |                             |                  |  |
|               |                 |              | 1.0 Dose    | Unspecified | Daily    |          |                             |                  |  |
| Batc          |                 | S            | Started:    |             |          | Stopped: |                             |                  |  |
| LOW-K (Oth    | ner drug)       |              |             |             | ason:    |          |                             |                  |  |
|               |                 |              | 2.0 Dose    | Unspecified | Daily    |          |                             |                  |  |
| Batc          |                 | 8            | Started:    |             |          | Stopped: |                             |                  |  |
| IAMOX (Oth    | ner drug)       |              |             |             | ason:    |          |                             |                  |  |
|               |                 |              |             | Unspecified | Daily    |          |                             |                  |  |
| Batc          |                 |              | Started:    |             |          | Stopped: |                             |                  |  |
| LDACTONE      | (Other drug)    |              |             |             | ason:    |          |                             |                  |  |
|               |                 |              | 50.0 Millig | ram         | Daily    |          |                             |                  |  |
| Batc          | h:              |              | Started:    |             |          | Stopped: |                             |                  |  |
| ahorator      | y Investigation | one:         |             |             |          |          |                             |                  |  |
| Date          | Type            | Range        | Date Tested | Result      |          |          | Details                     |                  |  |
|               | ,,              |              |             |             |          |          |                             |                  |  |
|               | I               |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
| dditiono      | Linformation    |              |             |             |          |          |                             |                  |  |
| aditiona      | I Information   | :            |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
|               |                 |              |             |             |          |          |                             |                  |  |
| ort Run: 06/0 | 06/2007 08:45AM | Database: p  | usime02     |             | ADRS004  |          |                             | Page 73 of 197   |  |



## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Reported: 03/08/1994 Weight: 70.00 Hospitalisation: Age: 76Y Onset Date: 27/07/1994 DOB: Outcome: Not yet recovered Causality: Causality possible Reaction Details:  Medicine Details:  STELAZINE (Suspected) Reason: Unspecified schizophrenia Tablet 30.0 Milligram Daily Oral Batch: Started: L TERM Stopped: 27/07/1994 |
|---|
| Onset Date: 27/07/1994 Outcome: Not yet recovered  Reaction Details:  Medicine Details:  STELAZINE (Suspected) Tablet  30.0 Milligram Daily Outcome: Not yet recovered Causality: Causality possible  Causality: Causality possible  Unspecified schizophrenia  |
| Outcome: Not yet recovered  Reaction Details:  Medicine Details:  STELAZINE (Suspected) Tablet  30.0 Milligram Daily Oral   |
| Medicine Details:  STELAZINE (Suspected) Tablet  30.0 Milligram Daily Oral  |
| Medicine Details:  STELAZINE (Suspected)  Tablet  30.0 Milligram  Daily  Oral   |
| STELAZINE (Suspected)  Tablet  Reason: Unspecified schizophrenia  Oral  Oral  |
| STELAZINE (Suspected)  Reason: Unspecified schizophrenia  Tablet 30.0 Milligram Daily Oral  |
| STELAZINE (Suspected)  Reason: Unspecified schizophrenia  Tablet 30.0 Milligram Daily Oral  |
| STELAZINE (Suspected)  Reason: Unspecified schizophrenia  Tablet 30.0 Milligram Daily Oral  |
| STELAZINE (Suspected)  Reason: Unspecified schizophrenia  Tablet 30.0 Milligram Daily Oral  |
| STELAZINE (Suspected)  Reason: Unspecified schizophrenia  Tablet 30.0 Milligram Daily Oral  |
| STELAZINE (Suspected)  Reason: Unspecified schizophrenia  Tablet 30.0 Milligram Daily Oral  |
| STELAZINE (Suspected)  Reason: Unspecified schizophrenia  Tablet 30.0 Milligram Daily Oral  |
| STELAZINE (Suspected)  Reason: Unspecified schizophrenia  Tablet 30.0 Milligram Daily Oral  |
| STELAZINE (Suspected)  Tablet  Reason: Unspecified schizophrenia  Oral  Oral  |
| STELAZINE (Suspected)  Reason: Unspecified schizophrenia  Tablet 30.0 Milligram Daily Oral  |
| STELAZINE (Suspected)  Reason: Unspecified schizophrenia  Tablet 30.0 Milligram Daily Oral  |
| STELAZINE (Suspected)  Reason: Unspecified schizophrenia  Tablet 30.0 Milligram Daily Oral  |
| Tablet 30.0 Milligram Daily Oral  |
|   |
| Batch: Started: L TERM Stopped: 27/07/1994  |
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| Laboratory Investigations   |
| Laboratory Investigations:  |
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| Additional Information:   |
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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report De                             | tails:         |          |                |        |                            |                        |  |  |  |
|---------------------------------------|----------------|----------|----------------|--------|----------------------------|------------------------|--|--|--|
| Case Numl                             | ber: 95134     | Seq:     | 1              |        | Gend                       | er: F                  |  |  |  |
| Repor                                 | ted: 18/08/199 | 94       |                |        | Weight: 65.00              |                        |  |  |  |
| Hospitalisation: Admitted to hospital |                |          |                |        | Age: 65Y                   |                        |  |  |  |
| Onset Date: 13/07/1994                |                |          |                |        | DC                         | B:                     |  |  |  |
|                                       | me: Not yet re | covered  |                |        | Causali                    | ty: Causality probable |  |  |  |
| Reaction D                            |                |          |                |        |                            |                        |  |  |  |
|                                       | eferred Term   | Se       | verity         | Repo   | ort Description            | Treatment              |  |  |  |
| Coordination                          | abnormal       |          |                |        |                            |                        |  |  |  |
| Dysphagia                             | dal d'acciden  | 0        |                |        |                            |                        |  |  |  |
| Extrapyramic                          |                | Severe   | 9              |        |                            |                        |  |  |  |
| Thinking abr                          | IOIIIIAI       |          |                |        |                            |                        |  |  |  |
|                                       |                |          |                |        |                            |                        |  |  |  |
| Medicine<br>STELAZINE (               |                |          |                | Poo    | son: Unspecified psychosis |                        |  |  |  |
| STELAZINE (                           | Suspected)     |          | 10.0 Mill      |        | Daily                      |                        |  |  |  |
| Batc                                  | h:             | St       | arted: 26/06/1 |        | Stopped: 15/07/1994        |                        |  |  |  |
|                                       |                |          |                |        |                            |                        |  |  |  |
|                                       |                |          |                |        |                            |                        |  |  |  |
|                                       |                |          |                |        |                            |                        |  |  |  |
|                                       |                |          |                |        |                            |                        |  |  |  |
|                                       |                | _        |                |        |                            |                        |  |  |  |
| Laborator<br>Date                     | y Investigat   | Range    | Date Tested    | Result | ח                          | etails                 |  |  |  |
| Date                                  | туре           | Kange    | Date Tested    | Result | <u> </u>                   | ctalis                 |  |  |  |
|                                       |                | <u> </u> |                | 1      |                            |                        |  |  |  |
|                                       |                |          |                |        |                            |                        |  |  |  |
|                                       |                |          |                |        |                            |                        |  |  |  |
|                                       |                |          |                |        |                            |                        |  |  |  |
|                                       |                |          |                |        |                            |                        |  |  |  |
| A dditiono                            | I Informatio   | <b>.</b> |                |        |                            |                        |  |  |  |
| Auditiona                             | ı ımormatio    | 11.      |                |        |                            |                        |  |  |  |
|                                       |                |          |                |        |                            |                        |  |  |  |
|                                       |                |          |                |        |                            |                        |  |  |  |
|                                       |                |          |                |        |                            |                        |  |  |  |
|                                       |                |          |                |        |                            |                        |  |  |  |

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# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Date                                    | formatio      | n:    |                  |        |               |                                  |                     |    |
|---|---------------|-------|------------------|--------|---------------|----------------------------------|---------------------|----|
|   |               |       |                  |        |               |                                  |                     |    |
|   | Туре          | Range | Date Tested      | Result |               | De                               | tails               |    |
| aboratory l                             | nvestigat     | ions: |                  |        |               |                                  |                     |    |
| Batch:                                  |               | s     | Started: 04/08/1 | 994    | St            | opped: 15/08/19                  | 994                 |    |
| TELAZINE (Sus                           | pected)       |       | 4.0 Milli        |        | son:<br>Daily |                                  |                     |    |
| edicine De                              |               |       |                  |        |               |                                  |                     |    |
| nnitus                                  |               |       |                  |        |               |                                  |                     |    |
| Prefer<br>rncope                        | red Term      | Se    | everity          | Rep    | ort Descripti | on                               | Treatment           |    |
| ction Deta                              |               | u<br> |                  |        |               | Causaiit                         | y: Causality possit | ле |
|   |               |       |                  |        |               | B:<br>y: Causality possible      |                     |    |
| Outcome:                                | 4 = 10 0 11 1 |       | <b>Age</b> : 79Y |        |               | <b>Age</b> : 79Y<br><b>DOB</b> : |                     |    |
| pitalisation:<br>Onset Date<br>Outcome: |               |       |                  |        |               | Weigh                            |                     |    |



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| eport D           | etails:                          |                              |                            |                |                              |
|-------------------|----------------------------------|------------------------------|----------------------------|----------------|------------------------------|
| Case Num          | ber: 96673                       | Seq: 1                       |                            |                | Gender: F                    |
| Repo              | rted: 27/10/199                  | 4                            |                            |                | Weight:                      |
| ospitalisat       | tion:                            |                              |                            |                | Age: 20Y                     |
|                   | Date: 18/03/199                  |                              |                            |                | DOB:                         |
|                   | me: Recovered                    | d                            |                            | C              | ausality: Causality possible |
| eaction <u>C</u>  |                                  | 1                            | T                          |                |                              |
|                   | eferred Term                     | Severity                     | Report De                  | escription     | Treatment                    |
| ystonia           |                                  |                              |                            |                | Cogentin                     |
|                   |                                  |                              |                            |                |                              |
|                   | Details:<br>(Other drug)         |                              | Reason:                    | Contraception  |                              |
| Pill              |                                  | 1.0                          | Dose Unspecified Daily     |                | Oral                         |
| Bate              | ch:                              | Started:                     |                            | Stopped:       |                              |
|                   |                                  |                              |                            |                | hima n hua ni a              |
| STELAZINE         | (Suspected)                      |                              | Reason:                    | Unspecified sc | nizopnrenia                  |
| STELAZINE         | (Suspected)                      | 10.0                         | Reason: Milligram Daily    |                | nizopnrenia                  |
| STELAZINE<br>Bate |                                  | 10.0<br><b>Started:</b> 17/0 | Milligram Daily            |                | 18/03/1994                   |
| Bato              |                                  | Started: 17/0                | Milligram Daily<br>03/1994 |                |                              |
| Bate              | <sub>ch:</sub><br>ry Investigati | Started: 17/0                | Milligram Daily<br>03/1994 |                | 18/03/1994                   |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report Deta               | aiis:                 |                           |              |                         |                          |  |
|---------------------------|-----------------------|---------------------------|--------------|-------------------------|--------------------------|--|
| Case Numbe                | er: 96705             | Seq: 1                    |              | Gen                     | der: M                   |  |
| Reporte                   | ed: 26/10/1994        | 1                         |              | Wei                     | ght: 85.00               |  |
| ospitalisatio             |                       |                           |              |                         | <b>\ge</b> : 73Y         |  |
|                           | <b>te:</b> 09/08/1994 |                           |              |                         | OB:                      |  |
|                           | e: Not yet rec        | covered                   |              | Causa                   | lity: Causality possible |  |
| eaction De                |                       | T                         |              |                         |                          |  |
|                           | erred Term            | Severity                  | Repor        | t Description           | Treatment                |  |
| )ystonia<br>lyperkinesia  |                       |                           |              |                         |                          |  |
|                           |                       |                           |              |                         |                          |  |
| Medicine D                |                       |                           | Reas         | on: Unspecified psychos | is                       |  |
|                           | plication             | 3.0                       |              | Daily Oral              |                          |  |
| Batch:                    |                       | Started:                  | L TERM       | 9/1994                  |                          |  |
|                           |                       |                           |              |                         |                          |  |
|                           | Investigati           |                           | ested Result |                         | Details                  |  |
| <b>_aboratory</b><br>Date | Investigati<br>Type   | <b>ONS:</b> Range Date Te | ested Result |                         | Details                  |  |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 97831 Seq: 1 Gender: F

Reported: 14/12/1994 Weight: 75.00 Hospitalisation: Age: 67Y

Onset Date: 31/08/1994 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

| Preferred Term       | Severity | Report Description | Treatment |
|----------------------|----------|--------------------|-----------|
| Micturition disorder |          |                    |           |

#### Medicine Details:

| Medicine Details.     |                     |         |            |            |
|-----------------------|---------------------|---------|------------|------------|
| AROPAX (Suspected)    |                     | Reason: | Depression |            |
| Tablet                | 40.0 Milligram      | Daily   |            | Oral       |
| Batch:                | Started: 01/06/1994 |         | Stopped:   | 28/12/1994 |
| STELAZINE (Suspected) |                     | Reason: | Depression |            |
| Tablet                | 2.0 Milligram       | Daily   |            | Oral       |
| Batch:                | Started: 01/06/1994 |         | Stopped:   | 28/12/1994 |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### Additional Information:

Previous hesitancy of severe nature with retention with tricyclic antidepressants. unipolar depression 40 years. physically well but for arthritis. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 99543 Seq: 1 Gender: F

Reported: 10/03/1995 Weight: 85.00 Hospitalisation: Age: 52Y

Onset Date: 07/12/1994 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term            | Severity | Report Description                  | Treatment |
|---------------------------|----------|-------------------------------------|-----------|
| Hepatic function abnormal |          | Abnormality in liver function tests |           |

### **Medicine Details:**

STELAZINE (Suspected) Reason: Unspecified schizophrenia

4.0 Milligram Daily

Batch: Started: 23/11/1994 Stopped:

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Abnormalities in liver function tests have reverted to normal despite continuing treatment.

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Hospitalisatio<br>Onset Da<br>Outcom  | ed: 16/03/1995 on: te: ne: Not yet reco | Seq: 1          |                                 | Weig<br>A<br>De                                  | ler: M<br>ht: 62.00<br>ge: 82Y<br>OB:<br>ity: Causality possible |
|---------------------------------------|---|-----------------|---------------------------------|--|--|
| Reaction De                           | erred Term                              | Severity        | Poport                          | Description                                      | Treatment  |
| Choreoatheto                          |   | Seventy         |                                 |  | Пеаннени   |
| Hepatic functi                        |   |                 | Brisk reflexes in leg           | nts of feet and toes                             |  |
| Tardive dyskir                        |   |                 |                                 | ks them and swallows                             |  |
| Tardive dyskii                        | icsia                                   |                 | a lot                           | ks them and swallows                             |  |
| Tremor                                |   |                 | Tremulousness of t              | he arms at rest                                  |  |
| Speech disord                         | der                                     |                 | Voice is rather trem            | ulous  |  |
| Dystonia                              |   |                 |                                 |  |  |
| Hyperreflexia                         |   |                 |                                 |  |  |
| Medicine D STELAZINE (S Tablet Batch: | uspected)                               | 1.0<br>Started: | Reasor<br>Milligram D<br>L TERM | e: Gi dis presum psycho<br>aily Oral<br>Stopped: | genic orig   |
| <b>Laboratory</b> Date                | ' Investigatio                          |                 | ed Result                       |  | Details  |
| Date                                  | Туре                                    | Range Date Test | ed Result                       |  | Details  |
|                                       |   | I               |                                 |  |  |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| ase num                                 | ber: 100057           | Seq:                  | 1                                     |                     |                  |               | Gender:   | : F                |
|---|-----------------------|-----------------------|---------------------------------------|---------------------|------------------|---------------|-----------|--------------------|
| Repor                                   | ted: 04/04/19         | 95                    |                                       |                     |                  |               | Weight:   | 0.00               |
| spitalisat                              | ion:                  |                       |                                       |                     |                  |               | Age:      | 44Y                |
| Onset D                                 | ate:                  |                       |                                       |                     |                  |               | DOB       |                    |
|   | me: Not yet re        | ecovered              |                                       |                     |                  | C             | ausality: | Causality possible |
| action D                                |                       | 1 -                   | 1                                     |                     |                  |               |           |                    |
|   | eferred Term          | Se                    | verity                                |                     | Report De        | scription     |           | Treatment          |
| ınaemia                                 |                       |                       |                                       |                     |                  |               |           |                    |
| eukopenia                               | ell sedimentati       | on roto i             |                                       |                     |                  |               |           |                    |
|   |                       |                       |                                       |                     |                  |               |           |                    |
|   |                       |                       |                                       |                     |                  |               |           |                    |
|   |                       |                       |                                       |                     |                  |               |           |                    |
|   |                       |                       |                                       |                     |                  |               |           |                    |
|   |                       |                       |                                       |                     |                  |               |           |                    |
|   |                       |                       |                                       |                     |                  |               |           |                    |
| ledicine                                |                       |                       |                                       |                     | Reason:          | Unspecified p | evehoois  |                    |
|   | (Suspectea)           |                       |                                       |                     |                  | Unspecified b | SVCHOSIS  |                    |
| SIELAZINE                               | ` ' '                 |                       | 10.0                                  | Milliarom           |                  |               | -         |                    |
|   |                       | St                    |                                       | Milligram           | Daily            |               | Oral      |                    |
| Bato                                    | :h:                   |                       | arted: 02/0                           | -                   |                  | Stopped:      | -         |                    |
| Bato                                    |                       |                       | arted: 02/0                           | -                   | Daily            |               | -         |                    |
|   | h:<br>INE HYDROCHLO   | ORIDE (Suspecte       | arted: 02/0                           | 3/1978              | Daily Reason:    |               | Oral      |                    |
| Bato<br>AMITRIPTYL<br>Bato              | ch:<br>INE HYDROCHLO  | ORIDE (Suspecte<br>St | tarted: 02/0<br>d)<br>50.0            | 3/1978              | Daily Reason:    | Stopped:      | Oral      |                    |
| Bato<br>AMITRIPTYL<br>Bato              | ch: INE HYDROCHLO ch: | ORIDE (Suspected St   | arted: 02/0<br>d)<br>50.0 f<br>arted: | 3/1978<br>Milligram | Reason:<br>Daily | Stopped:      | Oral      | ils                |
| Bato  AMITRIPTYL  Bato  Laborator  Date | ch:<br>INE HYDROCHLO  | ORIDE (Suspecte<br>St | tarted: 02/0<br>d)<br>50.0            | 3/1978  Milligram   | Reason:<br>Daily | Stopped:      | Oral      | ils                |

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 82 of 197



# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number: 100495 Reported: 01/05/1995 ospitalisation: Onset Date: Outcome: Unknown | Seq: 1             | W                                     | Gender: F Weight: Age: DOB: Causality: Causality possible |  |  |  |  |
|---|--------------------|---------------------------------------|---|--|--|--|--|
| eaction Details:  | Coverity           | Depart Description                    | Transferent   |  |  |  |  |
| Preferred Term hrombocytopenia  | Severity           | Report Description                    | Treatment   |  |  |  |  |
|   |                    |                                       |   |  |  |  |  |
| ledicine Details:<br>STELAZINE (Suspected)  |                    | Reason:                               |   |  |  |  |  |
|   | 0.0                |                                       |   |  |  |  |  |
|   |                    |                                       |   |  |  |  |  |
| aboratory Investigatio  | ns:                |                                       |   |  |  |  |  |
| Date Type   | Range Date Tested  | Result                                | Details   |  |  |  |  |
| Platelets   | X 10 ^ 9           | Platelet count 6 weeks ag approx.130. | o was 119, previously was                                 |  |  |  |  |
| dditional Information:  |                    |                                       |   |  |  |  |  |
| ort Run: 06/06/2007 08:46AM   | Database: pusime02 | ADRS004                               | Page 83 of 197  |  |  |  |  |



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number:100791Seq: 1Gender: MReported:12/05/1995Weight: 74.00Hospitalisation:Admitted to hospitalAge: 59Y

**Onset Date**: 20/03/1995 **DOB**:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

| Neaction Details. |          |                    |           |
|-------------------|----------|--------------------|-----------|
| Preferred Term    | Severity | Report Description | Treatment |
| Headache          |          |                    |           |
| Hypokalaemia      |          |                    |           |
| Hyponatraemia     |          |                    |           |
| Photophobia       |          |                    |           |
| Pyrexia           |          |                    |           |

#### **Medicine Details:**

| Medicine Details.     |                            |          |          |  |
|-----------------------|----------------------------|----------|----------|--|
| NATRILIX (Suspected)  | F                          |          |          |  |
| Tablet                | 1.0 Dose Unspecific        | ed Daily | Oral     |  |
| Batch:                | <b>Started:</b> 01/01/1990 |          | Stopped: |  |
| STELAZINE (Suspected) | F                          | Reason:  |          |  |
| Tablet                | 2.0 Milligram              | Daily    | Oral     |  |
| Batch:                | <b>Started:</b> 01/01/1990 |          | Stopped: |  |

**Laboratory Investigations:** 

| Date | Туре      | Range     | Date Tested | Result | Details |
|------|-----------|-----------|-------------|--------|---------|
|      | Potassium | 3.4 - 4.5 | 20/03/1995  | 2.9    |         |
|      | Sodium    | 134 - 143 | 20/03/1995  | 132    |         |

### **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.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 84 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE 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 | Type      | 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:**

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 85 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE 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:

## **Medicine Details:**

| <u>Medicine Details.</u>        |                     |         |          |  |
|---------------------------------|---------------------|---------|----------|--|
| THIORIDAZINE HYDROCHLORIDE (Sus | pected)             | Reason: |          |  |
|                                 | 100.0 Milligram     | Daily   |          |  |
| Batch:                          | Started: 18/03/1994 |         | Stopped: |  |
| ORPHENADRINE NOS (Suspected)    |                     | Reason: |          |  |
|                                 | 400.0 Milligram     | Daily   |          |  |
| Batch:                          | Started:            |         | Stopped: |  |

**Laboratory Investigations:** 

| <u> </u> | <del> </del> |       |             |        |         |
|----------|--------------|-------|-------------|--------|---------|
| 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:**

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 86 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| ospitalisation:<br>Onset Date<br>Outcome:   | : 19/05/199<br>: 22/03/199<br>Recovere    | 95            | e <b>q</b> : 1   |   |   |                                 | С        |                           |   |
|---|---|---------------|--|---|---|---------------------------------|----------|---------------------------|---|
| action Deta   | ils:                                      |               |  |   |   |                                 |          |                           |   |
|   |   |               |  |   |   |                                 |          |                           |   |
|   |   |               |  |   |   |                                 |          |                           |   |
|   |   |               |  |   |   |                                 |          |                           |   |
|   |   |               |  |   |   |                                 |          |                           |   |
|   |   |               |  |   |   |                                 |          |                           |   |
|   |   |               |  |   |   |                                 |          |                           |   |
|   |   |               |  |   |   |                                 |          |                           |   |
|   |   |               |  |   |   |                                 |          |                           |   |
|   |   |               |  |   |   |                                 |          |                           |   |
|   |   |               |  |   |   |                                 |          |                           |   |
|   |   |               |  |   |   |                                 |          |                           |   |
|   |   |               |  |   |   |                                 |          |                           |   |
| OLOXYL (Other   |   |               | 20   | Dose                                      |   | son:                            |          | Oral                      |   |
| COLOXYL (Other<br>Tablet  |   |               |  | Dose                                      | <b>Rea</b><br>e Unspecified   |                                 | Stonned: | Oral                      |   |
| Batch:  | drug)                                     | E (Other drug | Started:   | Dose                                      | e Unspecified   | Daily                           | Stopped: | Oral                      |   |
| COLOXYL (Other<br>Tablet  | drug)                                     | E (Other druç | Started:   |   | e Unspecified<br>Rea  | Daily                           | Stopped: | Oral                      |   |
| COLOXYL (Other<br>Tablet<br>Batch:  | drug)                                     | E (Other druç | Started:   |   | e Unspecified<br>Rea  | Daily                           | Stopped: | Oral                      |   |
| Tablet Batch:  MIPRAMINE HYD  | drug)<br>PROCHLORID                       | E (Other drug | Started:<br>g)<br>200.0  |   | e Unspecified<br><b>Rea</b><br>gram   | Daily                           |          | Oral                      |   |
| Tablet Batch: MIPRAMINE HYD   | drug)<br>PROCHLORID                       | E (Other druç | Started:  200.0  Started:  | Millig                                    | e Unspecified<br><b>Rea</b><br>gram   | Daily son: Daily son:           |          | Oral                      | s |
| Tablet Batch: MIPRAMINE HYD Batch: Batch:   | drug)<br>PROCHLORID                       | E (Other drug | Started:  200.0  Started:  | Millig                                    | e Unspecified<br>Rea<br>gram<br>Rea   | Daily son: Daily son:           |          |                           | S |
| Tablet Batch: MIPRAMINE HYD  Batch: MODECATE (Sus Injection Batch:                                  | drug)<br>PROCHLORID<br>pected)            |               | Started: 200.0 Started: 1.0 Started:   | Millig                                    | e Unspecified  Rea gram  Rea e Unspecified                                  | Daily son: Daily son:           | Stopped: |                           | S |
| Tablet Batch:  MIPRAMINE HYD  Batch:  MODECATE (Sus   | drug)<br>PROCHLORID<br>pected)            |               | Started: 200.0 Started: 1.0 Started: spected)  | Millig                                    | Reagram Reagram Reage Unspecified Rea                                       | Daily  son: Daily  son: Monthly | Stopped: |                           | S |
| Tablet Batch: MIPRAMINE HYD  Batch: MODECATE (Sus Injection Batch:                                  | drug) PROCHLORID pected)                  |               | Started: 200.0 Started: 1.0 Started: spected)  | Millig<br>Dose                            | Rea gram Rea e Unspecified Rea gram   | Daily  son: Daily  son: Monthly | Stopped: |                           |   |
| Tablet Batch:  MIPRAMINE HYD  Batch:  MODECATE (Sus Injection Batch:  RIFLUOPERAZI                  | PROCHLORID pected)                        | HLORIDE (Sus  | Started: 200.0 Started: 1.0 Started: spected) 10.0                                       | Millig<br>Dose                            | Rea gram Rea e Unspecified Rea gram   | Daily  son: Daily  son: Monthly | Stopped: | Intravenous               |   |
| Tablet Batch:  MIPRAMINE HYD  Batch:  MODECATE (Sus Injection Batch:  RIFLUOPERAZI                  | PROCHLORID pected)                        | HLORIDE (Sus  | Started: 200.0 Started: 1.0 Started: spected) 10.0                                       | Millig<br>Dose<br>Millig                  | Rea gram Rea e Unspecified Rea gram   | Daily  son: Daily  son: Monthly | Stopped: | Intravenous               | ı |
| Tablet Batch: MIPRAMINE HYD  Batch: MODECATE (Sus Injection Batch: RIFLUOPERAZI  Batch: Batch: Sodi | PROCHLORID  Pected)  NE HYDROCH  Type  um | ions:         | \$tarted: 200.0 \$tarted:  1.0 \$tarted: spected) 10.0 \$tarted: 14/  Date Tes: 23/03/19 | Millig  Dose  Millig /03/19               | Rea gram  Rea gram  Rea gram  Rea gram  Rea gram  Rea gram  94  Result  130 | Daily  son: Daily  son: Monthly | Stopped: | Intravenous<br>18/03/1994 | ı |
| Tablet Batch:  MIPRAMINE HYD  Batch:  MODECATE (Sus Injection Batch:  RIFLUOPERAZI  Batch:          | pected)  NE HYDROCH  Type  Jum  Jum       | ions:         | Started: 200.0 Started: 1.0 Started: spected) 10.0 Started: 14/                          | Millig<br>Dose<br>Millig<br>/03/19<br>ted | Reagram Reagram Reagram Reagram Reagram Reagram 94                          | Daily  son: Daily  son: Monthly | Stopped: | Intravenous<br>18/03/1994 | ı |

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 87 of 197



## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number:     | 100982                                | Seq: 1   |              |         | Gender:    | M                  |
|------------------|---------------------------------------|----------|--------------|---------|------------|--------------------|
| Reported:        | 19/05/1995                            |          |              |         | Weight:    |                    |
| Hospitalisation: |                                       |          |              |         | Age:       | 36                 |
| Onset Date:      | 22/03/1994                            |          |              |         |            | 19/02/1958         |
| Outcome:         | Recovered                             |          |              |         | Causality: | Causality possible |
| Reaction Detail  | s:                                    |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
| Medicine Deta    | ile:                                  |          |              |         |            |                    |
|                  | DROCHLORIDE (Sus                      | pected)  |              | Reason: |            |                    |
|                  | •                                     |          | .0 Milligram | Daily   |            |                    |
| Batch:           |                                       |          | 18/03/1994   | •       | Stopped:   |                    |
| ORPHENADRINE N   | OS (Suspected)                        |          |              | Reason: |            |                    |
|                  |                                       | 400.     | .0 Milligram | Daily   |            |                    |
| Batch:           |                                       | Started: |              |         | Stopped:   |                    |
|                  |                                       |          |              |         |            | <del>-</del>       |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
| Laboratory In    | vestigations:                         |          |              |         |            |                    |
|                  | · · · · · · · · · · · · · · · · · · · |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
| Additional Info  | armatian.                             |          |              |         |            |                    |
| Auditional into  | omation:                              |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |
|                  |                                       |          |              |         |            |                    |

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 88 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

DOB:

**Report Details:** 

Case Number: 102318 Seq: 1 Gender: F

Reported: 21/07/1995 Weight: 53.00 Hospitalisation: Age: 74Y

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

**Onset Date:** 

| ١, | teaction betails.       |          |                          |           |
|----|-------------------------|----------|--------------------------|-----------|
|    | Preferred Term          | Severity | Report Description       | Treatment |
|    | Mouth ulceration        | Severe   | Oropharyngeal ulceration |           |
|    | Dermatitis exfoliative  |          |                          |           |
|    | Oesophagitis ulcerative | Severe   |                          |           |

### **Medicine Details:**

STELAZINE (Suspected) Reason:

1.0 Dose Unspecified Daily

**Batch: Started:** 01/01/1995 **Stopped:** 28/04/1995

**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.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 89 of 197



## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report<br>Hospitalisati<br>Onset D |                                 |                       | 1           |        |           | Gende<br>Weight<br>Age<br>DOE<br>Causality | :<br>:    |
|------------------------------------|---------------------------------|-----------------------|-------------|--------|-----------|--|-----------|
| R <u>eaction D</u>                 | etails:                         |                       |             |        |           |  |           |
|                                    | eferred Term                    | Se                    | verity      | Repo   | ort Descr | ription                                    | Treatment |
| Anxiety                            |                                 |                       |             |        |           |  |           |
|                                    |                                 |                       |             |        |           |  |           |
| Medicine<br>RENITEC (Ot            |                                 |                       |             | Rea    | con:      |  |           |
| KENITEC (OL                        | ner drug <i>j</i>               |                       | 0.0         | Nea    | 5011.     |  |           |
| Batc                               | h:                              | S                     | tarted:     |        |           | Stopped:                                   |           |
| PARNATE (S                         |                                 |                       |             | Rea    | son:      |  |           |
|                                    |                                 |                       | 10.0 Milli  | igram  | Daily     |  |           |
| Batc                               | h:                              | S                     | tarted:     |        |           | Stopped:                                   |           |
| STELAZINE (                        | Suspected)                      |                       |             | Rea    | son:      |  |           |
|                                    |                                 |                       | 1.0 Milli   | igram  | Daily     |  |           |
| Batc                               | h:                              | S                     | tarted:     |        |           | Stopped:                                   |           |
| Laborator  Date                    | y Investigat<br><sup>Type</sup> | <b>ions:</b><br>Range | Date Tested | Result |           | Det  | ails      |
| Additiona                          | I Informatio                    | n:                    |             |        |           |  |           |

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## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Hospitalisation Onset Da Outcon | ed: 01/08/199<br>on:<br>ite:<br>ne: Unknown |                | 1           |        | Wei<br><i>J</i><br>C | der: M<br>ght:<br>Age:<br>OOB:<br>Ility: Causality possible |
|---------------------------------|---|----------------|-------------|--------|----------------------|---|
| Reaction De                     | ferred Term                                 | Se             | verity      | Repo   | ort Description      | Treatment   |
| Amnesia                         |   |                |             |        | сосрс                |   |
|                                 | <b>N</b> 444!In-                            |                |             |        |                      |   |
| Medicine E                      | <b>PETAIIS:</b><br>E MESYLATE (S            | uspected)      |             | Rea    | son:                 |   |
| Tablet                          |   | ,              | 0.0         |        | Oral                 |   |
| Batch                           |   | St             | tarted:     |        | Stopped:             |   |
| TRIFLUOPERA                     | AZINE HYDROCH                               | ILORIDE (Suspe | ected)      | Rea    |                      |   |
|                                 |   |                | 0.0         |        |                      |   |
| Batch                           | :   | St             | tarted:     |        | Stopped:             |   |
| <b>Laboratory</b> Date          | v Investigat                                | ions:<br>Range | Date Tested | Result |                      | Details   |
| Date                            | Турс  | range          | Date Tested | result |                      | Details   |
| Additional                      | Informatio                                  | n:             |             |        |                      |   |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

|                                      | tails:           |    |        |                      |                  |                           |               |
|--------------------------------------|------------------|----|--------|----------------------|------------------|---------------------------|---------------|
| Report<br>Iospitalisatio<br>Onset Da |                  |    | 1      |                      |                  | DO                        | nt:<br>e: 31Y |
| eaction De                           | etails:          |    |        |                      |                  |                           |               |
| Pre<br>Convulsion                    | eferred Term     | Se | verity |                      | Report De        | scription                 | Treatment     |
|                                      |                  |    |        |                      |                  |                           |               |
| <b>ledicine [</b><br>TEGRETOL (C     |                  |    | 4 5    | Dose Unspec          | Reason:          | Other&unspecified epil    | epsy          |
| Batch                                | h:               | St | arted: | Dooc Onoper          | omed Bany        | Stopped:                  |               |
| OSPOLOT (O                           | ther drug)       |    | 150.0  | Milligram            | Reason:<br>Daily | Other&unspecified epil    | epsy          |
| Batch                                |                  | St | arted: |                      | Bassani          | Stopped:                  |               |
|                                      | ner arug)        |    |        |                      | Reason:          |                           |               |
|                                      |                  |    |        | Milligram            | Daily            |                           |               |
| Batch                                |                  | St | 600.0  | Milligram            |                  | Stopped:                  |               |
| Batch                                | Suspected)       |    | arted: | Milligram            | Reason: Daily    | Paranoia                  | 995           |
| Batch<br>STELAZINE (S<br>Batch       | Suspected)<br>h: | Si | 2.0    | Milligram            | Reason:          | Paranoia                  | 995           |
| STELAZINE (S                         | Suspected)       | Si | 2.0    | Milligram<br>06/1995 | Reason:<br>Daily | Paranoia Stopped: 06/06/1 | 995<br>etails |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Report Details: | Rei | oort | Detai | ls: |
|-----------------|-----|------|-------|-----|
|-----------------|-----|------|-------|-----|

Case Number: 102754 Seq: 1 Gender: F

Reported: 09/08/1995 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

| Preferred Term   | Severity | Report Description | Treatment |
|------------------|----------|--------------------|-----------|
| Libido decreased |          |                    |           |

### **Medicine Details:**

STELAZINE (Suspected) Reason:

0.0

Batch: Started: 01/01/1991 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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 102778 Seq: 1 Gender: F

 Reported:
 09/08/1995
 Weight:

 Hospitalisation:
 Age:
 48Y

 Onset Date:
 28/07/1995
 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment                        |
|----------------|----------|--------------------|----------------------------------|
| Angioedema     | Geventy  |                    | Icu, hydrocortisone, adrenaline. |

## **Medicine Details:**

| ENALAPRIL MALEATE (Suspected) |                  | Reason:      | Essential beni | gn hypertension |        |
|-------------------------------|------------------|--------------|----------------|-----------------|--------|
|                               | 5.0 Mil          | ligram Dail  | /              |                 |        |
| Batch:                        | Started:         | L TERM       | Stopped:       |                 | CONTIN |
| STELAZINE (Suspected)         |                  | Reason:      | Depression     |                 |        |
|                               | 2.0 Mil          | ligram Dail  | /              |                 |        |
| Batch:                        | Started: 27/07/1 | 1995         | Stopped:       | 28/07/1995      |        |
| AROPAX (Suspected)            |                  | Reason:      | Depression     |                 |        |
|                               | 20.0 Mil         | lligram Dail | /              |                 |        |
| Batch:                        | Started: 27/07/1 | 1995         | Stopped:       | 28/07/1995      |        |
| PREMARIN (Suspected)          |                  | Reason:      | Menopausal s   | ymptoms         |        |
|                               | 1.2 Mil          | ligram Dail  | /              |                 |        |
| Batch:                        | Started:         | L TERM       | Stopped:       |                 | CONTIN |

**Laboratory Investigations:** 

| Date | Type | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

Patient had reaction to morphine= difficulty breathing.

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Case Number: 105355

Seq: 1

## THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

Gender: F

| spitalisation:                          |       |             |           |         |                | Weight:   | 68.00                |
|---|-------|-------------|-----------|---------|----------------|-----------|----------------------|
| opitalisationi.                         |       |             |           |         |                | Age:      | 42Y                  |
| Onset Date:                             |       |             | DOB:      |         |                |           |                      |
| Outcome: Not yet recov                  | vered |             |           |         | С              | ausality  | : Causality possible |
| ction Details:                          |       |             |           |         |                |           |                      |
| Preferred Term                          | Sev   | erity       | Rep       | ort Des | scription      |           | Treatment            |
| otosensitivity reaction                 |       |             |           |         |                |           |                      |
| sh maculo-papular<br>oth discolouration |       |             |           |         |                |           |                      |
| an discolouration                       |       |             |           |         |                |           |                      |
|   |       |             |           |         |                |           |                      |
|   |       |             |           |         |                |           |                      |
| edicine Details:                        |       |             |           |         |                |           |                      |
| OGENTIN (Other drug)                    |       |             | Rea       | son:    |                |           |                      |
| Capsule                                 |       | 0.5 N       | Milligram | As ne   | cessary        | Oral      |                      |
| Batch:                                  | Sta   | rted:       |           |         | Stopped:       |           |                      |
| ORMISON (Other drug)                    |       |             | Rea       | son:    |                |           |                      |
|   |       | 10.0 N      | Milligram | As ne   | cessary        |           |                      |
| Batch:                                  | Sta   | rted:       |           |         | Stopped:       |           |                      |
| ELAZINE (Suspected)                     |       |             | Rea       | son:    | Unspecified ps | ychosis   |                      |
| Oral application                        |       | 4.0 N       | Milligram | Daily   |                | Oral      |                      |
| Batch:                                  | Sta   | rted: 28/08 | 8/1995    |         | Stopped:       | 16/11/199 | 5                    |
| aboratory Investigațio                  | ns:   | Date Teste  |           |         | Сторрова       | Deta      |                      |
| Date Type                               |       |             |           | _       |                |           |                      |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 105644
 Seq: 1
 Gender: M

 Reported:
 02/01/1996
 Weight:

Hospitalisation: Admitted to hospital Age: 49Y
Onset Date: 14/11/1995
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

| Preferred Term                    | Severity | Report Description | Treatment                         |
|-----------------------------------|----------|--------------------|-----------------------------------|
| Blood creatine phosphokinase incr |          |                    |                                   |
| Consciousness fluctuating         |          |                    |                                   |
| Convulsion                        |          |                    |                                   |
| Hypocalcaemia                     |          |                    |                                   |
| Hyponatraemia                     |          |                    |                                   |
| Leukocytosis                      |          |                    |                                   |
| Neuroleptic malignant syndrome    |          |                    | Phenytoin; clonazepam, iv fluids. |
| Pyrexia                           |          |                    |                                   |

#### **Medicine Details:**

| Medicine Details.     |                 |         |          |            |
|-----------------------|-----------------|---------|----------|------------|
| LARGACTIL (Suspected) |                 | Reas    | on:      |            |
| Oral application      | 30.0 Mil        | lligram | Daily    | Oral       |
| Batch:                | Started: 01/07/ | 1995    | Stopped: | 15/11/1995 |
| STELAZINE (Suspected) |                 | Reas    | on:      |            |
| Oral application      | 15.0 Mil        | lligram | Daily    | Oral       |
| Batch:                | Started:        | L TERM  | Stopped: | 15/11/1995 |
|                       |                 |         |          |            |

**Laboratory Investigations:** 

| Date | Туре     | Range       | Date Tested | Result | Details |
|------|----------|-------------|-------------|--------|---------|
|      | Calcium  | 2.13 - 2.63 | 14/11/1995  | 2.09   |         |
|      | Calcium  | 2.13 - 2.63 | 15/11/1995  | 2.14   |         |
|      | Creatine | 0 - 250 U/L | 14/11/1995  | 2878   |         |
|      | Creatine | 0 - 250 U/L | 21/11/1995  | 2169   |         |
|      | Creatine | 0 - 250 U/L | 18/11/1995  | 29600  |         |
|      | Creatine | 0 - 250 U/L | 15/11/1995  | 61400  |         |

### **Additional Information:**

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



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 105644
 Seq: 1
 Gender: M

 Reported:
 02/01/1996
 Weight:

Hospitalisation: Admitted to hospital Age: 49Y

Onset Date: 14/11/1995 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

### **Medicine Details:**

| Medicine Details.     |                  |           |          |            |
|-----------------------|------------------|-----------|----------|------------|
| LARGACTIL (Suspected) |                  | Reason:   |          |            |
| Oral application      | 30.0 Milli       | igram Dai | ly       | Oral       |
| Batch:                | Started: 01/07/1 | 995       | Stopped: | 15/11/1995 |
| STELAZINE (Suspected) |                  | Reason:   |          |            |
| Oral application      | 15.0 Milli       | igram Dai | ly       | Oral       |
| Batch:                | Started:         | L TERM    | Stopped: | 15/11/1995 |

**Laboratory Investigations:** 

|      | . <u> </u>        |             |             |        |  |
|------|-------------------|-------------|-------------|--------|--|
| Date | Туре              | Range       | Date Tested | Result | Details  |
|      | Electroencephalog |             |             |        | Eeg - background q 6-7 h3, epileptiform dic l temporal and central |
|      | Neutrophils       | 2.00 - 7.50 | 14/11/1995  | 14.46  |  |
|      | Neutrophils       | 2.00 - 7.50 | 17/11/1995  | 6.55   |  |
|      | Sodium            | 136 - 145   | 14/11/1995  | 118    |  |
|      | Sodium            | 136 - 145   | 15/11/1995  | 134    |  |
|      | White blood cells | 4.0 - 11.0  | 14/11/1995  | 18.3   |  |

### **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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 105644
 Seq: 1
 Gender: M

 Reported:
 02/01/1996
 Weight:

Hospitalisation: Admitted to hospital Age: 49Y

Onset Date: 14/11/1995 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

| Medicine Details.     |               |           |         |          |            |
|-----------------------|---------------|-----------|---------|----------|------------|
| LARGACTIL (Suspected) |               |           | Reason: |          |            |
| Oral application      | 30.0          | Milligram | Daily   |          | Oral       |
| Batch:                | Started: 01/0 | 07/1995   |         | Stopped: | 15/11/1995 |
| STELAZINE (Suspected) |               |           | Reason: |          |            |
| Oral application      | 15.0          | Milligram | Daily   |          | Oral       |
| Batch:                | Started:      | L.        | TERM    | Stopped: | 15/11/1995 |

**Laboratory Investigations:** 

| Date | Туре              | Range      | Date Tested | Result | Details |
|------|-------------------|------------|-------------|--------|---------|
|      | White blood cells | 4.0 - 11.0 | 17/11/1995  | 8.8    |         |

### **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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 105768 Gender: M Seq: 1 Weight: Reported: 03/01/1996

Hospitalisation: Age: 36Y **Onset Date:** DOB:

Causality: Causality possible Outcome: Recovered with sequelae

Reaction Details:

| todotion Botans. |          |                    |  |
|------------------|----------|--------------------|--|
| Preferred Term   | Severity | Report Description | Treatment                              |
| Hypertonia       |          |                    |  |
| Pyrexia          |          |                    | Treated with 8 unilateral ect sessions |
| Tachycardia      |          |                    | 363310113                              |

### **Medicine Details:**

| DIAZEPAM (Suspected)   |          | Reason:     |  |
|------------------------|----------|-------------|--|
| Injection              | 0.0      | Intravenous |  |
| Batch:                 | Started: | Stopped:    |  |
| DROPERIDOL (Suspected) |          | Reason:     |  |
|                        | 0.0      |             |  |

Reason:

Unspecified schizophrenia

Started: Stopped:

> 50.0 Milligram Total

Batch: Started: Stopped:

**Laboratory Investigations:** 

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)

| Date | Туре     | Range  | Date Tested | Result | Details   |
|------|----------|--------|-------------|--------|---|
|      | Creatine | 25-125 |             |        | Ck level in plasma- 1180 on 2nd day of admission; peaked at 2574 on 3rd day |

### **Additional Information:**

Overdose with 50mg trifluoperazine

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Case Number: 105769

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

Gender: M

| espitalisation:                             |                 |                    |        |                      | Weight:   |  |  |
|---|-----------------|--------------------|--------|----------------------|---|--|--|
| 0 (5)                                       |                 | Age: 36Y<br>DOB:   |        |                      |   |  |  |
| Onset Date:                                 |                 |                    |        |                      |   |  |  |
| Outcome: Unknown                            |                 |                    |        | •                    | Causality: Causality possible                       |  |  |
| action Details:                             |                 |                    |        |                      | Ţ   |  |  |
| Preferred Term                              | Seve            |                    |        | oort Description     | Treatment   |  |  |
| peech disorder                              |                 | Muti               | ism    |                      |   |  |  |
| atatonia                                    |                 |                    |        |                      | Bromocriptine and further unilateral ect treatments |  |  |
| eukocytosis                                 |                 |                    |        |                      | armatorar cot trodunonts                            |  |  |
|   |                 |                    |        |                      |   |  |  |
| ledicine Details:                           | OPIDE (Syamoth  | .d\                | Б.     |                      |   |  |  |
| TRIFLUOPERAZINE HYDROCHL                    | OKIDE (Suspecte | 9 <b>d)</b><br>0.0 | Re     | ason:                |   |  |  |
| Batch:                                      | Start           |                    |        | Stopped              | :   |  |  |
| THIORIDAZINE HYDROCHLORIE                   |                 |                    | Re     | ason:                |   |  |  |
|   | ,               | 50.0 Millig        |        | Daily                |   |  |  |
| Batch:                                      | Start           | _                  |        | Stopped              | :   |  |  |
|   |                 |                    |        |                      |   |  |  |
| .aboratory Investigation Date Type Creatine |                 | ate Tested         | Result | Ck level rose to 804 | Details   |  |  |



Case Number: 106333

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

Gender: F

| Reported: 07/02/1996        |              |                      |        |          | Weigh                 | t:                |        |
|-----------------------------|--------------|----------------------|--------|----------|-----------------------|-------------------|--------|
| ospitalisation:             |              |                      |        |          | Ag                    | e: 18Y            |        |
| Onset Date:                 |              |                      |        |          | DO                    | B:                |        |
| Outcome: Unknown            |              |                      |        |          | Causalit              | y: Causality poss | ible   |
| action Details:             |              |                      |        |          |                       |                   |        |
| Preferred Term              | Se           | everity              | Rep    | ort Desc | ription               | Treatmer          | nt     |
| cne                         |              |                      |        |          |                       |                   |        |
| eight increased             |              |                      |        |          |                       |                   |        |
|                             |              |                      |        |          |                       |                   |        |
|                             |              |                      |        |          |                       |                   |        |
| edicine Details:            |              |                      |        |          |                       |                   |        |
| STELAZINE (Suspected)       |              |                      |        |          | nspecified schizophre | nia               |        |
| Oral application  Batch:    |              | 2.0 Milli<br>tarted: | gram   | Daily    | Oral Stopped:         |                   |        |
|                             |              |                      |        |          |                       |                   |        |
| aboratory Investigatio      |              | Data Tanta I         | D#     | I        |                       | 4-9-              |        |
| Date Type                   | Range        | Date Tested          | Result |          | De                    | etails            |        |
| dditional Information:      |              |                      |        |          |                       |                   |        |
| ort Run: 06/06/2007 08:46AM | Database: pu | usime02              |        | ADRS004  |                       | Page 101          | of 197 |



Case Number: 106972

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Reported: 07/0                             | 3/1996             | Weight:     |                         |                |                           |  |  |  |
|--|--------------------|-------------|-------------------------|----------------|---------------------------|--|--|--|
| lospitalisation:                           |                    |             | <b>Age</b> : 20         |                |                           |  |  |  |
| Onset Date:                                |                    |             | <b>DOB</b> : 24/05/1975 |                |                           |  |  |  |
| Outcome: Unki                              | nown               |             |                         | Causa          | ality: Causality probable |  |  |  |
| eaction Details:                           |                    |             |                         |                |                           |  |  |  |
| Preferred Te                               | rm S               | everity     | Repo                    | rt Description | Treatment                 |  |  |  |
| Agitation                                  |                    |             |                         |                |                           |  |  |  |
| Drug ineffective                           |                    |             |                         |                |                           |  |  |  |
| Tremor                                     |                    |             |                         |                |                           |  |  |  |
|  |                    |             |                         |                |                           |  |  |  |
|  |                    |             |                         |                |                           |  |  |  |
|  |                    |             |                         |                |                           |  |  |  |
|  |                    |             |                         |                |                           |  |  |  |
|  |                    |             |                         |                |                           |  |  |  |
| Medicine Details:<br>STELAZINE (Suspected) |                    |             | Reas                    | eon:           |                           |  |  |  |
| 3 I ELAZINE (Suspected)                    |                    | 15.0 Milli  |                         | Daily          |                           |  |  |  |
| Batch:                                     | 9                  | Started:    | gram                    | Stopped:       |                           |  |  |  |
|  |                    |             |                         |                |                           |  |  |  |
| Laboratory Inves                           | igations:          |             |                         |                |                           |  |  |  |
| Date Type                                  | Range              | Date Tested | Result                  |                | Details                   |  |  |  |
|  |                    |             |                         |                |                           |  |  |  |
| Additional Inform                          | ation:             |             |                         |                |                           |  |  |  |
| eport Run: 06/06/2007 0                    | 3:46AM Database: p | ousime02    | Α                       | DRS004         | Page 102 of 197           |  |  |  |



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 107695 Seq: 1 Gender: F

 Reported:
 03/04/1996
 Weight:
 50.00

 Hospitalisation:
 Age:
 27Y

 Onset Date:
 20/03/1996
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| Preferred Term       | Severity                               | Report Description | Treatment |
|----------------------|--|--------------------|-----------|
| Face oedema          | Required<br>Specialist<br>Consultation |                    |           |
| Gravitational oedema |  |                    |           |

#### **Medicine Details:**

| PAROXETINE HYDROCHLORIDE (S | uspected)           | Reason: | Depression            |  |
|-----------------------------|---------------------|---------|-----------------------|--|
|                             | 40.0 Milligram      | Daily   |                       |  |
| Batch:                      | Started: 01/01/1996 |         | Stopped:              |  |
| TRIFLUOPERAZINE HYDROCHLOR  | IDE (Suspected)     | Reason: | Unspecified psychosis |  |
|                             | 30.0 Milligram      | Daily   |                       |  |
| Batch:                      | Started: 01/12/1995 |         | Stopped:              |  |
| RISPERIDONE (Suspected)     |                     | Reason: | Unspecified psychosis |  |
|                             | 2.0 Milligram       | Daily   |                       |  |
| Batch:                      | Started: 10/03/1996 |         | Stopped:              |  |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Patient allegic to disprin. 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.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 103 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 109186 Seq: 1 Gender: F

Reported: 18/06/1996 Weight: 94.00 Hospitalisation: Age: 35Y

Onset Date: 31/12/1989 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Amenorrhoea    |          |                    |           |

### **Medicine Details:**

STELAZINE (Suspected) Reason:

Tablet 2.0 Milligram Daily Oral

**Batch: Started:** 01/01/1989 **Stopped:** 18/03/1996

**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.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 104 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 113206 Seq: 1 Gender: F

Reported: 18/11/1996 Weight: 65.00 Hospitalisation: Age: 71Y

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

Outcome: Recovered Causality: Causality certain

**Reaction Details:** 

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Pruritus       |          |                    |           |

### **Medicine Details:**

STELAZINE (Suspected) Reason: Anxiety neurosis

1.0 Milligram Daily

Batch: Started: Stopped:

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Patient was rechallenged on stelazine with same reaction occurring. see original report for other drugs.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 105 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 113207 Seq: 1 Gender: F

 Reported:
 18/11/1996
 Weight:
 67.00

 Hospitalisation:
 Age:
 34Y

 Onset Date:
 07/11/1996
 DOB:

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term | Severity                               | Report Description | Treatment |
|----------------|--|--------------------|-----------|
| Galactorrhoea  | Required<br>Specialist<br>Consultation |                    |           |

### **Medicine Details:**

| viedicine Details:       |          |                        |                  |           |
|--------------------------|----------|------------------------|------------------|-----------|
| STELAZINE (Suspected)    |          | Reason:                | Unspecified psyc | chosis    |
|                          | 10.0     | Milligram Daily        |                  |           |
| Batch:                   | Started: | L TERM                 | Stopped:         |           |
| AROPAX (Suspected)       |          | Reason:                | Depression       |           |
|                          | 20.0     | Milligram Daily        |                  |           |
| Batch:                   | Started: |                        | Stopped:         | 8W        |
| TRIQUILAR ED (Suspected) |          | Reason:                | Contraception    |           |
|                          | 1.0      | Dose Unspecified Daily |                  |           |
| Batch:                   | Started: | L TERM                 | Stopped: 1       | 2/09/1996 |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

Patient has previous history of galactorrhoea with melleril.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 106 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 113240 Seq: 1 Gender: F

Reported: 19/11/1996

Hospitalisation:
Onset Date:

Weight: 70.00
Age: 70Y
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment                              |
|----------------|----------|--------------------|--|
| Dyskinesia     |          | 1                  | Stop risperidone, re-instate stelazine |

### **Medicine Details:**

| STELAZINE (Suspected)   | Reason:  |           |         |                           |  |
|-------------------------|----------|-----------|---------|---------------------------|--|
|                         | 0.0      |           |         |                           |  |
| Batch:                  | Started: | L         | . TERM  | Stopped:                  |  |
| RISPERIDONE (Suspected) |          |           | Reason: | Unspecified schizophrenia |  |
|                         | 1.0      | Milligram | Daily   |                           |  |

**Batch: Started:** 23/07/1996 **Stopped:** 07/11/1996

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Patient was on stelazine for 30 years with no problems. patient is now back on stelazine and well.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 114703 Seq: 1 Gender: F
Reported: 23/01/1997 Weight:
Hospitalisation: Age: 52Y

**Onset Date**: 04/01/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| caction Details.                  |          |                    |                           |
|-----------------------------------|----------|--------------------|---------------------------|
| Preferred Term                    | Severity | Report Description | Treatment                 |
| Blood creatine phosphokinase incr |          |                    |                           |
| Catatonia                         |          |                    | Dantrolene, bromocriptine |
| Drug ineffective                  |          |                    |                           |
| Hyperglycaemia                    |          |                    |                           |
| Pyrexia                           |          |                    |                           |

#### **Medicine Details:**

| CARTIA (Suspected)    |              |           | Reason: |                               |  |
|-----------------------|--------------|-----------|---------|-------------------------------|--|
|                       | 100.0        | N 4:11:   |         | 0.77                          |  |
| Tablet                | 100.0        | Milligram | Daily   | Oral                          |  |
| Batch:                | Started:     |           | L TERM  | Stopped:                      |  |
| PREMARIN (Suspected)  |              |           | Reason: | Menopausal symptoms           |  |
| Tablet                | 625.0        | Microgran | n Daily | Oral                          |  |
| Batch:                | Started:     |           | L TERM  | Stopped:                      |  |
| COVERSYL (Suspected)  |              |           | Reason: | Essential benign hypertension |  |
| Tablet                | 4.0          | Milligram | Daily   | Oral                          |  |
| Batch:                | Started: 01/ | 01/1996   |         | Stopped:                      |  |
| STELAZINE (Suspected) |              | Reason:   |         |                               |  |
|                       | 8.0          | Milligram | Daily   |                               |  |
| Batch:                | Started:     |           | L TERM  | Stopped:                      |  |

**Laboratory Investigations:** 

| Date | Туре     | Range | Date Tested | Result | Details |
|------|----------|-------|-------------|--------|---------|
|      | Creatine |       | 04/01/1997  | 5136   |         |
|      | Creatine |       | 04/01/1997  | 8947   |         |
|      | Creatine |       | 05/01/1997  | 10356  |         |
|      | Creatine |       | 06/01/1997  | 7074   |         |
|      | Creatine |       | 07/01/1997  | 3663   |         |
|      | Creatine |       | 08/01/1997  | 1198   |         |

### **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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

|   | Seq: 1                      |                        | Gender: F                     |   |
|---|-----------------------------|------------------------|-------------------------------|---|
| Reported: 23/01/1997  |                             |                        | Weight:                       |   |
| Hospitalisation:  |                             |                        | Age: 52Y                      |   |
| Onset Date: 04/01/1997  |                             |                        | DOB:                          |   |
| Outcome: Not yet recovere                                     | d                           |                        | Causality: Causality possible | е |
| Reaction Details:   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
| Medicine Details:   |                             |                        |                               |   |
| CHLORPROMAZINE HYDROCHLORIDI                                  |                             | Reason:                |                               |   |
| Injection   | 150.0 Milligrar             | -                      | Intramuscular                 |   |
| Batch:  | <b>Started:</b> 03/01/1997  | Sto                    | opped: 04/01/1997             |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
| <b>Laboratory Investigations:</b>                             |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
|   |                             |                        |                               |   |
| Additional Information:                                       |                             |                        |                               |   |
|   | out indicates that start oc | curred sometime durir: | ng the year.                  |   |
| Additional Information: the dosage start date is not accurate | out indicates that start oc | curred sometime durir  | ng the year.                  |   |
|   | out indicates that start oc | ocurred sometime durin | ng the year.                  |   |
|   | out indicates that start oc | curred sometime durir  | ng the year.                  |   |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

|                |    |          | 4 1 | _   |     |     |
|----------------|----|----------|-----|-----|-----|-----|
| $\mathbf{\nu}$ | Δn | $\sim$ 1 | **  | ם ו | taı | ls: |
| 1              | CN | vi       | L   | UG  | Lai | 13. |

 Case Number:
 114828
 Seq: 1
 Gender:
 F

 Reported:
 29/01/1997
 Weight:

Hospitalisation:
Onset Date:
DOB:

Outcome: Unknown Causality: Causality possible

### **Reaction Details:**

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Dry mouth      | Severe   |                    |           |

### **Medicine Details:**

STELAZINE (Suspected)

Reason:

0.0

Batch: Started: Stopped:

COGENTIN (Suspected) Reason: Paralysis agitans

Tablet 2.0 Milligram Daily Oral Batch: Started: 01/10/1995 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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Onset Date:<br>Outcome: | 30/01/1997                |       |          |          |               |        |            |           |                |        |
|-------------------------|---------------------------|-------|----------|----------|---------------|--------|------------|-----------|----------------|--------|
| Outcome:                |                           |       |          |          |               |        |            | Weight:   |                |        |
| Outcome:                |                           |       |          |          |               |        |            | _         | : 92Y          |        |
|                         |                           |       |          |          |               |        |            | DOB       |                |        |
| 4 4                     | Recovered                 |       |          |          |               |        | С          | ausality  | : Causality po | ssible |
| <u>iction Detail</u>    | s:                        |       |          |          |               |        |            |           |                |        |
| Preferre                | d Term                    |       | Severity |          | Repo          | ort De | scription  |           | Treatm         | ent    |
| pertonia                |                           |       |          | Muscu    | ılar rigidity |        |            |           |                |        |
| onfusional state        |                           |       |          |          |               |        |            |           |                |        |
| yperhidrosis            |                           |       |          |          |               |        |            |           |                |        |
| euroleptic malig        | nant syndro               | me    |          |          |               |        |            |           |                |        |
| chycardia               |                           |       |          |          |               |        |            |           |                |        |
| edicine Deta            | sile:                     |       |          |          |               |        |            |           |                |        |
| ARDIZEM (Other o        |                           |       |          |          | Rea           | son:   |            |           |                |        |
| Tablet                  | <b>.</b>                  |       | 90.0     | Milligra |               | Daily  |            | Oral      |                |        |
| Batch:                  |                           |       | Started: | J        |               | ,      | Stopped:   |           |                |        |
| RANSIDERM-NITE          | O (Other dru              | g)    |          |          | Rea           | son:   |            |           |                |        |
| Cream                   |                           |       | 50.0     | Milligra | m             | Daily  |            | Transdern | mal            |        |
| Batch:                  |                           |       | Started: |          |               |        | Stopped:   |           |                |        |
| OLOFT (Suspecte         | d)                        |       |          |          | Rea           | son:   | Depression |           |                |        |
| Tablet                  |                           |       | 50.0     | Milligra | m             | Daily  |            | Oral      |                |        |
| Batch:                  |                           |       | Started: |          |               |        | Stopped:   |           |                |        |
| TELAZINE (Suspe         | cted)                     |       |          |          | Rea           | son:   | Depression |           |                |        |
| Tablet                  |                           |       | 1.0      | Milligra | m             | Daily  |            | Oral      |                |        |
| Batch:                  |                           |       | Started: |          |               |        | Stopped:   |           |                |        |
|                         |                           |       |          |          |               |        |            |           |                |        |
| boratory Inv            | <b>vestigatio</b><br>Type | Range | Date Tes | ted      | Result        |        |            | Deta      | aile           |        |
| Date                    | Турс                      | range | Date 163 | icu      | resuit        |        |            | DCta      | JII 3          |        |

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 111 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Reported: 23/05/19 ospitalisation: Onset Date: Outcome: Recover eaction Details:                                 |       | <b>j:</b> 1 |                         |      |                        | С                                       | DOI          | t:<br>e: 53Y |
|--|-------|-------------|-------------------------|------|------------------------|---|--------------|--------------|
| Preferred Term   | S     | everity     |                         | Repo | ort De                 | scription                               |              | Treatment    |
| Hyperaesthesia<br>Paraesthesia   |       |             | Heighteni<br>Tingling s |      |                        | and perception                          | on           |              |
| Medicine Details:  ZOLOFT (Suspected)  Tablet  Batch:  ZOLOFT (Suspected)  Tablet  Batch:  STELAZINE (Suspected) |       | Started:    | Milligram<br>Milligram  | Rea: | Daily<br>son:<br>Daily | Depression Stopped: Depression Stopped: | Oral<br>Oral | 02M          |
| STELAZINE (Suspected) Tablet   |       | 100.0       | Milligram               | Rea  | son:<br>Daily          |   | Oral         |              |
| Batch:   | !     | Started:    | <b>J</b>                |      |                        | Stopped:                                | -            |              |
| MOGADON (Suspected)  |       |             |                         | Rea  | son:                   |   |              |              |
| Tablet   |       | 0.0         |                         |      | Daily                  |   | Oral         |              |
| Batch:   |       | Started:    |                         |      |                        | Stopped:                                |              |              |
| aboratory Investiga  |       | 1_          | . 1                     |      |                        |   |              |              |
| <u>aboratory Investiga</u>   | Range | Date Test   | ed Res                  | sult |                        |   | De           | tails        |

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 112 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 118870 Seq: 1 Gender: F

Reported: 07/07/1997 Weight:
Hospitalisation: Age: 77Y

Onset Date: 31/12/1987 DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

| Preferred Term | Severity | Report Description       | Treatment      |  |
|----------------|----------|--------------------------|----------------|--|
| Dyskinesia     |          | Bucco-lingual dyskinesia | Drug withdrawn |  |

### **Medicine Details:**

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:

2.0 Milligram Daily

Batch: Started: 01/01/1987 Stopped:

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

Symptoms abated after withdrawal of drug. - 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.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 113 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| 119484<br>28/07/1997<br>17/07/1997 | Seq: 1                 |                                 |  |   |   |
|------------------------------------|------------------------|---------------------------------|--|---|---|
| 28/07/1997                         | -                      |                                 |  | Gender:   | М   |
| 7/07/1007                          |                        |                                 |  | Weight:   |   |
| 7/07/1007                          |                        |                                 |  | Age:  | 16Y   |
| 1/0//199/                          |                        |                                 |  | DOB:  |   |
| Recovered                          |                        |                                 | C  | ausality:   | Causality probable  |
| s:                                 |                        |                                 |  |   |   |
|                                    | Severity               | Repo                            | rt Description   |   | Treatment   |
|                                    |                        | Dystonic reaction               | of neck muscles  |   |   |
|                                    |                        |                                 |  |   |   |
|                                    |                        | Reas                            | son:   |   |   |
|                                    | 3.0 □                  | ose Unspecified                 | Daily  | Oral  |   |
|                                    | <b>Started</b> : 16/07 | <sup>7</sup> /1997              | Stopped:   | 17/07/1997  | •   |
| restigations                       | :                      |                                 |  |   |   |
|                                    |                        | d Result                        |  | Detai   | s   |
| -                                  |                        |                                 |  |   |   |
|                                    |                        | ils: cted) 3.0 E Started: 16/07 | ils: cted) Reas 3.0 Dose Unspecified Started: 16/07/1997 | Dystonic reaction of neck muscles  ils:  Reason: 3.0 Dose Unspecified Daily  Started: 16/07/1997 Stopped: | Dystonic reaction of neck muscles  ills:  cted)  Reason: 3.0 Dose Unspecified Daily Oral  Started: 16/07/1997 Stopped: 17/07/1997 |

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 114 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

|  | <b>Der:</b> 119935  |              | <b>q:</b> 1                               |                    |                       |          | nder: M           |                 |
|--|---|--------------|---|--------------------|-----------------------|----------|-------------------|-----------------|
| -  | ted: 15/08/199  | 97           |   |                    |                       |          | ight:             |                 |
| spitalisati  |   |              |   |                    |                       |          | <b>Age</b> : 91   |                 |
| Onset D  |   |              |   |                    |                       |          | <b>DOB</b> : 19/0 |                 |
|  | <b>ne:</b> Death, ma  | aybe drug    |   |                    |                       | Caus     | ality: Cau        | sality possible |
| action D   |   |              |   |                    |                       |          | 1                 |                 |
|  | eferred Term  |              | Severity                                  | Repo               | ort Desc              | cription |                   | Treatment       |
| euroleptic r   | nalignant synd  | Irome        |   |                    |                       |          |                   |                 |
|  |   |              |   |                    |                       |          |                   |                 |
|  |   |              |   |                    |                       |          |                   |                 |
| ledicine  <br>LORAZEPAM  | Details:<br>(Other drug)                                    |              |   | Rea                | son:                  |          |                   |                 |
| LORAZEPAM  | (Other drug)  |              | 0.0                                       | Rea                | son:                  | 24       |                   |                 |
| LORAZEPAM<br>Batc  | (Other drug)<br>h:  |              | 0.0<br><b>Started</b> :                   |                    |                       | Stopped: |                   |                 |
| LORAZEPAM  | (Other drug)<br>h:  |              | Started:                                  |                    | son:                  | Stopped: |                   |                 |
| LORAZEPAM<br>Batci<br>DIAZEPAM (C                                  | (Other drug) h: Other drug)                                 |              | Started:<br>0.0                           |                    |                       |          |                   |                 |
| LORAZEPAM<br>Batc<br>DIAZEPAM (C<br>Batc                           | (Other drug) h: Other drug)                                 |              | Started:                                  | Rea                | son:                  | Stopped: |                   |                 |
| LORAZEPAM<br>Batc<br>DIAZEPAM (C<br>Batc                           | (Other drug) h: Other drug)                                 |              | 0.0<br>Started:                           | Rea<br>Rea         | son:                  |          |                   |                 |
| Batci<br>DIAZEPAM (C<br>Batci<br>AMLODIPINE                        | (Other drug) h: Other drug) h: (Other drug)                 |              | 0.0 Started: 5.0 Milli                    | Rea<br>Rea         | son:                  | Stopped: |                   |                 |
| Batci<br>DIAZEPAM (C<br>Batci<br>AMLODIPINE<br>Batci               | (Other drug) h: Other drug) h: (Other drug)                 |              | 0.0<br>Started:                           | Rea<br>Rea<br>gram | son:                  |          |                   |                 |
| Batci<br>DIAZEPAM (C<br>Batci<br>AMLODIPINE<br>Batci               | (Other drug) h: Other drug) h: (Other drug)                 |              | 0.0 Started: 5.0 Milli Started:           | Rea<br>Rea<br>gram | son: Son: Daily Son:  | Stopped: |                   |                 |
| Batci<br>DIAZEPAM (C<br>Batci<br>AMLODIPINE<br>Batci               | (Other drug) h: Other drug) h: (Other drug) h: YDROCHLORIDE | (Other drug) | 0.0 Started: 5.0 Milli                    | Rea<br>Rea<br>gram | son:<br>son:<br>Daily | Stopped: |                   |                 |
| Batci<br>DIAZEPAM (C<br>Batci<br>AMLODIPINE<br>Batci<br>PRAZOSIN H | (Other drug) h: Other drug) h: (Other drug) h: YDROCHLORIDE | (Other drug) | 0.0 Started: 5.0 Milli Started: 2.0 Milli | Rea<br>Rea<br>gram | son: Son: Daily Son:  | Stopped: |                   |                 |
| Batci<br>DIAZEPAM (C<br>Batci<br>AMLODIPINE<br>Batci<br>PRAZOSIN H | (Other drug) h: Other drug) h: (Other drug) h: YDROCHLORIDE | (Other drug) | 0.0 Started: 5.0 Milli Started: 2.0 Milli | Rea<br>Rea<br>gram | son: Son: Daily Son:  | Stopped: | Details           |                 |

## **Additional Information:**

Long term exposure. patient died 12/06/1997 committee comment: include in annual fatality analysis

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number:      | 119935           | Seq: 1                    |              | Gender:                    | M                  |
|-------------------|------------------|---------------------------|--------------|----------------------------|--------------------|
| Reported:         | 15/08/1997       |                           |              | Weight:                    |                    |
| Hospitalisation:  |                  |                           |              | Age:                       | 91                 |
| Onset Date:       |                  |                           |              | DOB:                       | 19/03/1906         |
| Outcome:          | Death, maybe dru | ıg                        |              | Causality:                 | Causality possible |
| Reaction Detai    | =                |                           |              | -                          | • •                |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
| Madiaina Dat      | oilo             |                           |              |                            |                    |
| Medicine Det      |                  |                           | Reason:      |                            |                    |
| I AMOTIDINE (OUI) | er drug)         | 40.0 Milligram            | Daily        |                            |                    |
| Batch:            |                  | Started: 21/05/1997       | Dally        | Stopped:                   |                    |
|                   | E UVDBOCUI OBIDE |                           | Bassani      |                            |                    |
| IRIFLUOPERAZIN    | E HYDROCHLORIDE  |                           | Reason:      | Unspecified psychosis      |                    |
|                   |                  | 6.0 Milligram             | Daily        | <b>9</b> 4 1 05/00/4006    |                    |
| Batch:            |                  | Started:                  |              | <b>Stopped:</b> 05/06/1996 |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
| Laboratory In     | voetinatione     |                           |              |                            |                    |
| Laboratory III    | vestigations.    |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
| Additional Inf    | ormation.        |                           |              |                            |                    |
|                   |                  | 6/1997 committee comment: | include in a | annual fatality analysis   |                    |
| Ç                 |                  |                           |              | ., , <del></del>           |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |
|                   |                  |                           |              |                            |                    |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 121901
 Seq: 1
 Gender: M

 Reported:
 28/10/1997
 Weight:
 63.00

 Hospitalisation:
 Age:
 52Y

**Onset Date**: 26/10/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| todotion Botano.      |          |   |   |
|-----------------------|----------|---|---|
| Preferred Term        | Severity | Report Description                              | Treatment   |
| Pathological fracture |          | Neck of femur (r) & microfractures (r) cordyle. |   |
| Osteoporosis          |          |   | Needs rehabilitation and orthopedic intervention. |

## **Medicine Details:**

| STELAZINE (Suspected)       | Re                  | eason:      |            |
|-----------------------------|---------------------|-------------|------------|
| Tablet                      | 4.0 Milligram       | Daily       | Oral       |
| Batch:                      | Started:            | Stopped:    | CONTIN     |
| ANDROCUR (Suspected)        | Re                  | eason:      |            |
| Tablet                      | 100.0 Milligram     | Daily       | Oral       |
| Batch:                      | Started: 01/01/1992 | Stopped:    | 13/10/1997 |
| TOFRANIL (Suspected)        | Re                  | eason:      |            |
| Tablet                      | 25.0 Milligram      | Daily       | Oral       |
| Batch:                      | Started:            | Stopped:    | CONTIN     |
| PANADEINE FORTE (Suspected) | Re                  | eason: Pain |            |
| Tablet                      | 2.0 Dose Unspecifie | d Daily     | Oral       |
| Batch:                      | Started: 01/01/1997 | 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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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 123464 Seq: 1 Gender: M

Reported: 17/12/1997 Weight: 60.00 Hospitalisation: Age: 15Y

Onset Date: 16/10/1997 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

| caction betains. |          |                    |   |
|------------------|----------|--------------------|---|
| Preferred Term   | Severity | Report Description | Treatment   |
| Dystonia         |          |                    | Benztropine 0.8mg iv stat.<br>stelazine decreased to 2mg<br>bd. |

## **Medicine Details:**

| Medicine Details.     |                 |                    |        |  |
|-----------------------|-----------------|--------------------|--------|--|
| STELAZINE (Suspected) |                 | Reason: Depression |        |  |
|                       | 7.0 Milligram   | Daily              |        |  |
| Batch:                | Started:        | Stopped:           | CONTIN |  |
| ZOLOFT (Suspected)    |                 | Reason: Depression |        |  |
|                       | 100.0 Milligram | Daily              |        |  |
| Batch:                | Started:        | Stopped:           | CONTIN |  |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

Patient suffered symptoms after increasing dose of stelazine to 7mg. decreased back to 2 mg bd.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 123699 Seq: 1 Gender: F
Reported: 24/12/1997 Weight:
Hospitalisation: Admitted to hospital Age: 57Y

Onset Date: 05/09/1997 DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Details:

| Preferred Term    | Severity | Report Description                                | Treatment   |
|-------------------|----------|---|---|
| Hepatic failure   |          | Cryptogenic cirrhosis, subfulminant liver failure |   |
| Anorexia          |          |   |   |
| Ascites           |          |   |   |
| Encephalopathy    |          |   | Lactulose vitamin k, thiamine, omeprazole iv 5% nsa, iv antibiotics- cefotaxime and ampicillin (initially), iv fluids, sliding scale insulin-full liver transplant work-up. |
| Haematemesis      |          |   |   |
| Hepatic cirrhosis |          |   |   |

### **Medicine Details:**

| STELAZINE (Suspected) | STELAZINE (Suspected) |           |         | Reason:    |            |  |
|-----------------------|-----------------------|-----------|---------|------------|------------|--|
|                       | 0.0                   |           |         |            |            |  |
| Batch:                | Started:              |           |         | Stopped:   | 05/09/1997 |  |
| SERZONE (Suspected)   |                       |           | Reason: | Depression |            |  |
| Tablet                | 400.0                 | Milligram | Daily   |            | Oral       |  |
| Batch:                | Started:              |           |         | Stopped:   | 28/09/1997 |  |
| SEREPAX (Suspected)   |                       |           | Reason: |            |            |  |
| Tablet                | 30.0                  | Milligram | Daily   |            | Oral       |  |
| Batch:                | Started:              |           |         | Stopped:   | 28/09/1997 |  |

**Laboratory Investigations:** 

| Date | Туре       | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|---------|
|      | ALT = SGPT | (<40) | 05/09/1997  | 703    |         |
|      | ALT = SGPT | (<40) | 11/09/1997  | 236    |         |
|      | ALT = SGPT | (<40) | 22/09/1997  | 94     |         |
|      | ALT = SGPT | (<40) | 12/11/1997  | 47     |         |
|      | ALT = SGPT | (<40) | 24/09/1997  | 68     |         |
|      | AST = SGOT |       | 05/09/1997  | 1026   |         |
|      | AST = SGOT |       | 11/09/1997  | 322    |         |

#### Additional Information:

Patient had two to three drinks of alcohol daily. died on 13/11/97 during liver transplant. committee comment: include in annual fatality analysis the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 119 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 123699
 Seq: 1
 Gender:
 F

 Reported:
 24/12/1997
 Weight:

Hospitalisation: Admitted to hospital Age: 57Y
Onset Date: 05/09/1997
DOB:

Outcome: Death, maybe drug Causality: Causality possible

**Reaction Details:** 

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Jaundice       |          |                    |           |

### **Medicine Details:**

| STELAZINE (Suspected) |          | Reason:         |            |            |
|-----------------------|----------|-----------------|------------|------------|
|                       | 0.0      |                 |            |            |
| Batch:                | Started: |                 | Stopped:   | 05/09/1997 |
| SERZONE (Suspected)   |          | Reason:         | Depression |            |
| Tablet                | 400.0 N  | Milligram Daily |            | Oral       |
| Batch:                | Started: |                 | Stopped:   | 28/09/1997 |
| SEREPAX (Suspected)   |          | Reason:         |            |            |
| Tablet                | 30.0 N   | Milligram Daily |            | Oral       |
| Batch:                | Started: |                 | Stopped:   | 28/09/1997 |

# **Laboratory Investigations:**

| Date | Туре      | Range     | Date Tested | Result | Details |
|------|-----------|-----------|-------------|--------|---------|
|      | Albumin   | ( 36-48 ) | 05/09/1997  | 29     |         |
|      | Albumin   | ( 36-48 ) | 11/09/1997  | 25     |         |
|      | Albumin   | ( 36-48 ) | 24/09/1997  | 26     |         |
|      | Albumin   | ( 36-48 ) | 12/11/1997  | 26     |         |
|      | Bilirubin | (<18)     | 05/09/1997  | 372    |         |
|      | Bilirubin | (<18)     | 11/09/1997  | 483    |         |
|      | Bilirubin | (<18)     | 22/09/1997  | 548    |         |

#### **Additional Information:**

Patient had two to three drinks of alcohol daily. died on 13/11/97 during liver transplant. committee comment: include in annual fatality analysis the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 123699
 Seq: 1
 Gender:
 F

 Reported:
 24/12/1997
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 05/09/1997
DOB:

Outcome: Death, maybe drug Causality: Causality possible

**Reaction Details:** 

#### **Medicine Details:**

| vieulcine Delans.     |                 |                    |            |
|-----------------------|-----------------|--------------------|------------|
| STELAZINE (Suspected) |                 | Reason:            |            |
|                       | 0.0             |                    |            |
| Batch:                | Started:        | Stopped:           | 05/09/1997 |
| SERZONE (Suspected)   |                 | Reason: Depression |            |
| Tablet                | 400.0 Milligram | Daily              | Oral       |
| Batch:                | Started:        | Stopped:           | 28/09/1997 |
| SEREPAX (Suspected)   |                 | Reason:            |            |
| Tablet                | 30.0 Milligram  | Daily              | Oral       |
| Batch:                | Started:        | Stopped:           | 28/09/1997 |

**Laboratory Investigations:** 

| Date | Type         | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|---------|
|      | Bilirubin    | (<18) | 24/09/1997  | 550    |         |
|      | Bilirubin    | (<18) | 12/11/1997  | 395    |         |
|      | GGT = SGGT = | (<60) | 05/09/1997  | 229    |         |
|      | GGT = SGGT = | (<60) | 11/09/1997  | 128    |         |
|      | GGT = SGGT = | (<60) | 22/09/1997  | 68     |         |
|      | GGT = SGGT = | (<60) | 24/09/1997  | 57     |         |
|      | GGT = SGGT = | (<60) | 12/11/1997  | 60     |         |

#### Additional Information:

Patient had two to three drinks of alcohol daily. died on 13/11/97 during liver transplant. committee comment: include in annual fatality analysis the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 121 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 123699
 Seq: 1
 Gender:
 F

 Reported:
 24/12/1997
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 05/09/1997
DOB:

Outcome: Death, maybe drug Causality: Causality possible

**Reaction Details:** 

#### **Medicine Details:**

| Medicine Details.     |          |           |         |            |            |
|-----------------------|----------|-----------|---------|------------|------------|
| STELAZINE (Suspected) |          |           | Reason: |            |            |
|                       | 0.0      |           |         |            |            |
| Batch:                | Started: |           |         | Stopped:   | 05/09/1997 |
| SERZONE (Suspected)   |          |           | Reason: | Depression |            |
| Tablet                | 400.0    | Milligram | Daily   |            | Oral       |
| Batch:                | Started: |           |         | Stopped:   | 28/09/1997 |
| SEREPAX (Suspected)   |          |           | Reason: |            |            |
| Tablet                | 30.0     | Milligram | Daily   |            | Oral       |
| Batch:                | Started: |           |         | Stopped:   | 28/09/1997 |

**Laboratory Investigations:** 

| Date | Туре         | Range | Date Tested | Result | Details  |
|------|--------------|-------|-------------|--------|--|
|      | Immunology   |       |             |        | 24/9/97- auto-antibodies-negative.   |
|      | Liver biopsy |       |             |        | 26/9/97 - liver biopsy- cirrhosis in evolution with marked bile ductular proliferation and cholestasis. specific features indicationg aetiology are not seen. 18/11/97- established cirrhosis without specific features to indicate etiology. focal inflammatory activity is seen. |

#### Additional Information:

Patient had two to three drinks of alcohol daily. died on 13/11/97 during liver transplant. committee comment: include in annual fatality analysis the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 122 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 123699
 Seq: 1
 Gender:
 F

 Reported:
 24/12/1997
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 05/09/1997
DOB:

Outcome: Death, maybe drug Causality: Causality possible

**Reaction Details:** 

### **Medicine Details:**

| STELAZINE (Suspected) |          | Reason:         |            |            |
|-----------------------|----------|-----------------|------------|------------|
|                       | 0.0      |                 |            |            |
| Batch:                | Started: |                 | Stopped:   | 05/09/1997 |
| SERZONE (Suspected)   |          | Reason:         | Depression |            |
| Tablet                | 400.0 M  | lilligram Daily |            | Oral       |
| Batch:                | Started: |                 | Stopped:   | 28/09/1997 |
| SEREPAX (Suspected)   |          | Reason:         |            |            |
| Tablet                | 30.0 M   | lilligram Daily |            | Oral       |
| Batch:                | Started: |                 | Stopped:   | 28/09/1997 |

**Laboratory Investigations:** 

| Date | Type       | Range    | Date Tested | Result | Details   |
|------|------------|----------|-------------|--------|---|
|      | Other data |          |             |        | 29/9/97 abdomen ultrasound - evidence of cirrhosis and ascites. 22/9/97 hepatitis serology negative, cmv, ebv negative. |
|      | SAP = ALP  | (35-125) | 05/09/1997  | 278    |   |
|      | SAP = ALP  | (35-125) | 11/09/1997  | 219    |   |
|      | SAP = ALP  | (35-125) | 22/09/1997  | 250    |   |
|      | SAP = ALP  | (35-125) | 24/09/1997  | 196    |   |
|      | SAP = ALP  | (35-125) | 12/11/1997  | 204    |   |

#### Additional Information:

Patient had two to three drinks of alcohol daily. died on 13/11/97 during liver transplant. committee comment: include in annual fatality analysis the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 123 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Danast Da               | 4-:1   |           |               |               |                 |          |                |            |                      |
|-------------------------|--------|-----------|---------------|---------------|-----------------|----------|----------------|------------|----------------------|
| Report De               |        |           |               | 4             |                 |          |                |            |                      |
| Case Numb               |        |           | Seq:          | 1             |                 |          |                | Gender     |                      |
| Repori<br>Iospitalisati |        | 03/02/199 | 8             |               |                 |          |                | Weight     |                      |
| -                       |        | 19/01/199 | ıΩ            |               |                 |          |                | Age<br>DOB |                      |
|                         |        | Recovere  |               |               |                 |          | C              |            | : Causality possible |
| eaction D               |        |           | u .           |               |                 |          | •              | aacanty    | . Gaddanty possible  |
|                         |        | ed Term   | Se            | everity       | Repo            | ort Des  | scription      |            | Treatment            |
| xtrapyramic             | dal di | sorder    |               | E             | xtrapyramidal o | dystonia | а              |            |                      |
| Hypotension             |        |           |               |               |                 |          |                |            |                      |
| Somnolence              | !      |           |               |               |                 |          |                |            |                      |
| Medicine                | Deta   | ails:     |               |               |                 |          |                |            |                      |
| ZUCLOPENT               |        |           | (Suspected)   |               | Rea             | son:     | Unspecified ps | sychosis   |                      |
| Inject                  |        |           |               | 100.0 N       | lilligram       | 1 time   |                | Intramuso  | cular                |
| Batc                    | h:     |           | s             | tarted: 19/01 | /1998           |          | Stopped:       | 19/01/199  | 98                   |
| TRIFLUOPER              | RAZIN  | E HYDROCH | ILORIDE (Susp | ected)        | Rea             | son:     | Unspecified ps | sychosis   |                      |
| Table                   | et     |           |               |               | lilligram       | Daily    |                | Oral       |                      |
| Batc                    | h:     |           | S             | tarted:       |                 |          | Stopped:       | 19/01/199  | 98                   |
| Laborator               |        |           |               |               |                 |          |                |            |                      |
| Date                    |        | Туре      | Range         | Date Tested   | d Result        |          |                | Deta       | ails                 |
|                         |        |           |               | <u> </u>      | _1              |          |                |            |                      |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 125321 Seq: 1 Gender: M

Reported: 26/02/1998 Weight:

Hospitalisation: Age: 61Y
Onset Date: 10/02/1998
DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

|   | Preferred Term   | Severity | Report Description | Treatment        |
|---|------------------|----------|--------------------|------------------|
| F | Thrombocytopenia |          |                    | Ceased stelazine |

#### **Medicine Details:**

| FLUOXETINE HYDROCHLORIDE (Other | r drug)             | Reason: | Depression                     |  |
|---------------------------------|---------------------|---------|--------------------------------|--|
| Oral application                | 40.0 Milligram      | Daily   | Oral                           |  |
| Batch:                          | Started: 01/01/1998 |         | Stopped:                       |  |
| WARFARIN SODIUM (Other drug)    |                     | Reason: | Acute myocard infarc,no hypert |  |
| Tablet                          | 3.5 Milligram       | Daily   | Oral                           |  |
| Batch:                          | Started: 01/01/1993 |         | Stopped:                       |  |
| PERINDOPRIL (Other drug)        |                     | Reason: | Acute myocard infarc,no hypert |  |
| Tablet                          | 8.0 Milligram       | Daily   | Oral                           |  |
| Batch:                          | Started: 01/01/1993 |         | Stopped:                       |  |
| DIGOXIN (Other drug)            |                     | Reason: | Acute myocard infarc,no hypert |  |
|                                 |                     | Daile   | Onel                           |  |
| Tablet                          | 250.0 Microgram     | Daily   | Oral                           |  |

**Laboratory Investigations:** 

| Date | Туре      | Range | Date Tested | Result | Details                                 |
|------|-----------|-------|-------------|--------|---|
|      | Platelets |       |             |        | Platelet levels dropped from 194-> 113. |

### **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.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Report Details | : |
|----------------|---|
|----------------|---|

 Case Number:
 125321
 Seq: 1
 Gender: M

 Reported:
 26/02/1998
 Weight:

Hospitalisation: Age: 61Y
Onset Date: 10/02/1998
DOB:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

#### **Medicine Details:**

| Medicine Details.                   |                     |         |                                |
|-------------------------------------|---------------------|---------|--------------------------------|
| ISOSORBIDE MONONITRATE (Other drug) |                     | Reason: | Acute myocard infarc,no hypert |
| Tablet                              | 120.0 Milligram     | Daily   | Oral                           |
| Batch:                              | Started: 01/01/1993 |         | Stopped:                       |
| STELAZINE (Suspected)               |                     | Reason: | Unspecified psychosis          |
| Tablet                              | 2.0 Gram            | Daily   | Oral                           |
| Batch:                              | Started: 15/01/1998 |         | <b>Stopped</b> : 13/02/1998    |

# **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.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 126882 Seq: 1 Gender: F

 Reported: 23/04/1998
 Weight:

 Hospitalisation:
 Age: AD

 Onset Date: 20/04/1998
 DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

| Preferred Term               | Severity | Report Description | Treatment |
|------------------------------|----------|--------------------|-----------|
| Congenital hand malformation |          |                    |           |

### **Medicine Details:**

STELAZINE (Suspected)Reason:DepressionTablet2.0 MilligramDailyOral

Batch: Started: L TERM Stopped:

### **Laboratory Investigations:**

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

Baby born with partial adactyly of split hand on I side. his 2nd, 3rd & 4th digits on the I hand were only stumps with nail beds.

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**Additional Information:** 

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number: 128100   Seq: 1   Gender: F           Reported: 05/06/1998   Ospitalisation: Onset Date: 01/05/1998   Outcome: Recovered  | Report De    | etails:                                |       |              |               |           |        |      |                         |           |              |
|--|--------------|--|-------|--------------|---------------|-----------|--------|------|-------------------------|-----------|--------------|
| Age: 77Y   DOB: Outcome   Recovered   Recovered   Report Desaility   Causality   possible  | Case Num     | ber: 128100                            | Se    | <b>q</b> : 1 |               |           |        |      | Gende                   | er: F     |              |
| Conset Date: 01/05/1998  | Repor        | ted: 05/06/199                         | 98    | -            | Weight: 58.00 |           |        |      |                         |           |              |
| Outcome: Recovered seaction Details:  Preferred Term Severity Report Description Treatment  Confusional state Hallucination  Medicine Details:  SINEMET (Other drug) Reason: Paralysis agitans 3.0 Dose Unspecified Daily Batch: Started: LTERM Stopped:  ZANTAC (Other drug) Reason: Ulcer of duodenum w/o ment perf 300.0 Milligram Daily Batch: Started: LTERM Stopped:  ASTRIX 100 (Other drug) Reason: Discovered Started: LTERM Stopped:  ASTRIX 100 (Other drug) Reason: Discovered Started: LTERM Stopped:  NOTEN (Other drug) Reason: Essential benign hypertension 50.0 Milligram Daily Batch: Started: LTERM Stopped:  NOTEN (Other drug) Reason: Essential benign hypertension 50.0 Milligram Daily Batch: Started: LTERM Stopped:   | ospitalisat  | ion:                                   |       |              |               |           |        |      | Ag                      | e: 77Y    |              |
| ### Severity   Report Description   Treatment  | Onset D      | Date: 01/05/199                        | 98    |              |               |           |        |      | DO                      | B:        |              |
| ### Severity   Report Description   Treatment  | Outco        | me: Recovere                           | d     |              |               |           |        |      | Causalit                | y: Causal | ity possible |
| Preferred Term   | eaction D    | etails:                                |       |              |               |           |        |      |                         |           |              |
| Medicine Details:  SINEMET (Other drug)  Batch:  Started:  Started |              |  | ļ     | Severity     |               | R         | eport  | De   | scription               | Т         | reatment     |
| Medicine Details:  SINEMET (Other drug)  Batch:  Started:  Started | Confusional  | state                                  |       |              |               |           |        |      |                         |           |              |
| SINEMET (Other drug)   Started:   Started:   L TERM   Stopped:   | Hallucinatio | n                                      |       |              |               |           |        |      |                         |           |              |
| Started:   Started:   L TERM   Stopped:      |              |  |       |              |               |           |        |      |                         |           |              |
| Batch:         Started:         L TERM         Stopped:           ZANTAC (Other drug)         Reason:         Ulcer of duodenum w/o ment perf           300.0         Milligram         Daily           Batch:         Started:         L TERM         Stopped:           ASTRIX 100 (Other drug)         100.0         Milligram         Daily           Batch:         Started:         L TERM         Stopped:           NOTEN (Other drug)         Reason:         Essential benign hypertension           50.0         Milligram         Daily           Batch:         Started:         L TERM         Stopped:    -aboratory Investigations:  | SINEMET (O   | ther drug)                             |       |              |               | F         | Reason | :    | Paralysis agitans       |           |              |
| ZANTAC (Other drug)  Reason: Ulcer of duodenum w/o ment perf  300.0 Milligram Daily  Batch: Started: L TERM Stopped:  100.0 Milligram Daily  Batch: Started: L TERM Stopped:  NOTEN (Other drug)  Reason: Essential benign hypertension  50.0 Milligram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:  Reason: Essential benign hypertension  50.0 Milligram Daily  Batch: L TERM Stopped:   |              |  |       | 3.0          | Dose          | Unspecifi | ed Da  | aily |                         |           |              |
| Batch:         Started:         L TERM         Stopped:           ASTRIX 100 (Other drug)         Reason:         100.0 Milligram Daily           Batch:         Started:         L TERM         Stopped:           NOTEN (Other drug)         Reason:         Essential benign hypertension           50.0 Milligram Daily         Daily           Batch:         Started:         L TERM         Stopped:  |              |  |       | Started:     |               | L TEF     | RM     |      |                         |           |              |
| Batch:         Started:         L TERM         Stopped:           ASTRIX 100 (Other drug)         Reason:           100.0         Milligram         Daily           Batch:         Started:         L TERM         Stopped:           NOTEN (Other drug)         Reason:         Essential benign hypertension           50.0         Milligram         Daily           Batch:         Started:         L TERM         Stopped:   -aboratory Investigations:   | ZANTAC (Ot   | her drug)                              |       |              |               |           |        |      | Ulcer of duodenum w/o   | ment perf |              |
| ASTRIX 100 (Other drug)  Reason:  100.0 Milligram Daily  Batch: L TERM Stopped:  NOTEN (Other drug)  Reason: Essential benign hypertension  50.0 Milligram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:   |              |  |       |              | Millign       |           |        | aily |                         |           |              |
| Batch: Started: L TERM Stopped:  NOTEN (Other drug) Reason: Essential benign hypertension  50.0 Milligram Daily  Batch: Started: L TERM Stopped:  L TERM Stopped:  |              |  |       | Started:     |               |           |        |      | Stopped:                |           |              |
| Batch: Started: L TERM Stopped:  NOTEN (Other drug) Reason: Essential benign hypertension  50.0 Milligram Daily  Batch: Started: L TERM Stopped:  -aboratory Investigations:   | ASTRIX 100   | (Other drug)                           |       | 400.0        | N 4:11:       |           |        |      |                         |           |              |
| NOTEN (Other drug)  Started:  Reason: Essential benign hypertension  Daily  Batch: Started: L TERM Stopped:  -aboratory Investigations:  | D-4-         | . L.                                   |       |              | Milligr       |           |        | ally | 04                      |           |              |
| 50.0 Milligram Daily  Batch: Started: L TERM Stopped:  aboratory Investigations:   |              |  |       | Started:     |               |           |        |      |                         | lancian   |              |
| Batch: Started: L TERM Stopped:  _aboratory Investigations:  | NOTEN (Oth   | er arug)                               |       | 50.0         | Millian       |           |        |      | Essential benign hyperi | lension   |              |
| _aboratory Investigations:   | Rate         | sh:                                    |       |              | wiiiigi       |           |        | ally | Stonned:                |           |              |
|  | Date         | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, |       | Starteu.     |               |           | ZIVI   |      | эторрец.                |           |              |
| Date Type Range Date Tested Result Details   |              |  |       |              |               |           |        |      |                         |           |              |
|  | Date         | Type                                   | Range | Date Tes     | ted           | Result    |        |      | De                      | etails    |              |
|  |              |  |       |              |               |           |        |      |                         |           |              |
|  |              |  |       |              |               |           |        |      |                         |           |              |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report Details:  |              |           |                  |                |   |       |
|--|--------------|-----------|------------------|----------------|---|-------|
| Case Number: 128100 Reported: 05/06/1998 Iospitalisation: Onset Date: 01/05/1998 Outcome: Recovered eaction Details: | Seq: 1       |           |                  |                | Gender:<br>Weight:<br>Age:<br>DOB:<br>ausality: | 58.00 |
|  |              |           |                  |                |   |       |
| Medicine Details:  LUMIN (Other drug)  |              |           | Reason:          | Depression     |   |       |
|  |              | Milligram | Daily            |                |   |       |
| Batch: COGENTIN (Suspected)  | Started:     |           | L TERM Reason:   | Stopped:       |   |       |
| O O DEITHIN (Ouspecteu)  | 2.0          | Milligram | Daily            |                |   |       |
| Batch:   | Started: 30/ |           | ,                | Stopped:       | 04/05/1998                                      |       |
| STELAZINE (Suspected)  | 1.0          | Milligram | Reason:<br>Daily | Unspecified ps | ychosis   |       |
| Batch:   | Started:     |           | L TERM           | Stopped:       | 04/05/1998                                      |       |
| LARGACTIL (Suspected)  |              | Milligram | Reason: Daily    | Unspecified ps |   |       |
| _aboratory Investigations:   | Started:     |           | L TERM           | эторрец.       | 04/05/1998                                      |       |
| Additional Information:  |              |           |                  |                |   |       |
|  |              |           |                  |                |   |       |

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number: 130398                | <b>Seq:</b> 1                          |                    | Ge              | nder: M                      |
|------------------------------------|--|--------------------|-----------------|------------------------------|
| Reported: 21/08/1998               |  |                    | We              | ight:                        |
| spitalisation:                     |  |                    |                 | Age:                         |
| Onset Date:                        |  |                    |                 | DOB:                         |
| Outcome: Recovered                 |  |                    | Caus            | ality: Causality possible    |
| action Details:                    |  |                    |                 |                              |
| Preferred Term                     | Severity                               |                    | ort Description | Treatment                    |
| pordination abnormal               | Required<br>Specialist<br>Consultation | Inability to stand | up              |                              |
| sual disturbance                   | Required<br>Specialist<br>Consultation |                    |                 | Aropax and stelazine ceased. |
| adioina Dataila                    |  |                    |                 |                              |
| edicine Details: ROPAX (Suspected) |  | Rea                | son:            |                              |
| Tablet                             | 20.0                                   | Milligram          | Daily Ora       | I                            |
| Batch:                             | Started:                               | 3                  | Stopped:        |                              |
| TELAZINE (Suspected)               |  | Rea                | son:            |                              |
| Oral application                   | 5.0                                    | Milligram          | Daily Ora       | I                            |
| Batch:                             | Started:                               |                    | Stopped:        |                              |
| aboratory Investigation            | s:                                     |                    |                 |                              |
|                                    | Range Date Teste                       | ed Result          |                 | Details                      |
| dditional Information:             |  |                    |                 |                              |
| ort Run:06/06/2007 08:46AM D       | atabase: pusime02                      | A                  | DRS004          | Page 130 of 197              |



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 132873
 Seq: 1
 Gender: M

 Reported:
 05/11/1998
 Weight:

Hospitalisation: Age: 21Y
Onset Date: 26/10/1998
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

| <u> </u>       |          |                         |           |
|----------------|----------|-------------------------|-----------|
| Preferred Term | Severity | Report Description      | Treatment |
| Angioedema     |          | Swollen tongue and lips |           |
| Dyspnoea       |          |                         |           |

# **Medicine Details:**

| VENTOLIN (Other drug) | R                          | Reason: Asthma        |                 |        |
|-----------------------|----------------------------|-----------------------|-----------------|--------|
| Inhalation            | 2.0 Dose Unspecifie        | ed As necessary       | Inhalation      |        |
| Batch:                | Started:                   | Stopped               | d:              |        |
| BECOTIDE (Other drug) | R                          | Reason: Asthma        |                 |        |
| Inhalation            | 200.0 Microgram            | As necessary          | Inhalation      |        |
| Batch:                | Started: 01/09/1998        | Stopped               | d:              |        |
| LUVOX (Other drug)    | R                          | Reason: Depression    |                 |        |
| Tablet                | 1.0 Dose Unspecifie        | ed Daily              | Oral            |        |
| Batch:                | <b>Started:</b> 25/09/1998 | Stopped               | d:              | CONTIN |
| STELAZINE (Suspected) | R                          | Reason: Specific disc | orders of sleep |        |
|                       | 2.0 Milligram              | Daily                 |                 |        |
| Batch:                | <b>Started:</b> 25/10/1998 | Stopped               | d: 27/10/1998   |        |

**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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**Report Details:** 

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number:                            | 132873        | Seq: 1                        | G                          | ender: M         |            |
|---|---------------|-------------------------------|----------------------------|------------------|------------|
| Reported:                               | 05/11/1998    |                               | W                          | eight:           |            |
| Hospitalisation:                        |               |                               |                            | Age: 21Y         |            |
| Onset Date:                             | 26/10/1998    |                               |                            | DOB:             |            |
| Outcome:                                | Recovered     |                               | Cau                        | sality: Causalit | y possible |
| Reaction Detail                         | ls:           |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
| Medicine Deta                           | aile:         |                               |                            |                  |            |
| ZOLOFT (Suspecte                        |               |                               | Reason: Depression         |                  |            |
| 20201 1 (Odopeote                       | ,             | 100.0 Milligram               | Daily                      |                  |            |
| Batch:                                  |               | Started: 25/07/1998           | Stopped: 25                | 5/00/1008        |            |
| Batcii.                                 |               | Started: 25/07/1990           | Stopped. 23                | 0/09/1990        |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
| Laboratory                              | vootigationa  |                               |                            |                  |            |
| Laboratory In                           | vestigations: |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
| Additional Info                         | ormation:     |                               |                            |                  |            |
|   |               | y accurate but indicates that | start occurred sometime du | uring the month. |            |
| 2 2 0 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 |               | ,                             |                            | <b>J</b>         |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |
|   |               |                               |                            |                  |            |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number: 132964   | Seq: 1                              |                               | Gen                     | der: M    |  |  |
|---|-------------------------------------|-------------------------------|-------------------------|-----------|--|--|
| Reported: 06/11/1998  |                                     | Weight:<br>Age: 70Y           |                         |           |  |  |
| lospitalisation:  |                                     |                               |                         |           |  |  |
| Onset Date: 21/10/1998  |                                     | DOB:                          |                         |           |  |  |
| Outcome: Recovered  |                                     | Causality: Causality possible |                         |           |  |  |
| eaction Details:  |                                     |                               |                         | т         |  |  |
| Preferred Term  | Severity                            | Report Des                    | cription                | Treatment |  |  |
| Asthenia  |                                     |                               |                         |           |  |  |
| Medicine Details:   |                                     |                               |                         |           |  |  |
| MONOPRIL (Suspected)  |                                     | Reason:                       | Essential benign hyp    | ertension |  |  |
| Tablet  | 0.0                                 |                               | Oral                    |           |  |  |
| Batch:  | Started:                            |                               | Stopped:                | CONTIN    |  |  |
| STELAZINE (Suspected)   |                                     | Reason:                       | Jnspecified psychos     | is        |  |  |
|   | 0.0                                 |                               | Oral                    | 0.0117111 |  |  |
| Tablet  | Started:                            |                               | Stopped:                | CONTIN    |  |  |
| Batch:  | Otartea.                            | D                             | O I                     |           |  |  |
| Batch: NICORETTE GUM (Suspected)  |                                     |                               | Smoker                  |           |  |  |
| Batch: NICORETTE GUM (Suspected) Oral application                                     | 4.0 Mill                            | ligram As nec                 | essary Oral             | CONTIN    |  |  |
| Batch: NICORETTE GUM (Suspected)  |                                     |                               |                         |           |  |  |
| Batch:  NICORETTE GUM (Suspected)  Oral application  Batch:  Laboratory Investigation | 4.0 Mill Started: 21/10/1           | ligram As nec                 | essary Oral<br>Stopped: | CONTIN    |  |  |
| Batch:  NICORETTE GUM (Suspected)  Oral application  Batch:  Laboratory Investigation | 4.0 Mill<br><b>Started:</b> 21/10/1 | ligram As nec                 | essary Oral<br>Stopped: | CONTIN    |  |  |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 136279
 Seq: 1
 Gender:
 F

 Reported:
 17/02/1999
 Weight:

Hospitalisation: Treated in outpatient department only. Age: 43

**Onset Date**: 19/07/1998 **DOB**: 04/03/1955

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term | Severity | Report Description                        | Treatment                              |
|----------------|----------|---|--|
| Torticollis    |          | Contraction of (r) sterno-mastoid muscle. |  |
| Tongue oedema  |          | Swollen tongue.                           |  |
| Tetany         |          | Tetany of right hand.                     |  |
| Dyspnoea       |          |   | Prednisone 50mg iv & cogentin 2mg/2ml. |
| Headache       |          |   |  |
| Hypertension   |          |   |  |
| Tachycardia    |          |   |  |

### **Medicine Details:**

STELAZINE (Suspected)Reason:Anxiety neurosisTablet15.0 MilligramDailyOral

**Batch: Started:** 18/07/1998 **Stopped:** 19/07/1998

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

Sequelae: patient represented with reoccurance of symptoms - iv cogentin repeated. back injury 1995 - chronic back pain. changes medication often. ? medication history.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

Report Details:

Case Number:138579Seq: 1Gender: MReported:19/04/1999Weight:Hospitalisation:Age:

**Onset Date**: 01/04/1999 **DOB**:

Outcome: Unknown Causality: Causality possible

### Reaction Details:

| Preferred Term            | Severity | Report Description      | Treatment |
|---------------------------|----------|-------------------------|-----------|
| Hepatomegaly              |          | Enlarged liver          |           |
| Hepatic function abnormal |          | Liver enzyme raised     |           |
| Leukocytosis              |          | Raised white cell count |           |
| Cough                     |          |                         |           |
| Hepatic steatosis         |          |                         |           |
| Splenomegaly              |          |                         |           |

#### **Medicine Details:**

| inculcing Details.         |                     |                                   |  |
|----------------------------|---------------------|-----------------------------------|--|
| ALCOHOL (Suspected)        |                     | Reason:                           |  |
|                            | 0.0                 |                                   |  |
| Batch:                     | Started:            | Stopped:                          |  |
| FLUPENTHIXOL DECANOATE (Su | ispected)           | Reason:                           |  |
|                            | 0.0                 |                                   |  |
| Batch:                     | Started:            | Stopped:                          |  |
| TRIFLUOPERAZINE HYDROCHLO  | RIDE (Suspected)    | Reason:                           |  |
|                            | 0.0                 |                                   |  |
| Batch:                     | Started:            | Stopped:                          |  |
| CLOZARIL (Suspected)       |                     | Reason: Unspecified schizophrenia |  |
| Tablet                     | 0.0                 | Daily Oral                        |  |
| Batch:                     | Started: 17/03/1999 | Stopped:                          |  |
|                            |                     |                                   |  |

## **Laboratory Investigations:**

| Date | Туре         | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|---------|
|      | ALT = SGPT   |       | 01/04/1999  | 72     |         |
|      | AST = SGOT   |       | 01/04/1999  | 58     |         |
|      | Bilirubin    |       | 01/04/1999  | 30     |         |
|      | GGT = SGGT = |       | 01/04/1999  | 182    |         |
|      | SAP = ALP    |       | 01/04/1999  | 118    |         |

### **Additional Information:**

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 139252 Seq: 1 Gender: M
Reported: 06/05/1999 Weight:
Hospitalisation: Age: 23Y

Onset Date: 03/05/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| teaction Details. |          |                    |               |
|-------------------|----------|--------------------|---------------|
| Preferred Term    | Severity | Report Description | Treatment     |
| Agitation         |          |                    | Ceased zoloft |
| Chills            |          |                    |               |
| Confusional state |          |                    |               |
| Dizziness         |          |                    |               |
| Migraine          |          |                    |               |
| Nausea            |          |                    |               |
| Vomiting          |          |                    |               |

### **Medicine Details:**

| AURORIX (Interaction)   |                     | Reason: | Depression |            |
|-------------------------|---------------------|---------|------------|------------|
| Tablet                  | 900.0 Milligram     | Daily   |            | Oral       |
| Batch:                  | Started:            |         | Stopped:   |            |
| ZOLOFT (Interaction)    |                     | Reason: | Depression |            |
|                         | 5.0 Milligram       | Daily   |            |            |
| Batch:                  | Started: 03/05/1999 |         | Stopped:   | 04/05/1999 |
| STELAZINE (Interaction) |                     | Reason: |            |            |
|                         | 5.0 Milligram       | Daily   |            |            |
| Batch:                  | Started:            |         | Stopped:   |            |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

See original report for details of other drug therapy: serepax.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Re | port | Details: |  |
|----|------|----------|--|
|----|------|----------|--|

 Case Number:
 140218
 Seq: 1
 Gender:
 F

 Reported:
 03/06/1999
 Weight:

Hospitalisation: Age: 74

Onset Date: DOB: 17/07/1924

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

|                         | caction Details. |  |                                     |                   |
|-------------------------|------------------|--|-------------------------------------|-------------------|
|                         | Preferred Term   | Severity                               | Report Description                  | Treatment         |
| Extrapyramidal disorder |                  | Required<br>Specialist<br>Consultation | In particulary mild neck stiffness. | Stelazine ceased. |

## **Medicine Details:**

STELAZINE (Suspected) Reason: Anxiety neurosis

Tablet 10.0 Milligram Daily Oral

Batch: Started: 20/01/1999 Stopped: 26/02/1999 1M

# **Laboratory Investigations:**

|   | Date | Type | Range | Date Tested | Result | Details |
|---|------|------|-------|-------------|--------|---------|
| ĺ |      |      |       |             |        |         |

### **Additional Information:**

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 142654
 Seq: 1
 Gender: M

 Reported:
 16/08/1999
 Weight:

Hospitalisation: Age: 52

**Onset Date:** DOB: 23/03/1947

Outcome: Unknown Causality: Causality possible

### **Reaction Details:**

| Preferred Term           | Severity | Report Description                                 | Treatment |
|--------------------------|----------|--|-----------|
| Paresis                  |          | Calf muscles became weak and has problems standing |           |
| Insomnia                 |          | Difficulty in falling asleep.                      |           |
| Paraesthesia             |          | Feels like"worms and ants"crawling in his muscles. |           |
| Arthralgia               |          | Joint pains in arms and legs.                      |           |
| Agitation                |          | Pain diminishes when he moves around.              |           |
| Myalgia                  |          | Pain in the muscle.                                |           |
| Drug withdrawal syndrome |          | When he falls asleep pain and tension alleviated.  |           |
| Hyperkinesia             |          |  |           |

### **Medicine Details:**

| STELAZINE (Suspected) | Reason:                      |                     |
|-----------------------|------------------------------|---------------------|
| Oral application      | 2.0 Milligram Daily          | Oral                |
| Batch:                | Started: 01/01/1971 L TERM 5 | Stopped: 28/01/1999 |

**Laboratory Investigations:** 

|   | Date | Type | Range | Date Tested | Result | Details |
|---|------|------|-------|-------------|--------|---------|
| ĺ |      |      |       |             |        |         |

## **Additional Information:**

See original report for details of other drugs. - inderal, aurorix, valium and mysaline. symptoms occurred after patient stopped taking stelazine for 28 years. patient has suffered from anxiety since he was a teenager. 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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 144134
 Seq: 1
 Gender:
 F

 Reported:
 28/09/1999
 Weight:

Hospitalisation:
Onset Date: 16/09/1999
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| 100000000000000000000000000000000000000 |          |                    |           |
|---|----------|--------------------|-----------|
| Preferred Term                          | Severity | Report Description | Treatment |
| Micturition disorder                    |          | Urinary retention  |           |

## **Medicine Details:**

| MENOPREM (Suspected)         | ected) Reason:  |                |          |  |  |
|------------------------------|-----------------|----------------|----------|--|--|
|                              | 0.0 Dose Unsp   | ecified 1 time |          |  |  |
| Batch:                       | Started:        |                | Stopped: |  |  |
| THYROXINE SODIUM (Suspected) |                 | Reason:        |          |  |  |
|                              | 200.0 Milligram | Daily          |          |  |  |
| Batch:                       | Started:        |                | Stopped: |  |  |
| SODIUM VALPROATE (Suspected) |                 | Reason:        |          |  |  |
|                              | 800.0 Milligram | Daily          |          |  |  |
| Batch:                       | Started:        |                | Stopped: |  |  |
| STELAZINE (Suspected)        |                 | Reason:        |          |  |  |
|                              | 5.0 Milligram   | Daily          |          |  |  |
| Batch:                       | Started:        |                | Stopped: |  |  |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

P/h of allergies to penicillin, bactrim, serzone.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Report | Details: |
|--------|----------|
|--------|----------|

 Case Number:
 144134
 Seq: 1
 Gender:
 F

 Reported:
 28/09/1999
 Weight:

Hospitalisation: Age: 49Y
Onset Date: 16/09/1999
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

## **Medicine Details:**

| KEMADRIN (Suspected) | Reason:  |           |         |          |
|----------------------|----------|-----------|---------|----------|
|                      | 100.0 M  | Milligram | Daily   |          |
| Batch:               | Started: |           |         | Stopped: |
| NORVASC (Suspected)  |          |           | Reason: |          |
|                      | 10.0 M   | Milligram | Daily   |          |
| Batch:               | Started: |           |         | Stopped: |
| SEREPAX (Suspected)  |          |           | Reason: |          |
|                      | 30.0 M   | Milligram | Daily   |          |
| Batch:               | Started: |           |         | Stopped: |
| TAZAC (Suspected)    |          |           | Reason: |          |
|                      | 300.0 M  | Milligram | Daily   |          |
| Batch:               | Started: |           |         | Stopped: |

# **Laboratory Investigations:**

### **Additional Information:**

P/h of allergies to penicillin, bactrim, serzone.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 140 of 197



Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Hospitalisation:<br>Onset Date:         | 28/09/1999<br>16/09/1999<br>Not yet recovered | Seq: 1         |                  | Gender:<br>Weight:<br>Age:<br>DOB:<br>Causality: | 49Y |
|---|---|----------------|------------------|--|-----|
| Medicine Deta                           |   |                |                  |  |     |
| AROPAX (Suspect                         | ed)   | 20.0 Milligram | Reason:<br>Daily |  |     |
| Batch:                                  |   | Started:       | Daily            | Stopped:   |     |
| Laboratory In                           | vestigations:                                 |                |                  |  |     |
| Additional Inf<br>P/h of allergies to p | ormation:<br>penicillin, bactrim, se          | erzone.        |                  |  |     |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE 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:

| 100.00.00.00.00.    |          |                                 |   |
|---------------------|----------|---------------------------------|---|
| Preferred Term      | Severity | Report Description              | Treatment   |
| Renal failure acute |          | Acute on chronic renal failure. |   |
| Constipation        |          | <u> </u>                        | 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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE 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   | 2.0      | Milligram | Daily   | Oral                      |  |
| Batch:   | Started: | l         | TERM    | Stopped:                  |  |
|  |          |           |         |                           |  |
| Laboratory Investigations:   |          |           |         |                           |  |
| Additional Information:  |          |           |         |                           |  |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 146097 Seq: 1 Gender: F
Reported: 23/11/1999 Weight:

Hospitalisation:
Onset Date: 31/12/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| todotion Dotanoi   |          |                    |   |
|--------------------|----------|--------------------|---|
| Preferred Term     | Severity | Report Description | Treatment   |
| Tardive dyskinesia |          | movements.         | Patient is now receiving concomitant valium and cogentin. |

## **Medicine Details:**

| wedicine Details:     |                     |            |  |
|-----------------------|---------------------|------------|--|
| STELAZINE (Suspected) |                     | Reason:    |  |
|                       | 0.0                 |            |  |
| Batch:                | Started:            | Stopped:   |  |
| CLOZARIL (Suspected)  |                     | Reason:    |  |
| Tablet                | 350.0 Milligram     | Daily Oral |  |
| Batch:                | Started: 01/01/1997 | Stopped:   |  |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

Patient was previously taking stelazine before commencing clozaril and there was a period of overlap of use of the two drugs. - 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: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 149695
 Seq: 1
 Gender: M

 Reported:
 28/02/2000
 Weight:

Hospitalisation: Age: 48Y
Onset Date: 16/02/2000 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| 100.00.00.00.00.   |          |                    |                        |
|--------------------|----------|--------------------|------------------------|
| Preferred Term     | Severity | Report Description | Treatment              |
| Constipation       |          |                    |                        |
| Headache           | Severe   |                    | Supportvive, aspalgin. |
| Hyperhidrosis      |          |                    |                        |
| Myalgia            |          |                    |                        |
| Nightmare          |          |                    |                        |
| Visual disturbance |          |                    |                        |

#### **Medicine Details:**

STELAZINE (Suspected) Reason: Depression

2.0 Milligram Daily

**Batch: Started:** 15/02/2000 **Stopped:** 21/02/2000

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Pt also taking efexor xr.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 145 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 149906
 Seq: 1
 Gender:
 F

 Reported:
 02/03/2000
 Weight:

Hospitalisation:
Onset Date: 26/02/2000
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

| todotion Dotano |          |   |           |
|-----------------|----------|---|-----------|
| Preferred Term  | Severity | Report Description                            | Treatment |
| Hypertension    |          | Bp 200/100.                                   |           |
| Headache        |          | Severe headache in morning 26,27,28 february. |           |

#### **Medicine Details:**

| 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 |
|---|------|------|-------|-------------|--------|---------|
| ĺ |      |      |       |             |        |         |

#### **Additional Information:**

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 146 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 149951 Seq: 1 Gender: M

Reported: 03/03/2000 Weight: 98.00 Hospitalisation: Age: 52Y

**Onset Date**: 17/02/2000 **DOB**:

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

| teaction betails. |          |                    |           |  |  |  |  |  |
|-------------------|----------|--------------------|-----------|--|--|--|--|--|
| Preferred Term    | Severity | Report Description | Treatment |  |  |  |  |  |
| Depersonalisation |          | Spaced out.        |           |  |  |  |  |  |
| Nausea            |          |                    |           |  |  |  |  |  |
| Stupor            |          |                    |           |  |  |  |  |  |
| Vertigo           |          |                    |           |  |  |  |  |  |
| Vomiting          |          |                    |           |  |  |  |  |  |

## **Medicine Details:**

STELAZINE (Suspected) Reason: Otr spec symp psychopathol nec

 Tablet
 2.0 Milligram
 Daily
 Oral

 Batch:
 Started: 17/02/2000
 Stopped: 19/02/2000

**Laboratory Investigations:** 

|   | Date | Type | Range | Date Tested | Result | Details |
|---|------|------|-------|-------------|--------|---------|
| ĺ |      |      |       |             |        |         |

#### **Additional Information:**

Patient also taking prothiaden, valium, zantac, doryx, klacid.

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 147 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

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

Case Number: 149952 Seq: 1 Gender: M

Reported: 03/03/2000 Weight: 85.00 Hospitalisation: Age: 69Y

Onset Date: 02/02/2000 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| Cachon Details.   |          |                    |           | _ |
|-------------------|----------|--------------------|-----------|---|
| Preferred Term    | Severity | Report Description | Treatment |   |
| Diarrhoea         |          |                    | Imodium   | 1 |
| Rash erythematous |          |                    |           |   |

## **Medicine Details:**

ZOLOFT (Suspected) Reason: Depression

Tablet 200.0 Milligram Daily Oral

**Batch: Started:** 02/11/1999 **Stopped:** 16/02/2000

STELAZINE (Suspected) Reason: Depression

2.0 Milligram Daily

Batch: Started: 26/11/1999 Stopped: 09/02/2000

**Laboratory Investigations:** 

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

## **Additional Information:**

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 148 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 150326 Seq: 1 Gender: F
Reported: 13/03/2000 Weight:

Hospitalisation: Hospitalisation prolonged
Onset Date: 14/02/2000
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Details:

| Preferred Term      | Severity | Report Description                    | Treatment |
|---------------------|----------|---------------------------------------|-----------|
| Intra-uterine death |          | Patient has a haemoglobin of 9.5g/d1. |           |

#### **Medicine Details:**

STELAZINE (Suspected)

Oral application

Reason: Unspecified psychosis

Daily

Oral

Oral

Batch: Started: 05/01/2000 Stopped:

BENZTROPINE MESYLATE (Suspected) Reason:

1.0 Milligram Daily

Batch: Started: Stopped:

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Patient became pregnant whilst on clozaril. patient had a miscarriage and has a haemoglobin of 9.5g/dl

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 149 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 150766 Seq: 1 Gender: F

Reported: 27/03/2000 Weight:
Hospitalisation: Age: 80

**Onset Date:** 30/11/1999 **DOB:** 26/01/1919

Outcome: Recovered Causality: Causality probable

**Reaction Details:** 

| Preferred Term | Severity | Report Description | Treatment         |
|----------------|----------|--------------------|-------------------|
| Hypertonia     |          |                    | Stelazine ceased. |

## **Medicine Details:**

STELAZINE (Suspected) Reason:

1.0 Milligram Daily

Batch: Started: Stopped: 02/12/1999

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Patient also taking atenolol, warfarin, rastinon, lanoxin.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 150900
 Seq: 1
 Gender:
 F

 Reported:
 28/03/2000
 Weight:

Hospitalisation: Age: 43Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

| Preferred Term     | Severity | Report Description  | Treatment |
|--------------------|----------|---------------------|-----------|
| Hyperacusis        |          | Heightened hearing. |           |
| Sexual dysfunction |          | Sexual arrousal.    |           |
| Insomnia           |          |                     |           |

#### **Medicine Details:**

STELAZINE (Suspected) Reason: Unspecified schizophrenia

15.0 Milligram Daily

Batch: 83520 Started: L TERM Stopped:

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Stelazine batch number: 83520. patient has taken other batches with no effects until batch 84810.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 150903 Seq: 1 Gender: F
Reported: 28/03/2000 Weight:
Hospitalisation: Age: 43Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

| Г | Veaction Details. |          |  |           |
|---|-------------------|----------|--|-----------|
|   | Preferred Term    | Severity | Report Description                             | Treatment |
|   | Hallucination     |          | Flashing picture images.                       |           |
|   | Hallucination     |          | Heard voices and felt spaced out after 1 dose. |           |
|   | Hyperacusis       |          | Heightened hearing.                            |           |
|   | Tinnitus          |          |  |           |

#### **Medicine Details:**

STELAZINE (Suspected) Reason: Unspecified schizophrenia

15.0 Milligram Daily

Batch: 84810 Started: L TERM Stopped:

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Stelazine batch number: 84810. patient has taken other batches with no effects since batch 83520.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 152274 Seq: 1 Gender: M

Reported: 02/05/2000 Weight:
Hospitalisation: Age: 47

Onset Date: DOB: 05/09/1952

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| reaction Details. |          |                    |  |
|-------------------|----------|--------------------|--|
| Preferred Term    | Severity | Report Description | Treatment  |
| Hypertonia        |          | <u> </u>           | Benztropine, anxiety reduction techniques and massage. |

## **Medicine Details:**

STELAZINE (Suspected) Reason: Nervousness

2.0 Milligram Daily

Batch: Started: L TERM Stopped:

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Patient experienced symptoms after the discontinuation of stelazine.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 157203 Seq: 1 Gender: F

Reported: 25/08/2000 Weight: 92.00 Hospitalisation: Age: 56

**Onset Date**: 03/07/2000 **DOB**: 07/07/1943

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| <u> </u>       |                          |                    |           |
|----------------|--------------------------|--------------------|-----------|
| Preferred Term | Severity                 | Report Description | Treatment |
| Headache       | Required Visit to Doctor | Moderate headaches |           |

## **Medicine Details:**

STELAZINE (Suspected)

Oral application

Batch:

Reason: Anxiety neurosis

Daily

Oral

Started: L TERM

Stopped:

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Patient also taking renitec, zoloft, lipitor, estraderm, rani-2. reaction occurred with new formulation of product.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 158460
 Seq: 1
 Gender:
 F

 Reported:
 12/10/2000
 Weight:
 47.4

Reported: 12/10/2000 Weight: 47.00
Hospitalisation: Admitted to hospital Age: 46

**Onset Date**: 15/06/2000 **DOB**: 25/10/1953

Outcome: Recovered Causality: Causality possible

Reaction Details:

| Preferred Term           | Severity                 | Report Description | Treatment  |
|--------------------------|--------------------------|--------------------|--|
| Fatigue                  | Required Visit to Doctor | Feeling tired.     | Stelazine ceased. patient admitted for new medication. |
| Nausea                   | Required Visit to Doctor | Slight nausea.     |  |
| Apathy                   | Required Visit to Doctor | Withdrawn.         |  |
| Anorexia                 | Required Visit to Doctor |                    |  |
| Drug withdrawal syndrome | Required Visit to Doctor |                    |  |
| Ear pain                 | Required Visit to Doctor |                    |  |

#### **Medicine Details:**

| STELAZINE (Suspected) |                     | Reason: | Unspecified schizophrenia |
|-----------------------|---------------------|---------|---------------------------|
| Oral application      | 12.0 Milligram      | Daily   | Oral                      |
| Batch:                | Started: 01/10/1996 |         | Stopped: 15/06/2000       |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

The reporting doctor is certain the reaction was due to her underlying disease re emerging after the cessation of her stelazine. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 158460 Seq: 1 Gender: F

Reported: 12/10/2000 Weight: 47.00
Hospitalisation: Admitted to hospital Age: 46

**Onset Date**: 15/06/2000 **DOB**: 25/10/1953

Outcome: Recovered Causality: Causality possible

Reaction Details:

| • |                    |                          |                    |           |
|---|--------------------|--------------------------|--------------------|-----------|
|   | Preferred Term     | Severity                 | Report Description | Treatment |
|   | Psychotic disorder | Required Visit to Doctor |                    |           |

#### **Medicine Details:**

| STELAZINE (Suspected) |                     | Reason: | Unspecified schizophrenia |
|-----------------------|---------------------|---------|---------------------------|
| Oral application      | 12.0 Milligram      | Daily   | Oral                      |
| Batch:                | Started: 01/10/1996 |         | Stopped: 15/06/2000       |

## **Laboratory Investigations:**

#### **Additional Information:**

The reporting doctor is certain the reaction was due to her underlying disease re emerging after the cessation of her stelazine. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 165082
 Seq: 1
 Gender: F

 Reported:
 01/06/2001
 Weight:

Hospitalisation: Age: 24

Onset Date: DOB: 16/05/1977

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

| Preferred Term | Severity | Report Description | Treatment  |
|----------------|----------|--------------------|--|
| Hyperkinesia   |          |                    | 24.2.01 patient started stelazine po 1mg tid. 1.3.01 stelazine was stopped. 3.3.01 she started diazepam 15mg qd. 6.3.01 she started cogentin 1mg qd. |

#### **Medicine Details:**

| Medicine Details.     |                     |              |                             |  |
|-----------------------|---------------------|--------------|-----------------------------|--|
| XENICAL (Suspected)   |                     | Reason: Obe  | sity othr than endoc origin |  |
| Tablet                | 360.0 Milligram     | Daily        | Oral                        |  |
| Batch:                | Started: 10/02/2001 | S            | Stopped: 20/02/2001         |  |
| STELAZINE (Suspected) |                     | Reason: Anxi | ety neurosis                |  |
| Oral application      | 3.0 Milligram       | Daily        | Oral                        |  |
| Batch:                | Started: 24/02/2001 | s            | Stopped: 01/03/2001         |  |

**Laboratory Investigations:** 

|   | Date | Туре | Range | Date Tested | Result | Details |
|---|------|------|-------|-------------|--------|---------|
| ĺ |      |      |       |             |        |         |

#### **Additional Information:**

The patient has a history of bipolar disorder/psychosis since 4.6.99, ankle injury since 1998, depression since 1999 and social phobia since 1999.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 170968 Seq: 1 Gender: F

Reported: 10/12/2001 Weight: 111.00 Hospitalisation: Age: 17

**Onset Date**: 12/07/2001 **DOB**: 20/10/1983

Outcome: Not yet recovered Causality: Causality possible

Reaction Details:

| Preferred Term          | Severity | Report Description                                 | Treatment                                   |
|-------------------------|----------|--|---|
| Extrapyramidal disorder |          | Cogwheel rigidity, dribbling, slow shuffling gait. | Stelazine ceased. date of recovery 18.7.01. |

## **Medicine Details:**

| EPILIM (Other drug)  |                   | Reason:    |          |
|----------------------|-------------------|------------|----------|
| Tablet               | 800.0 Millig      | gram Daily | Oral     |
| Batch:               | Started:          |            | Stopped: |
| EFEXOR (Other drug)  |                   | Reason:    |          |
|                      | 150.0 Millig      | gram Daily |          |
| Batch:               | Started:          |            | Stopped: |
| INDERAL (Other drug) |                   | Reason:    | Migraine |
|                      | 20.0 Millig       | gram Daily |          |
| Batch:               | Started:          |            | Stopped: |
| ZYPREXA (Suspected)  |                   | Reason:    |          |
| Tablet               | 12.5 Millig       | gram Daily | Oral     |
| Batch:               | Started: 01/05/20 | 001        | Stopped: |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

The dose start dates for zyprexia and stelazine are not necessarily accurate but indicates the drug was started sometime in the month.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report Detail                             | s:  |  |                |                       |                           |
|---|---|--|----------------|-----------------------|---------------------------|
| Hospitalisation:<br>Onset Date:           | 10/12/2001<br>12/07/2001<br>Not yet recovered | Seq: 1                                       |                |                       | 111.00                    |
| Reaction Detai                            | 15.   |  |                |                       |                           |
|   |   |  |                |                       |                           |
|   |   |  |                |                       |                           |
|   |   |  |                |                       |                           |
|   |   |  |                |                       |                           |
|   |   |  |                |                       |                           |
|   |   |  |                |                       |                           |
| Medicine Deta                             |   |  | Danani         |                       |                           |
| STELAZINE (Susp                           | ectea)  | 20.0 Milliaram                               | Reason:        |                       |                           |
| Batch:                                    |   | 20.0 Milligram<br><b>Started:</b> 28/07/2000 | Daily          | Stopped:              |                           |
|   |   |  |                |                       |                           |
| Laboratory In                             | vestigations:                                 |  |                |                       |                           |
|   |   |  |                |                       |                           |
|   |   |  |                |                       |                           |
|   |   |  |                |                       |                           |
| Additional Inf The dose start date month. |   | stelazine are not necessaril                 | / accurate but | indicates the drug wa | s started sometime in the |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 172751 Seq: 1 Gender: M
Reported: 13/02/2002 Weight:

**Hospitalisation**: Admitted to hospital **Age**: 71

**Onset Date**: 27/01/2001 **DOB**: 07/07/1929

Outcome: Recovered Causality: Causality possible

Reaction Details:

| todotion Botano: |                             | - |   |
|------------------|-----------------------------|---|---|
| Preferred Term   | Severity Report Description |   | Treatment   |
| Hyponatraemia    |                             |   |   |
| Polydipsia       |                             |   | Stelazine ceased. fluid restricted. patient was admitted to hospital. |

#### **Medicine Details:**

| BENZTROPINE MESYLATE (Other drug) | ) Reason: |           |         |                       |  |
|-----------------------------------|-----------|-----------|---------|-----------------------|--|
|                                   | 2.0       | Milligram | As ne   | cessary               |  |
| Batch:                            | Started:  |           |         | Stopped:              |  |
| OLANZAPINE (Other drug)           |           |           | Reason: | Unspecified psychosis |  |
|                                   | 10.0      | Milligram | Daily   |                       |  |
| Batch:                            | Started:  |           | S TERM  | Stopped:              |  |
| SALAZOPYRIN (Other drug)          |           |           | Reason: | Regional enteritis    |  |
|                                   | 1.5       | Gram      | Daily   |                       |  |
| Batch:                            | Started:  |           |         | Stopped:              |  |
| STELAZINE (Suspected)             |           |           | Reason: | Unspecified psychosis |  |
|                                   | 5.0       | Milligram | Daily   |                       |  |
| Batch:                            | Started:  |           | L TERM  | Stopped:              |  |

**Laboratory Investigations:** 

| Date | Туре   | Range | Date Tested | Result | Details |
|------|--------|-------|-------------|--------|---------|
|      | Sodium |       | 27/02/2001  | 120    |         |
|      | Sodium |       | 28/02/2001  | 140    |         |

#### **Additional Information:**

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DOB: 07/07/1929

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 172752
 Seq: 1
 Gender: M

 Reported:
 13/02/2002
 Weight:

**Hospitalisation**: Admitted to hospital **Age**: 71

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

Onset Date: 14/03/2001

| Preferred Term  | Severity | Report Description   | Treatment  |
|---|----------|----------------------|--|
| Convulsion Blood creatine phosphokinase incr Confusional state Dyskinesia Hypertonia Hyponatraemia Neuroleptic malignant syndrome | Severity | Tonic/clonic seizure | Patient was admitted to icu, given benztropine 2mg but no effect, olanzapine ceased, |
| Pyrexia   |          |                      | saline given and fluid restriction.  |

#### **Medicine Details:**

| BENZTROPINE MESYLATE (Other drug) |          |           | Reason: | Disturbance of coordination |
|-----------------------------------|----------|-----------|---------|-----------------------------|
|                                   | 2.0      | Milligram | As ne   | ecessary                    |
| Batch:                            | Started: |           | L TERM  | Stopped:                    |
| SULFASALAZINE (Other drug)        |          |           | Reason: | Regional enteritis          |
|                                   | 1.5      | Gram      | Daily   |                             |
| Batch:                            | Started: |           | L TERM  | Stopped:                    |
| STELAZINE (Suspected)             |          |           | Reason: | Unspecified psychosis       |
|                                   | 5.0      | Milligram | Daily   |                             |
| Batch:                            | Started: |           | L TERM  | Stopped:                    |
| OLANZAPINE (Suspected)            |          |           | Reason: | Schizophrenia               |
|                                   | 10.0     | Milligram | Daily   |                             |
| Batch:                            | Started: |           | S TERM  | Stopped:                    |

**Laboratory Investigations:** 

| Date | Туре     | Range | Date Tested | Result | Details |
|------|----------|-------|-------------|--------|---------|
|      | Creatine |       | 16/03/2001  | 10,780 |         |
|      | Creatine |       | 17/03/2001  | 6840   |         |

#### **Additional Information:**

Patient had stanage movements lip-smacking, constant swallowing, neck extension, ocular movements.

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Causality: Causality possible

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 172752
 Seq: 1
 Gender: M

 Reported:
 13/02/2002
 Weight:

Hospitalisation: Admitted to hospital Age: 71

**Onset Date**: 14/03/2001 **DOB**: 07/07/1929

Outcome: Not yet recovered

#### **Reaction Details:**

| Preferred Term     | Severity | Report Description | Treatment |
|--------------------|----------|--------------------|-----------|
| Tardive dyskinesia |          |                    |           |

## **Medicine Details:**

| BENZTROPINE MESYLATE (Other drug) |          |           | Reason: | Disturbance of coordination |
|-----------------------------------|----------|-----------|---------|-----------------------------|
|                                   | 2.0      | Milligram | As ne   | ecessary                    |
| Batch:                            | Started: |           | L TERM  | Stopped:                    |
| SULFASALAZINE (Other drug)        |          |           | Reason: | Regional enteritis          |
|                                   | 1.5      | Gram      | Daily   |                             |
| Batch:                            | Started: |           | L TERM  | Stopped:                    |
| STELAZINE (Suspected)             |          |           | Reason: | Unspecified psychosis       |
|                                   | 5.0      | Milligram | Daily   |                             |
| Batch:                            | Started: |           | L TERM  | Stopped:                    |
| OLANZAPINE (Suspected)            |          |           | Reason: | Schizophrenia               |
|                                   | 10.0     | Milligram | Daily   |                             |
| Batch:                            | Started: |           | S TERM  | Stopped:                    |

# **Laboratory Investigations:**

#### **Additional Information:**

Patient had stanage movements lip-smacking, constant swallowing, neck extension, ocular movements.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report De   | tails:                               |                  |                       |        |          |            |          |        |                 |           |        |                     |     |         |                  |       |
|---|--------------------------------------|------------------|-----------------------|--------|----------|------------|----------|--------|-----------------|-----------|--------|---------------------|-----|---------|------------------|-------|
| Hospitalisatio<br>Onset Da<br>Outcon                  | ed: 19/<br>on:<br>ate: 09/<br>ne: Re | 03/200<br>12/200 | 2                     | Seq: 1 |          |            |          |        |                 | C         | DO     | ht:<br>ge: 8<br>OB: | 35Y | ality p | ossible          |       |
| eaction De  | etails:<br>ferred T                  |                  | 1                     | Carrar |          |            | Dan      |        |                 |           |        | 1                   |     | Troot   |                  |       |
| Hypertonia<br>Tremor<br>Hyperkinesia<br>Tardive dyski |                                      | erm              |                       | Sever  |          | Rigidity I | both arn | ns and | scription neck. | on        |        | Stela               |     |         | ment<br>d, benzh | nexol |
| Medicine [  |                                      |                  | PS (Other o           | drug)  |          |            | Rea      | son:   | Unspe           | cified gl | aucoma | 1                   |     |         |                  |       |
| Eye D   | rops                                 |                  |                       |        | 2.0      | Dose Uns   | pecified | Daily  |                 |           | Ophth  | almic               |     |         |                  |       |
| Batch   | n:                                   |                  |                       | Starte | ed:      |            |          |        | Sto             | pped:     |        |                     | C   | NITNC   |                  |       |
| STELAZINE (S  | Suspecte                             | d)               |                       |        |          |            | Rea      | son:   | Depres          | ssion     |        |                     |     |         |                  |       |
| Tablet  |                                      |                  |                       |        | 2.0      | Milligram  |          | Daily  |                 |           | Oral   |                     |     |         |                  |       |
| Batch   | n:                                   |                  |                       | Starte | ed:      |            |          |        | Sto             | pped:     | 09/12/ | 2001                |     |         |                  |       |
| <b>Laborator</b> Date                                 | <b>y Inves</b><br>Typ                |                  | <b>ions:</b><br>Range | Da     | te Teste | ed R       | esult    |        |                 |           | 2      | )etails             |     |         |                  |       |
| Additional  | Inforr                               | natio            | n:                    | ,      |          | •          |          |        |                 |           |        |                     |     |         |                  |       |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report Details:  |                                    |                                       |   |                      |                            |
|--|------------------------------------|---------------------------------------|---|----------------------|----------------------------|
| Case Number: 176279  | Seq: 1                             |                                       |   | Gender:              | : F                        |
| Reported: 14/06/2002   |                                    |                                       | ,   | Weight:              |                            |
| ospitalisation:  |                                    |                                       |   | Age:                 | : 71Y                      |
| Onset Date: 12/04/2002   |                                    |                                       |   | DOB                  | :                          |
| Outcome: Recovered   |                                    |                                       | Ca  | ausality:            | : Causality possible       |
| eaction Details:   |                                    |                                       |   |                      |                            |
| Preferred Term   | Severity                           | Report De                             | escription  |                      | Treatment                  |
| oordination abnormal   |                                    |                                       |   |                      |                            |
| ait disturbance  |                                    |                                       |   |                      |                            |
| alpitations  |                                    |                                       |   |                      |                            |
| achycardia   |                                    |                                       |   | Ce                   | eased stelazine and colofa |
|  |                                    |                                       |   |                      |                            |
| ledicine Details:  |                                    |                                       |   |                      |                            |
|  |                                    | Reason:                               |   |                      |                            |
|  | 0.0                                | Reason:                               |   |                      |                            |
|  | 0.0<br>Started:                    | Reason:                               | Stopped:  |                      |                            |
| PREDNISONE (Other drug)  Batch:  |                                    | Reason:<br>Reason:                    | Stopped:<br>Chron isch hea  | rt dis no hy         | yper                       |
| PREDNISONE (Other drug)  Batch:  | Started:                           | Reason:                               | Chron isch hea  | rt dis no hy<br>Oral | yper                       |
| PREDNISONE (Other drug)  Batch:  SOSORBIDE DINITRATE (Other drug)  | Started:                           | Reason:                               | Chron isch hea  | •                    | yper                       |
| PREDNISONE (Other drug)  Batch: SOSORBIDE DINITRATE (Other drug)  Tablet  Batch:                                   | Started:                           | Reason:                               | Chron isch hea<br>ecessary  | •                    | yper                       |
| PREDNISONE (Other drug)  Batch:  SOSORBIDE DINITRATE (Other drug)  Tablet  Batch:                                  | Started:                           | Reason: Milligram As ne               | Chron isch hea ecessary  Stopped:  Emphysema ecessary                           | •                    | yper                       |
| PREDNISONE (Other drug)  Batch:  SOSORBIDE DINITRATE (Other drug)  Tablet  Batch:  SALBUTAMOL (Other drug)  Batch: | Started: 5.0 Started:              | Reason: Milligram As ne               | Chron isch hea ecessary Stopped: Emphysema ecessary Stopped:                    | Oral                 | yper                       |
| PREDNISONE (Other drug)  Batch: ISOSORBIDE DINITRATE (Other drug)  Tablet  Batch: SALBUTAMOL (Other drug)  Batch:  | Started: 5.0 Started:              | Reason: Milligram As ne               | Chron isch hea ecessary  Stopped:  Emphysema ecessary                           | Oral                 | yper                       |
| Tablet Batch: SALBUTAMOL (Other drug)  | Started: 5.0 Started: 0.0 Started: | Reason: Milligram As ne Reason: As ne | Chron isch hea ecessary  Stopped:  Emphysema ecessary  Stopped:  Congestive hea | Oral                 | yper                       |

#### **Additional Information:**

Type

Range

Date

Allergic to penicillin, sulphur, iodine, arthritis medications(unspecifield) patient has dementia-stelazine to calm her.

Date Tested

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Result

Details



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Re | port | Detai | ls: |
|----|------|-------|-----|
|----|------|-------|-----|

 Case Number:
 176279
 Seq: 1
 Gender:
 F

 Reported:
 14/06/2002
 Weight:

Hospitalisation: Age: 71Y
Onset Date: 12/04/2002 DOB:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

## **Medicine Details:**

| SODIUM VALPROATE (Other drug) |          |           | Reason: |                 |                 |
|-------------------------------|----------|-----------|---------|-----------------|-----------------|
| Tablet                        | 400.0    | Milligram | Daily   |                 | Oral            |
| Batch:                        | Started: |           |         | Stopped:        |                 |
| RAMIPRIL (Other drug)         |          |           | Reason: | Essential beni  | gn hypertension |
| Tablet                        | 2.5      | Milligram | Daily   |                 | Oral            |
| Batch:                        | Started: |           |         | Stopped:        |                 |
| COLOFAC (Suspected)           |          |           | Reason: | Irritable colon |                 |
| Tablet                        | 405.0    | Milligram | Daily   |                 | Oral            |
| Batch:                        | Started: |           |         | Stopped:        | 16/04/2002      |
| STELAZINE (Suspected)         |          |           | Reason: | Anxiety neuro   | sis             |
| Tablet                        | 2.0      | Milligram | Daily   |                 | Oral            |
| Batch:                        | Started: |           |         | Stopped:        | 16/04/2002      |

# **Laboratory Investigations:**

#### **Additional Information:**

Allergic to penicillin, sulphur, iodine, arthritis medications(unspecifield) patient has dementia-stelazine to calm her.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 176673
 Seq: 1
 Gender:
 F

 Reported:
 26/06/2002
 Weight:

Hospitalisation: Age: 84Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Details:

| Preferred Term | Severity                               | Report Description | Treatment                                     |
|----------------|--|--------------------|---|
|                | Required<br>Specialist<br>Consultation |                    | Stelazine ceased. required medical attention. |

## **Medicine Details:**

| TRITACE (Other drug)  |          |           | Reason: | Essential benign hypertension | ١      |
|-----------------------|----------|-----------|---------|-------------------------------|--------|
| Oral application      | 1.2      | Milligram | Daily   | Oral                          |        |
| Batch:                | Started: |           |         | Stopped:                      |        |
| IMDUR (Other drug)    |          |           | Reason: | Chron isch heart dis no hyper |        |
| Oral application      | 60.0     | Milligram | Daily   | Oral                          |        |
| Batch:                | Started: |           |         | Stopped:                      | CONTIN |
| SOLPRIN (Other drug)  |          |           | Reason: | Chron isch heart dis no hyper |        |
| Oral application      | 150.0    | Milligram | Daily   | Oral                          |        |
| Batch:                | Started: |           |         | Stopped:                      | CONTIN |
| CELEBREX (Other drug) |          |           | Reason: | Osteoarthritis                |        |
|                       | 400.0    | Milligram | Daily   |                               |        |
| Batch:                | Started: |           |         | Stopped:                      | CONTIN |

**Laboratory Investigations:** 

| Date | Type | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Patient has suffered from restless legs for 2 years.

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**Report Details:** 

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Reported:               |            | Seq: 1   |                  |       |                |            |                    |
|-------------------------|------------|----------|------------------|-------|----------------|------------|--------------------|
| •                       | 26/06/2002 |          |                  |       |                | Weight:    |                    |
| spitalisation:          |            |          |                  |       |                | Age:       | 84Y                |
| Onset Date:             |            |          |                  |       |                | DOB:       |                    |
| Outcome:                | Unknown    |          |                  |       | С              | ausality:  | Causality possible |
| ction Detai             | ils:       |          |                  |       |                |            |                    |
|                         |            |          |                  |       |                |            |                    |
|                         |            |          |                  |       |                |            |                    |
|                         |            |          |                  |       |                |            |                    |
|                         |            |          |                  |       |                |            |                    |
|                         |            |          |                  |       |                |            |                    |
|                         |            |          |                  |       |                |            |                    |
|                         |            |          |                  |       |                |            |                    |
|                         |            |          |                  |       |                |            |                    |
|                         |            |          |                  |       |                |            |                    |
|                         |            |          |                  |       |                |            |                    |
|                         |            |          |                  |       |                |            |                    |
|                         |            |          |                  |       |                |            |                    |
| edicine Deta            |            |          | Rea              |       | Ootooorthritio |            |                    |
| ALTRATE (Other          |            | 1.0      |                  |       | Osteoarthritis | Oral       |                    |
| Oral application Batch: | ation      |          | Dose Unspecified | Daily |                | Oral       | CONTIN             |
|                         | ( )        | Started: | Dan              |       | Stopped:       |            | CONTIN             |
| TELAZINE (Susp          | ectea)     | 2.0      | Rea              |       |                | Oral       |                    |
| Tablet                  |            |          | Milligram        | Daily | 04             | Oral       |                    |
| Batch:                  | 4 D        | Started: | D                |       | Stopped:       | 08/11/2000 |                    |
| NEMET-M (Susp           | ectea)     | 0.0      | Rea              |       |                | 01         |                    |
| Tablet                  |            |          | Dose Unspecified | Dally |                | Oral       | CONTIN             |
| Batch:                  |            | Started: | L TERM           |       | Stopped:       |            | CONTIN             |

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 167 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

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

Case Number: 177701 Seq: 1 Gender: F

Reported: 05/08/2002 Weight: 53.00 Hospitalisation: Age: 66Y

**Onset Date**: 28/08/2001 **DOB**:

Outcome: Recovered Causality: Causality possible

**Reaction Details:** 

| todotion Botano.        |          |                    |  |
|-------------------------|----------|--------------------|--|
| Preferred Term          | Severity | Report Description | Treatment  |
| Fall                    |          | '                  | Ceased stelazine, fluid restriction. required medical attention. |
| Orthostatic hypotension |          |                    |  |

#### **Medicine Details:**

STELAZINE (Suspected) Reason: Schizophrenia

10.0 Milligram Daily

Batch: Started: Stopped: 14/08/2001

LASIX (Suspected) Reason:

40.0 Milligram Daily

Batch: Started: Stopped: 09/08/2001

**Laboratory Investigations:** 

| Date | Туре   | Range | Date Tested | Result | Details |
|------|--------|-------|-------------|--------|---------|
|      | Sodium |       |             |        | Na 119  |

#### **Additional Information:**

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 168 of 197



Report Details:

Case Number: 180797

**Reported:** 18/12/2002

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

Gender: F

**Weight:** 85.00

| Hospitalisation: Hospitalisation prolonged |                 |               |             | Age: 73                                |  |   |          |  |
|--|-----------------|---------------|-------------|--|--|---|----------|--|
|  | ate: 16/10/2002 | 2             |             | <b>DOB:</b> 02/02/1929                 |  |   |          |  |
|  | me: Unknown     |               |             |  | Causali  | ty: Causality possi   | ble      |  |
| eaction D                                  |                 |               | .,          |  | (D : "   | T + ,   |          |  |
|  | eferred Term    |               | verity      | •                                      | ort Description                                | Treatmen  | t        |  |
| Tremor                                     |                 | Sever         | tri         | as previously of fluoperazine u tremor | on thioridazine and ontil Nov 2001, ceased due | Thioridazine and<br>Trifluoperazine ceas<br>Admitted to hospital. | ed.      |  |
| <b>M</b> edicine                           |                 |               |             |  |  |   |          |  |
|  | IE HYDROCHLORII | DE (Suspected | )           | Rea                                    | son:   |   |          |  |
| Table                                      |                 |               |             |  | Oral   |   |          |  |
| Batc                                       |                 |               | arted:      | Dee                                    | Stopped:                                       |   |          |  |
| TRIFLUOPER                                 | RAZINE HYDROCHI | -ORIDE (Suspe | ctea)       | Rea                                    | son:   |   |          |  |
| Batc                                       | h:              | St            | arted:      |  | Stopped:                                       |   |          |  |
| I aborator                                 | y Investigati   | ons:          |             |  |  |   |          |  |
| Date                                       | Type            | Range         | Date Tested | Result                                 | D  | etails  |          |  |
| Bato                                       | 1,400           | rango         | Date Feeted | rtocait                                |  | otano   |          |  |
| Additiona                                  | I Information   | :             |             |  |  |   | <u> </u> |  |
| eport Run: 06/0                            | 06/2007 08:46AM | Database: pu  | sime02      | A                                      | DRS004   | Page 169  | of 197   |  |



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 191184 Seq: 1 Gender: F

Reported: 09/10/2003 Weight: 80.00 Hospitalisation: Age: 73

Onset Date: DOB: 11/11/1929

Outcome: Not yet recovered Causality: Causality possible

**Reaction Details:** 

| Preferred Term    | Severity | Report Description      | Treatment |
|-------------------|----------|-------------------------|-----------|
| Movement disorder |          | Parkinson-like symptoms |           |

## **Medicine Details:**

STELAZINE (Suspected) Reason:

Tablet 1.0 Milligram Daily Oral

Batch: Started: Stopped: 01/10/2003

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Other drugs: Zantac, Noten, Astrix, Vioxx, Caltrate, Paracetamol, Quinate, Lasix, Slow-K and Stemzine.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 197315 Seq: 1 Gender: M

Reported: 13/05/2004 Weight: 90.00 Hospitalisation: Age: 59

**Onset Date**: 28/04/2004 **DOB**: 07/07/1944

Outcome: Recovered Causality: Causality possible

Reaction Details:

| • | <u> </u>       |          |                         | 1                |
|---|----------------|----------|-------------------------|------------------|
|   | Preferred Term | Severity | Report Description      | Treatment        |
|   | Mood swings    |          | Aggressive mood swings. | Grisovin ceased. |
|   | Flushing       |          | Flushes in face.        |                  |

#### **Medicine Details:**

| Medicine Details.       |                     |                                      |
|-------------------------|---------------------|--------------------------------------|
| GRISOVIN (Interaction)  |                     | Reason: Unspecified systemic mycosis |
| Tablet                  | 500.0 Milligram     | Daily Oral                           |
| Batch:                  | Started: 28/04/2004 | <b>Stopped:</b> 06/05/2004           |
| STELAZINE (Interaction) |                     | Reason:                              |
| Tablet                  | 2.0 Milligram       | Daily Oral                           |
| Batch:                  | Started:            | Stopped:                             |

**Laboratory Investigations:** 

|   | Date | Туре | Range | Date Tested | Result | Details |
|---|------|------|-------|-------------|--------|---------|
| ĺ |      |      |       |             |        |         |

#### **Additional Information:**

Ceased taking Grisovin and now back to normal. Patient also taking Zoton, Daonil, Diamicron MR, Atacand, Lipitor and Norvasc.

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Report Details:

Case Number: 201389

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

Gender: F

| Repoi            | rted: 30/09/200   | 4            |             |                      |                 | Weigh | nt: 0.00  |  |
|------------------|-------------------|--------------|-------------|----------------------|-----------------|-------|---|--|
| Hospitalisation: |                   |              |             | <b>Age</b> : 74Y     |                 |       |   |  |
| Onset D          | Date: 12/07/200   | 4            |             | DOB:                 |                 |       |   |  |
| Outco            | me: Recovered     | i            |             | Causality: Causality |                 |       |   |  |
| Reaction D       |                   | <u> </u>     |             |                      |                 |       |   |  |
|                  | eferred Term      | Se           | everity     |                      | ort Description |       | Treatment   |  |
| Hypokalaen       | nia               |              | Н           | yponatraemia         | , hypokalaemia  |       | Taper down Stelazine and ac<br>Risperidone gradually. |  |
| Hyponatrae       | mia               |              |             |                      |                 |       | r tioponiuono graduany.                               |  |
|                  |                   |              |             |                      |                 |       |   |  |
|                  |                   |              |             |                      |                 |       |   |  |
|                  |                   |              |             |                      |                 |       |   |  |
|                  |                   |              |             |                      |                 |       |   |  |
|                  |                   |              |             |                      |                 |       |   |  |
|                  |                   |              |             |                      |                 |       |   |  |
| Medicine         | Details:          |              |             |                      |                 |       |   |  |
| COLOXYL (C       |                   |              |             | Re                   | ason:           |       |   |  |
| )                |                   |              |             |                      |                 |       |   |  |
| Bato             | ch:               | S            | tarted:     |                      | Stop            | ped:  |   |  |
| DUROLAX (        |                   |              |             | Re                   | ason:           |       |   |  |
|                  | pository          |              | Recta       |                      |                 |       |   |  |
| Bato             |                   |              | tarted:     |                      | Stop            | ped:  |   |  |
| NULAX FRU        | IT LAXATIVE (Othe | r drug)      |             |                      |                 |       |   |  |
| Bato             | ch:               | s            | tarted:     |                      | Ston            | ped:  |   |  |
| SENOKOT (        |                   |              |             | Re                   | ason:           | p     |   |  |
|                  | <u>-</u> -        |              |             |                      |                 |       |   |  |
| Bato             | ch:               | s            | tarted:     |                      | Stop            | ped:  |   |  |
| Lahorato         | ry Investigati    | one.         |             |                      |                 |       |   |  |
| Date             | Type              | Range        | Date Tested | Result               |                 | D     | etails  |  |
| 30/09/2004       | Potassium         |              |             |                      | K+= 2.5         |       |   |  |
| 30/09/2004       | Potassium         |              | <u> </u>    | <u> </u>             | K+= 2.5         |       |   |  |
|                  |                   |              |             |                      |                 |       |   |  |
|                  |                   |              |             |                      |                 |       |   |  |
|                  |                   |              |             |                      |                 |       |   |  |
| Additiona        | al Information    | 1:           |             |                      |                 |       |   |  |
|                  |                   |              |             |                      |                 |       |   |  |
|                  |                   |              |             |                      |                 |       |   |  |
|                  |                   |              |             |                      |                 |       |   |  |
|                  |                   |              |             |                      |                 |       |   |  |
| lamant Deve      | 10010007 00 1011  | Databa       | .ai.aa 20   |                      | ADD0004         |       | D 4=- 4/  |  |
| eport Run: 06/   | /06/2007 08:46AM  | Database: pu | usime02     |                      | ADRS004         |       | Page 172 of 197                                       |  |



Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Hospitalisation:<br>Onset Date: | 30/09/2004<br>12/07/2004<br>Recovered | Seq: 1   |         | DOB      | 0.00<br>74Y |
|---------------------------------|---------------------------------------|----------|---------|----------|-------------|
| Medicine Det                    | ails:                                 |          |         |          |             |
| PANADOL (Other                  |                                       |          | Reason: |          |             |
| Batch:                          |                                       | Started: |         | Stopped: |             |
| CANESTEN (Other                 | r drug)                               |          | Reason: |          |             |
| Cream                           |                                       |          |         | Topical  |             |
| Batch:                          |                                       | Started: | _       | Stopped: |             |
| BETADINE (Other                 | drug)                                 |          | Reason: |          |             |
| Batch:                          |                                       | Started: |         | Stopped: |             |
| POLY-TEARS (Oth                 | ner drug)                             |          | Reason: |          |             |
| Batch:                          |                                       | Started: |         | Stopped: |             |
| Laboratory In                   | vestigations:                         |          |         |          |             |
| Additional Inf                  | formation:                            |          |         |          |             |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Seq: 1         |                                  | Gender:<br>Weight:<br>Age:<br>DOB:<br>Causality:           | 0.00<br>74Y  |
|----------------|----------------------------------|--|--|
|                |                                  |  |  |
|                | Reason:                          |  |  |
| - · · ·        |                                  |  |  |
| Started:       | Posson:                          | Stopped:   |  |
|                | Reason.                          |  |  |
| Started:       |                                  | Stopped:   |  |
|                | Reason:                          |  |  |
| Started:       |                                  | Stopped:   |  |
|                | Reason:                          |  |  |
| 25.0 Milligram | Daily                            | Oral   |  |
| Started:       |                                  | Stopped:   |  |
|                |                                  |  |  |
|                |                                  |  |  |
|                | Started: Started: 25.0 Milligram | Reason: Started: Reason: Started: Reason: Started: Reason: | Reason: Started: Stopped: Reason: Started: Stopped: Reason: Started: Stopped: Reason: Started: Stopped: Reason: Oral |

Report Run: 06/06/2007 08:46AM Database: pusime02 ADRS004 Page 174 of 197



Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

|                                | 201389       | Seq: 1                                     |         | Gender        |                      |
|--------------------------------|--------------|--|---------|---------------|----------------------|
| Reported:                      | 30/09/2004   |  |         | Weight        | : 0.00               |
| ospitalisation:                |              |  |         | _             | : 74Y                |
| Onset Date:                    | 12/07/2004   |  |         | DOE           |                      |
| Outcome:                       | Recovered    |  |         | Causality     | : Causality possible |
| eaction Detail                 | ls:          |  |         |               |                      |
|                                |              |  |         |               |                      |
|                                |              |  |         |               |                      |
|                                |              |  |         |               |                      |
|                                |              |  |         |               |                      |
|                                |              |  |         |               |                      |
|                                |              |  |         |               |                      |
|                                |              |  |         |               |                      |
|                                |              |  |         |               |                      |
|                                |              |  |         |               |                      |
|                                |              |  |         |               |                      |
|                                |              |  |         |               |                      |
|                                |              |  |         |               |                      |
| Medicine Deta                  | ails:        |  |         |               |                      |
| PENICILLIN NOS (S              | Suspected)   |  | Reason: |               |                      |
| Injection                      |              | 5.0 Gram                                   | Daily   | Intraveno     | us                   |
| Batch:                         |              | Started: 05/07/2004                        |         | Stopped:      |                      |
| RULIDE (Suspected              | d)           |  | Reason: |               |                      |
|                                | ۵,           |  | Reason. |               |                      |
| Tablet                         | <b>-</b> ,   | 300.0 Milligram                            | Daily   | Oral          |                      |
|                                | <b>-</b> ,   | 300.0 Milligram <b>Started:</b> 05/07/2004 |         | Oral Stopped: |                      |
| Tablet                         | ,            |  |         |               |                      |
| Tablet                         |              |  |         |               |                      |
| Tablet <b>Batch</b> :          |              | Started: 05/07/2004                        |         |               |                      |
| Tablet <b>Batch</b> :          |              | Started: 05/07/2004                        |         |               |                      |
| Tablet <b>Batch</b> :          |              | Started: 05/07/2004                        |         |               |                      |
| Tablet <b>Batch</b> :          |              | Started: 05/07/2004                        |         |               |                      |
| Tablet <b>Batch</b> :          |              | Started: 05/07/2004                        |         |               |                      |
| Tablet <b>Batch</b> :          |              | Started: 05/07/2004                        |         |               |                      |
| Tablet <b>Batch</b> :          |              | Started: 05/07/2004                        |         |               |                      |
| Tablet <b>Batch</b> :          |              | Started: 05/07/2004                        |         |               |                      |
| Tablet Batch:                  |              | Started: 05/07/2004                        |         |               |                      |
| Tablet Batch:                  | vestigations | Started: 05/07/2004                        |         |               |                      |
| Tablet Batch:                  | vestigations | Started: 05/07/2004                        |         |               |                      |
| Tablet  Batch:  _aboratory Inv | vestigations | Started: 05/07/2004                        |         |               |                      |
| Tablet                         | vestigations | Started: 05/07/2004                        |         |               |                      |
| Tablet Batch:                  | vestigations | Started: 05/07/2004                        |         |               |                      |

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**Report Details:** 

**Hospitalisation:** 

Case Number: 201638

Reported: 11/10/2004

Onset Date: 15/08/2004

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

Gender: M

Weight: 0.00

**Age**: 40 **DOB**:

|                                 | covered       |                        |  | (                 | Causality        | y: Causality possible |
|---------------------------------|---------------|------------------------|--|-------------------|------------------|-----------------------|
| action Details:  Preferred Term | Se            | verity                 | Reno   | rt Description    |                  | Treatment             |
| onvulsion                       |               | Pa<br>mo<br>gra<br>exi | <del>-                                    </del> |                   |                  | Amisulpride ceased.   |
| yskinesia<br>yperhidrosis       |               |                        |  |                   |                  |                       |
|                                 |               |                        |  |                   |                  |                       |
|                                 |               |                        |  |                   |                  |                       |
| ledicine Details:               |               |                        |  |                   |                  |                       |
| CLOPIXOL (Interaction)          |               |                        | Reas   | on: Unspecified p | sychosis         |                       |
| Batch:                          | St            | arted:                 |  | Stopped:          |                  |                       |
| STELAZINE (Interaction)         |               |                        | Reas   | son:              |                  |                       |
|                                 |               |                        |  |                   | Oral             |                       |
| Batch:                          | St            | arted:                 |  | Stopped:          |                  |                       |
| SOLIAN (Interaction)            |               | 0000 0 14:11           | Reas   | ·                 | 0 1              |                       |
| Tablet  Batch:                  | 64            | 800.0 Mill arted:      | ıgram  | Daily             | Oral<br>25/09/20 | 004 0                 |
| PARACETAMOL (Other drug)        | 31            | arteu.                 | Reas   |                   | 25/09/20         | 0                     |
| ANAOLIAMOL (Other drug)         |               |                        | Neas   |                   | Oral             |                       |
| Batch:                          | St            | arted:                 |  | Stopped:          |                  |                       |
|                                 |               |                        |  | •                 |                  |                       |
| aboratory Investigati Date Type | ONS:<br>Range | Date Tested            | Result   |                   | Do               | tails                 |
|                                 |               |                        |  |                   |                  |                       |



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number: 20247  |   |              |  |                        |
|---|---|--------------|--|------------------------|
| 2430 Hullibel. 2027/  | '3 <b>Seq:</b> 1                              |              | Gende  | er: F                  |
| Reported: 11/11/  | /2004   | Weight: 0.00 |  |                        |
| ospitalisation: Admit   | ted to hospital                               |              | Ag   | <b>e</b> : 53          |
| Onset Date:   |   |              | DC   | <b>B</b> : 13/10/1951  |
| Outcome: Unkno  | own   |              | Causali  | ty: Causality possible |
| eaction Details:  |   |              |  |                        |
| Preferred Terr  | n Severity                                    | Repo         | ort Description  | Treatment              |
| Suicide attempt   | brolonged x                                   | 150mg Efexor | by overdose. Ingested 28 XR and Alcohol plus 4-6 ne and was unconscious. |                        |
| oss of consciousness  | Caused or prolonged inpatient hospitalisation |              |  |                        |
| Overdose  | Caused or prolonged inpatient hospitalisation |              |  |                        |
| Madiaina Dataila  |   |              |  |                        |
| Medicine Details: DIAZEPAM (Other drug)                               |   | Rea          | son:   |                        |
| Batch:  | Started:                                      |              | Stopped:   |                        |
|   |   | _            |  |                        |
| LARGACTIL (Other drug)  |   | Reas         | son:   |                        |
| LARGACTIL (Other drug)  |   | Rea          | son:   |                        |
| Batch:  | Started:                                      |              | Stopped:   |                        |
| Batch:<br>STELAZINE (Suspected)                                       | Started:                                      | Rea:         | Stopped:   |                        |
| Batch: STELAZINE (Suspected) Tablet                                   |   |              | Stopped:  Son:  Oral   |                        |
| Batch: STELAZINE (Suspected) Tablet Batch:                            | Started:<br>Started:                          | Rea          | Stopped:  Oral  Stopped: 09/02/2   | 005 0                  |
| Batch: STELAZINE (Suspected) Tablet Batch:                            |   |              | Stopped:  Oral  Stopped: 09/02/2   | 0005 0                 |
| Batch: STELAZINE (Suspected) Tablet Batch:                            |   | Rea          | Stopped:  Oral  Stopped: 09/02/2   | 005 0                  |
| Batch: STELAZINE (Suspected) Tablet Batch: ALCOHOL (Suspected) Batch: | Started:<br>Started:                          | Rea          | Stopped: Oral Stopped: 09/02/2   | 0005 0                 |
| Batch: STELAZINE (Suspected) Tablet Batch: ALCOHOL (Suspected)        | Started:<br>Started:                          | Rea:         | Stopped: Oral Stopped: 09/02/2 son: Stopped:                             | 005 0                  |

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Report Details:

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number:                          | 202473           | Seq: 1             |              |         |            | Gender:    | F                  |
|---------------------------------------|------------------|--------------------|--------------|---------|------------|------------|--------------------|
| Reported:                             | 11/11/2004       |                    |              |         |            | Weight:    | 0.00               |
| Hospitalisation:                      | Admitted to hos  | pital              |              |         |            | Age:       | 53                 |
| Onset Date:                           |                  |                    |              |         |            | DOB:       | 13/10/1951         |
| Outcome:                              | Unknown          |                    |              |         | (          | Causality: | Causality possible |
| eaction Detai                         | ils:             |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
| Medicine Det                          | aile:            |                    |              |         |            |            |                    |
| EFEXOR-XR (Sus                        |                  |                    |              | Reason: | Depression |            |                    |
|                                       | nodified release | 150.0              | Milligram    | Daily   | •          | Oral       |                    |
| Batch:                                |                  | Started: 15        |              | . ,     | Stopped    |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
| Laboratory In                         | vestigations:    |                    |              |         |            |            |                    |
|                                       | J                |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
|                                       |                  |                    |              |         |            |            |                    |
| Additional In                         | formation        |                    |              |         |            |            |                    |
|                                       |                  | ide attemnts, sles | ening disord | er      |            |            |                    |
|                                       |                  | ide attempts, slee | eping disord | er      |            |            |                    |
| Additional Interpretation             |                  | ide attempts, slee | eping disord | er      |            |            |                    |
| Additional Int<br>Patient has a histo |                  | ide attempts, slee | eping disord | er      |            |            |                    |
|                                       |                  | ide attempts, slee | eping disord | er      |            |            |                    |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 207224
 Seq: 1
 Gender:
 F

 Reported:
 19/04/2005
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 53
Onset Date: 14/01/2005
DOB: 13/10/1951

Outcome: Recovered Causality: Causality possible

Reaction Details:

| Preferred Term           | Severity                                      | Report Description                          | Treatment |
|--------------------------|---|---|-----------|
| Overdose                 | Caused or prolonged inpatient hospitalisation | she experienced withdrawal effects - really | hospital. |
| Drug withdrawal syndrome | Caused or prolonged inpatient hospitalisation |   |           |

#### Medicine Details:

| Medicine Details:     |                     |                    |            |
|-----------------------|---------------------|--------------------|------------|
| PANADOL (Suspected)   |                     | Reason:            |            |
| Batch:                | Started:            | Stopped:           |            |
| EFEXOR-XR (Suspected) |                     | Reason: Depression |            |
| Capsule               | 150.0 Milligram     | Daily              | Oral       |
| Batch:                | Started: 15/07/2004 | Stopped:           |            |
| STELAZINE (Suspected) |                     | Reason:            |            |
| Tablet                | 1.0 Dose Unspe      | cified Daily       | Oral       |
| Batch:                | Started:            | Stopped:           | 09/02/2005 |

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

#### **Additional Information:**

Prior to Efexor-XR, patient was on paroxetine, which did not help with depression. Patient advised she finds Efexor-XR helped, but life stresses "just get too much sometimes".

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 207224
 Seq: 1
 Gender:
 F

 Reported:
 19/04/2005
 Weight:
 0.00

Hospitalisation: Admitted to hospital Age: 53

**Onset Date**: 14/01/2005 **DOB**: 13/10/1951

Outcome: Recovered Causality: Causality possible

Reaction Details:

| caction betails. |   |                    |           |
|------------------|---|--------------------|-----------|
| Preferred Term   | Severity                                      | Report Description | Treatment |
| Headache         | Caused or prolonged inpatient hospitalisation |                    |           |
| Tremor           | Caused or prolonged inpatient hospitalisation |                    |           |

## **Medicine Details:**

| PANADOL (Suspected)   |                     | Reason:                    |
|-----------------------|---------------------|----------------------------|
| Batch:                | Started:            | Stopped:                   |
| EFEXOR-XR (Suspected) |                     | Reason: Depression         |
| Capsule               | 150.0 Milligram     | Daily Oral                 |
| Batch:                | Started: 15/07/2004 | Stopped:                   |
| STELAZINE (Suspected) |                     | Reason:                    |
| Tablet                | 1.0 Dose Uns        | pecified Daily Oral        |
| Batch:                | Started:            | <b>Stopped:</b> 09/02/2005 |

# **Laboratory Investigations:**

#### **Additional Information:**

Prior to Efexor-XR, patient was on paroxetine, which did not help with depression. Patient advised she finds Efexor-XR helped, but life stresses "just get too much sometimes".

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**Additional Information:** 

## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

|  | oer: 207850   | Seq: 1                     |                                   | Ger                | nder: F                   |
|--|---|----------------------------|-----------------------------------|--------------------|---------------------------|
| Repor  | ted: 16/05/2005   |                            | Weight: 62.00                     |                    |                           |
| ospitalisati                                     |   |                            |                                   |                    | Age: 27Y                  |
| Onset D  | ate: 15/04/1999   |                            |                                   | 1                  | DOB:                      |
| Outco  | me: Unknown   |                            |                                   | Causa              | ality: Causality possible |
| action D   |   |                            | _                                 |                    |                           |
|  | eferred Term  | Severity                   | Report De                         | escription         | Treatment                 |
| uscle rigidi                                     | ty  |                            | The patient experienc and tremor. | ed muscle rigidity | Benztropine given.        |
| nerapy regi<br>remor                             | men changed   |                            | and tremor.                       |                    |                           |
|  |   |                            |                                   |                    |                           |
|  |   |                            |                                   |                    |                           |
| edicine  | Details:  |                            |                                   |                    |                           |
|  | <b>Details:</b><br>RBONATE (Other dru                               | g)                         | Reason:                           |                    |                           |
|  | RBONATE (Other dru  | g)<br>Started:             | Reason:                           | Stopped:           |                           |
| LITHIUM CAF                                      | RBONATE (Other dru  |                            | Reason:                           | Stopped:           |                           |
| LITHIUM CAR<br>Batc<br>CLONAZEPA<br>Batc         | RBONATE (Other dru<br>h:<br>M (Other drug)<br>h:                    |                            |                                   | Stopped:           |                           |
| LITHIUM CAR<br>Batc<br>CLONAZEPA<br>Batc         | RBONATE (Other dru<br>h:<br>M (Other drug)<br>h:                    | Started:                   |                                   |                    |                           |
| Batc CLONAZEPA Batc DIAZEPAM (C                  | RBONATE (Other dru<br>h:<br>M (Other drug)<br>h:<br>Other drug)     | Started:                   | Reason:                           |                    |                           |
| Batc<br>CLONAZEPA<br>Batc<br>DIAZEPAM (C         | RBONATE (Other dru<br>h:<br>M (Other drug)<br>h:<br>Other drug)     | Started:                   | Reason:                           | Stopped:           |                           |
| Batc<br>CLONAZEPA<br>Batc<br>DIAZEPAM (C         | RBONATE (Other dru h: M (Other drug) h: Other drug) h: (Other drug) | Started:                   | Reason:<br>Reason:                | Stopped:           |                           |
| Batc CLONAZEPA  Batc DIAZEPAM (C  Batc ZOPICLONE | RBONATE (Other dru h: M (Other drug) h: Other drug) h: (Other drug) | Started: Started: Started: | Reason:<br>Reason:                | Stopped:           |                           |

Clinical trial RODOS WAVE I: RODOS. The patient experienced sedation and extrapyramydal symptoms on 13/1/1999, rigidity on 18/1/1999, slow movements on 16/2/1999, slurred speech on 18/2/1999, parkinsonism on 1/3/1999, constipation on 2/3/1999 and difficulty falling asleep on 3/5/1999.



## THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number:        | 207850           | Seq: 1      |         | Gender:                   | F  |
|---------------------|------------------|-------------|---------|---------------------------|--|
| Reported:           | 16/05/2005       |             |         | Weight:                   | 62.00  |
| lospitalisation:    |                  |             |         | Age:                      | 27Y  |
| Onset Date:         | 15/04/1999       |             |         | DOB:                      |  |
| Outcome:            | Unknown          |             |         | Causality:                | Causality possible                           |
| eaction Detai       |                  |             |         | ,                         | <b>,</b> , , , , , , , , , , , , , , , , , , |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
| <u>Medicine Det</u> | ails:            |             |         |                           |  |
| METAMUCIL (Other    | er drug)         |             | Reason: |                           |  |
|                     |                  |             |         |                           |  |
| Batch:              |                  | Started:    |         | Stopped:                  |  |
| PARACETAMOL (       | Other drug)      |             | Reason: |                           |  |
|                     |                  |             |         |                           |  |
| Batch:              |                  | Started:    |         | Stopped:                  |  |
| SODIUM VALPRO       | ATE (Other drug) |             | Reason: |                           |  |
|                     |                  |             |         |                           |  |
| Batch:              |                  | Started:    |         | Stopped:                  |  |
| TRIFLUOPERAZIN      | IE HYDROCHLORIDE | (Suspected) | Reason: | Unspecified schizophrenia |  |
|                     |                  | ,           |         | ·                         |  |
| Batch:              |                  | Started:    |         | Stopped:                  |  |
|                     |                  |             |         |                           |  |
| Laboratory In       | vestigations:    |             |         |                           |  |
| -                   | _                |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |
|                     |                  |             |         |                           |  |

#### **Additional Information:**

Clinical trial RODOS WAVE I: RODOS. The patient experienced sedation and extrapyramydal symptoms on 13/1/1999, rigidity on 18/1/1999, slow movements on 16/2/1999, slurred speech on 18/2/1999, parkinsonism on 1/3/1999, constipation on 2/3/1999 and difficulty falling asleep on 3/5/1999.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Re  | nn | rt | De                     | tail | ls:      |
|-----|----|----|------------------------|------|----------|
| 176 | μυ |    | $\mathbf{D}\mathbf{c}$ | tai  | <b>.</b> |

Case Number: 207850 Seq: 1 Gender: F

Reported: 16/05/2005 Weight: 62.00 Hospitalisation: Age: 27Y

Onset Date: 15/04/1999 DOB:

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

### **Medicine Details:**

| Medicine Details.     |                     |               |                      |  |
|-----------------------|---------------------|---------------|----------------------|--|
| RISPERDAL (Suspected) |                     | Reason: Unspe | cified schizophrenia |  |
|                       | 5.0 Milligram       | Daily         | Oral                 |  |
| Batch:                | Started: 04/02/1999 | Sto           | opped:               |  |
| LORAZEPAM (Suspected) |                     | Reason:       |                      |  |
| Tablet                | 1.0 Milligram       | Daily         | Oral                 |  |
| Batch:                | Started: 19/01/1999 | Sto           | opped:               |  |

# **Laboratory Investigations:**

#### **Additional Information:**

Clinical trial RODOS WAVE I: RODOS. The patient experienced sedation and extrapyramydal symptoms on 13/1/1999, rigidity on 18/1/1999, slow movements on 16/2/1999, slurred speech on 18/2/1999, parkinsonism on 1/3/1999, constipation on 2/3/1999 and difficulty falling asleep on 3/5/1999.

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Case Number: 208732

Reported: 16/06/2005

Hospitalisation: Admitted to hospital

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

Gender: M

**Weight:** 0.00 **Age:** 70

| Outcome:                  |            |                           | <b>DOB:</b> 09/05/1935 |                                     |  |           |  |  |
|---------------------------|------------|---------------------------|------------------------|-------------------------------------|--|-----------|--|--|
| 4! D -4 - !               | Unknown    |                           |                        | Causality: Causality possible       |  |           |  |  |
| <u>action Detai</u>       | ils:       |                           |                        |                                     |  |           |  |  |
| Preferre                  | ed Term    | Sev                       | verity                 | Rep                                 | ort Description                            | Treatment |  |  |
| Splenomegaly              |            | Incapa<br>ability         | city/dis               | oresented with s<br>granulomas thro | splenomegaly, ill defined<br>ombocytopenia |           |  |  |
| ranuloma                  |            | Incapa<br>ability         | city/dis               |                                     |  |           |  |  |
| hrombocytopen             | ia         | Incapa<br>ability         | city/dis               |                                     |  |           |  |  |
|                           |            |                           |                        |                                     |  |           |  |  |
|                           |            |                           |                        |                                     |  |           |  |  |
| ledicine Deta             | ails:      |                           |                        |                                     |  |           |  |  |
| ZOLOFT (Other dr          |            |                           |                        | Rea                                 | son:                                       |           |  |  |
|                           |            | _                         |                        |                                     |  |           |  |  |
| Batch:                    |            | Started: Stopped:         |                        |                                     |  |           |  |  |
| SOMAC (Other dru          | ng)        |                           |                        | Rea                                 | son:                                       |           |  |  |
| Batch:                    |            | Sta                       | arted:                 | Stopped:                            |  |           |  |  |
| YLOPRIM (Other            | drug)      |                           |                        | Rea                                 | son:                                       |           |  |  |
|                           |            |                           |                        |                                     |  |           |  |  |
| Batch:<br>STELAZINE (Susp | ected)     | Started: Stopped: Reason: |                        |                                     |  |           |  |  |
| / (                       | ,          |                           |                        |                                     |  |           |  |  |
| Batch:                    |            | Sta                       | arted:                 | d: Stopped:                         |  |           |  |  |
| aboratory In              | vestigatio | nns:                      |                        |                                     |  |           |  |  |
| Date                      | Туре       |                           | Date Teste             | d Result                            | D  | Petails   |  |  |
|                           |            |                           |                        |                                     |  |           |  |  |



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 209226
 Seq: 1
 Gender: M

 Reported:
 29/06/2005
 Weight:
 0.00

Hospitalisation: Age: 17

**Onset Date:** 31/05/2005 **DOB:** 18/04/1988

Outcome: Unknown Causality: Causality possible

Reaction Details:

| Preferred Term                    | Severity                                      | Report Description   | Treatment        |
|-----------------------------------|---|--|------------------|
|                                   | Caused or prolonged inpatient hospitalisation | The patient also experienced possible neuroleptic malignant syndrome.  |                  |
| Transaminases increased           |   | The patient experienced elevated creatinine kinase after commencing Clozaril and mild elevation of liver function tests. | Clozaril ceased. |
| Blood creatine phosphokinase incr |   |  |                  |

#### **Medicine Details:**

| STELAZINE (Suspected)        |                     | Reason:                      |          |
|------------------------------|---------------------|------------------------------|----------|
|                              |                     | Oral                         |          |
| Batch:                       | Started:            | Stopped:                     |          |
| LITHIUM CARBONATE (Suspected | )                   | Reason:                      |          |
| Tablet                       |                     | Oral                         |          |
| Batch:                       | Started:            | Stopped:                     |          |
| BIPERIDEN HYDROCHLORIDE (Su  | spected)            | Reason:                      |          |
| Batch:                       | Started:            | Stopped:                     | 0        |
| CLOZAPINE (Suspected)        |                     | Reason: Unspecified schizopl | nrenia   |
| Tablet                       | 75.0 Milligram      | Daily Oral                   |          |
| Batch:                       | Started: 22/04/2005 | <b>Stopped:</b> 01/06        | 6/2005 0 |

# **Laboratory Investigations:**

| Date       | Туре     | Range | Date Tested | Result | Details           |
|------------|----------|-------|-------------|--------|-------------------|
| 29/06/2005 | Creatine |       | 31/05/2005  | 1400   | pretreatment -100 |
| 29/06/2005 | Creatine |       | 08/06/2005  | 500    | pretreatment -100 |
| 29/06/2005 | Creatine |       | 15/06/2005  | 10,700 | pretreatment -100 |
| 29/06/2005 | Creatine |       | 24/06/2005  | 90     | pretreatment -100 |

#### **Additional Information:**

Report 210231 is the first sequence to this report.



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 210231
 Seq: 1
 Gender:
 M

 Reported:
 28/07/2005
 Weight:
 0.00

Hospitalisation: Age: 17

**Onset Date**: 22/04/2005 **DOB**: 18/04/1988

Outcome: Unknown Causality: Causality possible

**Reaction Details:** 

| todotion Botano.                  |          |   |           |
|-----------------------------------|----------|---|-----------|
| Preferred Term                    | Severity | Report Description  | Treatment |
| Hypertension                      |          | The patient experienced hypertension and tachycardia whilst on Clozapine treatment. |           |
| Blood creatine phosphokinase incr |          |   |           |
| Tachycardia                       |          |   |           |

### **Medicine Details:**

STELAZINE (Suspected) Reason: Unspecified schizophrenia

10.0 Milligram

**Batch**: **Started**: **Stopped**: 01/06/2005 0

BIPERIDEN HYDROCHLORIDE (Suspected) Reason:

8.0 Milligram

Batch: Started: Stopped: 01/06/2005 0

LITHIUM CARBONATE (Suspected) Reason:

2500.0 Milligram

**Batch: Started: Stopped:** 01/06/2005 0

CLOZAPINE (Suspected) Reason: Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

**Batch**: **Started**: 22/04/2005 **Stopped**: 01/06/2005 0

**Laboratory Investigations:** 

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

Report 209226 is the second sequence to this report.

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number:210449Seq:1Gender:MReported:05/08/2005Weight:0.00Hospitalisation:Admitted to hospitalAge:-1

Onset Date: 03/03/2005 DOB: 28/06/2005

Outcome: Recovered 08/03/2005 Causality: Causality probable

**Reaction Details:** 

| todotion Botanoi                  |          |  |                         |
|-----------------------------------|----------|--|-------------------------|
| Preferred Term                    | Severity | Report Description   | Treatment               |
| Body temperature increased        |          | Patient experienced creatine kinase increased and also temp increased to 37.5. | Trifluoperazine ceased. |
| Blood creatine phosphokinase incr | Death    |  |                         |

### **Medicine Details:**

DICLOXACILLIN SODIUM (Other drug) Reason:

2.0 Gram

**Batch: Started:** 28/02/2005 **Stopped:** 04/03/2005

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:

2.0 Milligram Daily

**Batch: Started:** 01/03/2005 **Stopped:** 03/03/2005

**Laboratory Investigations:** 

| Date       | Туре     | Range | Date Tested | Result | Details  |
|------------|----------|-------|-------------|--------|--|
| 05/08/2005 | Creatine |       | 21/02/2005  | 189    | CK value for 03/03/05 - after a total 3 x 1mg doses Trifluoperazine. |
| 05/08/2005 | Creatine |       | 03/03/2005  |        | CK value for 03/03/05 - after a total 3 x 1mg doses Trifluoperazine. |
| 05/08/2005 | Creatine |       | 04/03/2005  | 724    | CK value for 03/03/05 - after a total 3 x 1mg doses Trifluoperazine. |

#### **Additional Information:**

History: Previous NMS 2002 with Quetiapine.

Report Run: 06/06/2007 08:47AM Database: pusime02 ADRS004 Page 187 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 210449 Seq: 1 Gender: M

Reported: 05/08/2005 Weight: 0.00
Hospitalisation: Admitted to hospital Age: -1

Onset Date: 03/03/2005 DOB: 28/06/2005

Outcome: Recovered 08/03/2005 Causality: Causality probable

**Reaction Details:** 

**Medicine Details:** 

DICLOXACILLIN SODIUM (Other drug) Reason:

2.0 Gram

Batch: Started: 28/02/2005 Stopped: 04/03/2005

TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:

2.0 Milligram Daily

**Batch: Started:** 01/03/2005 **Stopped:** 03/03/2005

**Laboratory Investigations:** 

| Date       | Туре     | Range | Date Tested | Result | Details   |
|------------|----------|-------|-------------|--------|---|
| 05/08/2005 | Creatine |       | 08/03/2005  | 127    | CK value for 03/03/05 - after a total 3 x 1mg doses<br>Trifluoperazine. |
| 05/08/2005 | Creatine |       | 15/03/2005  | 43     | CK value for 03/03/05 - after a total 3 x 1mg doses<br>Trifluoperazine. |

#### **Additional Information:**

History: Previous NMS 2002 with Quetiapine.

Report Run: 06/06/2007 08:47AM Database: pusime02 ADRS004 Page 188 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** Gender: M Case Number: 211157 Seq: 1 Reported: 29/08/2005 Weight: 0.00 Hospitalisation: Age: 61Y Onset Date: 01/03/2005 DOB: Outcome: Not yet recovered Causality: Causality possible Reaction Details: Preferred Term Severity Report Description Treatment Tardive dyskinesia The patient experienced rolling of the Caused or prolonged tongue, tremor of the hands and chest inpatient hospitalisation Chest pain Caused or prolonged inpatient hospitalisation Tremor Caused or prolonged inpatient hospitalisation **Medicine Details: TEMAZEPAM** (Other drug) Reason: **Tablet** 10.0 Milligram Oral Batch: Started: 15/09/2004 Stopped: ISOSORBIDE DINITRATE (Other drug) Reason: **Tablet** 60.0 Milligram Oral Started: 15/09/2004 Stopped: Batch: **DILTIAZEM HYDROCHLORIDE (Other drug)** Reason: Capsule 180.0 Milligram Oral

**Laboratory Investigations:** 

**METOPROLOL TARTRATE (Other drug)** 

Batch:

Tablet

Batch:

|   | Date | Type | Range | Date Tested | Result | Details |
|---|------|------|-------|-------------|--------|---------|
| ĺ |      |      |       |             |        |         |

Reason:

Stopped:

Stopped:

Oral

Started: 15/09/2004

Started: 15/09/2004

50.0 Milligram

### **Additional Information:**

Report Run: 06/06/2007 08:47AM Database: pusime02 ADRS004 Page 189 of 197



# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Onset Date: 01/03/2005 DOB: Outcome: Not yet recovered Causality: Causality possible action Details:    Causality: Causality possible   Causality: Causality: Causality possible   Causality: Causality: Causality possible   Causality: Caus | ation: Age: 61Y Dobs: Dobs: come: Not yet recovered Causality: Causality possible  Details:  PEDETAILS:  Reason: Licetion 50.0 Milligram Weekly Latch: Started: 15/09/2004 Stopped:  PERAZINE HYDROCHLORIDE (Suspected) Libelet 5.0 Milligram As necessary Oral Latch: Started: 15/09/2004 Stopped:  Reason: Libelet 15.0 Milligram Daily Oral   | Deported                            |                   |                |          | Gender.    |                    |
|--|--|-------------------------------------|-------------------|----------------|----------|------------|--------------------|
| Onset Date: 01/03/2005 DOB: Outcome: Not yet recovered Causality: Causality possible raction Details:    Causality: Causality possible raction Details:   Causality: Causality possible raction Details:   Causality: Causality possible raction Details:   Causality: Causality possible raction Details:   Causality: Causality possible raction Details:   Causality: Causality possible raction Details:   Causality: Causality possible raction Details:   Causality: Causality possible raction Details:   Causality: Causality | E Date: 01/03/2005 Causality: Causality possible  Causality: Causality: Causality possible  Causality: Cau | Reported.                           | 29/08/2005        |                |          | Weight:    | 0.00               |
| Outcome: Not yet recovered Causality: Causality possible action Details:    Causality: Causality possible  | Causality: Causality possible  Petails:  etails: Petails: Petails: Petails: Petails: Petails: Petails: Petails: Petails: Petails: Petails: Petails: Petails: Petails: Petails: Petails: Pe | ospitalisation:                     |                   |                |          | Age:       | 61Y                |
| Reason: Injection Details:  Started: 15/09/2004  Reason:   | PERAZINE HYDROCHLORIDE (Suspected)  PERAZINE HYDROCHLORIDE (Suspected)  Started: 15/09/2004  Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  Started: 15/09/2004  Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  Started: 15/09/2004  Reason:  Started: 15/09/2004  Stopped:  Reason:  Started: 15/09/2004  Stopped:  Reason:  Started: 15/09/2004  Stopped:  Reason:  Reason:  Reason:   | -                                   | 01/03/2005        |                |          | _          |                    |
| Redicine Details:    Tedicine Details:   FlupenthixOL Decanoate (Suspected)   Reason:   Injection   Started: 15/09/2004   Stopped:   TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)   Reason:   TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)   TRIFL | PERAZINE HYDROCHLORIDE (Suspected)  PERAZINE HYDROCHLORIDE (Suspected)  Started: 15/09/2004  Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  Started: 15/09/2004  Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  Started: 15/09/2004  Stopped:  Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  Started: 15/09/2004  Stopped:  Stopped:  Reason:  Stopped:  Reason:  Reason:  Reason:  Reason:  | Outcome:                            | Not yet recovered | d              |          | Causality: | Causality possible |
| edicine Details:  ELUPENTHIXOL DECANOATE (Suspected) Injection So.0 Milligram Weekly Batch: Started: 15/09/2004 Stopped:  RIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:   | PERAZINE HYDROCHLORIDE (Suspected)  Started: 5.0 Milligram As necessary Oral atch: Started: 15/09/2004 Stopped:  Started: 15/09/2004 Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  Started: 15/09/2004 Stopped:  Started: 15/09/2004 Stopped:  |                                     |                   |                |          | -          |                    |
| Injection 50.0 Milligram Weekly  Batch: Started: 15/09/2004 Stopped:  RIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:   | Reason:  |                                     |                   |                |          |            |                    |
| Reason:   Injection   50.0   Milligram   Weekly   Stopped:   Started: 15/09/2004   Stopped:   Sto   | Reason:  Section 50.0 Milligram Weekly  Started: 15/09/2004 Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  Albert 5.0 Milligram As necessary Oral  Stopped:  Stopped:  Reason:  Reason:  Stopped:  St |                                     |                   |                |          |            |                    |
| FLUPENTHIXOL DECANOATE (Suspected)  Injection  Started: 15/09/2004  Reason:  Stopped:  FRIFLUOPERAZINE HYDROCHLORIDE (Suspected)  Reason:  | Reason:  |                                     |                   |                |          |            |                    |
| FLUPENTHIXOL DECANOATE (Suspected)  Injection  50.0 Milligram  Weekly  Batch: Started: 15/09/2004  Stopped:  FRIFLUOPERAZINE HYDROCHLORIDE (Suspected)  Reason:  | Reason:  Section 50.0 Milligram Weekly  Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  Albert 5.0 Milligram As necessary Oral  Stopped:  Stopped:  Reason:  Stopped:  Reason:  Stopped:  St |                                     |                   |                |          |            |                    |
| FLUPENTHIXOL DECANOATE (Suspected)  Injection  50.0 Milligram  Weekly  Batch:  Started: 15/09/2004  TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)  Reason:   | Reason:  Stection 50.0 Milligram Weekly  Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  Stopped:  Stopped:  Reason:  As necessary Oral  Stopped:  S |                                     |                   |                |          |            |                    |
| FLUPENTHIXOL DECANOATE (Suspected) Injection 50.0 Milligram Weekly Batch: Started: 15/09/2004 Stopped: TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:   | Reason:  |                                     |                   |                |          |            |                    |
| FLUPENTHIXOL DECANOATE (Suspected) Injection 50.0 Milligram Weekly Batch: Started: 15/09/2004 Stopped: TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:   | Reason:  |                                     |                   |                |          |            |                    |
| FLUPENTHIXOL DECANOATE (Suspected) Injection 50.0 Milligram Weekly Batch: Started: 15/09/2004 Stopped: TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:   | Reason:  Section 50.0 Milligram Weekly  Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  As necessary Oral  Stopped:  Stopped:  Reason:  Stopped:  Reason:  Stopped:  Reason:  Stopped:  Stop |                                     |                   |                |          |            |                    |
| FLUPENTHIXOL DECANOATE (Suspected)  Injection  50.0 Milligram  Weekly  Batch: Started: 15/09/2004  TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)  Reason:  | Reason:  Section 50.0 Milligram Weekly  Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  As necessary Oral  Stopped:  Stopped:  Reason:  Stopped:  Reason:  Stopped:  Reason:  Stopped:  Stop |                                     |                   |                |          |            |                    |
| FLUPENTHIXOL DECANOATE (Suspected)  Injection  50.0 Milligram  Weekly  Batch: Started: 15/09/2004  TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)  Reason:  | Reason:  Section 50.0 Milligram Weekly  Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  Stopped:  Reason:  Started: 15/09/2004 Stopped:  Reason:  Stopped:  Reason:  Stopped:  Sto |                                     |                   |                |          |            |                    |
| Injection 50.0 Milligram Weekly  Batch: Started: 15/09/2004 Stopped:  TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:  | Reason:  Section 50.0 Milligram Weekly  Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  Stopped:  Reason:  Started: 15/09/2004 Stopped:  Reason:  Stopped:  Reason:  Stopped:  Sto |                                     |                   |                |          |            |                    |
| FLUPENTHIXOL DECANOATE (Suspected)  Injection  50.0 Milligram  Weekly  Batch: Started: 15/09/2004  TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)  Reason:  | Reason:  |                                     |                   |                |          |            |                    |
| FLUPENTHIXOL DECANOATE (Suspected)  Injection  50.0 Milligram  Weekly  Batch: Started: 15/09/2004  TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)  Reason:  | Reason:  Stection 50.0 Milligram Weekly  Stopped:  PERAZINE HYDROCHLORIDE (Suspected)  Stopped:  Stopped:  Reason:  As necessary Oral  Stopped:  S | ledicine Deta                       | ails:             |                |          |            |                    |
| Batch: Started: 15/09/2004 Stopped: TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:  | Atch: Started: 15/09/2004 Stopped:  PERAZINE HYDROCHLORIDE (Suspected) Reason:  Albert 5.0 Milligram As necessary Oral  Actch: Started: 15/09/2004 Stopped:  INE (Suspected) Reason:  Ablert 15.0 Milligram Daily Oral   |                                     |                   | ted)           | Reason:  |            |                    |
| Batch: Started: 15/09/2004 Stopped: TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:  | Atch: Started: 15/09/2004 Stopped:  PERAZINE HYDROCHLORIDE (Suspected) Reason:  Albert 5.0 Milligram As necessary Oral  Actch: Started: 15/09/2004 Stopped:  INE (Suspected) Reason:  Ablert 15.0 Milligram Daily Oral   |                                     |                   |                | Weekly   |            |                    |
| TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) Reason:  | PERAZINE HYDROCHLORIDE (Suspected)  As necessary Oral  Started: 15/09/2004  Reason:  INE (Suspected)  Reason:  Stopped:  Reason:  Daily Oral   |                                     |                   |                | •        | Stopped:   |                    |
|  | ablet 5.0 Milligram As necessary Oral atch: Started: 15/09/2004 Stopped:  TINE (Suspected) Reason: ablet 15.0 Milligram Daily Oral   |                                     | E HYDROCHLORIDE   |                | Reason:  |            |                    |
|  | Atch: Started: 15/09/2004 Stopped:  INE (Suspected) Reason:  Ablet 15.0 Milligram Daily Oral   |                                     |                   |                | As neces | ssary Oral |                    |
| Batch: Started: 15/09/2004 Stopped:  | Reason: ablet 15.0 Milligram Daily Oral  |                                     |                   |                |          | •          |                    |
|  | ablet 15.0 Milligram Daily Oral  | Batch:                              |                   |                |          |            |                    |
|  |  |                                     | spected)          |                | Reason:  |            |                    |
|  | ···PP···   | OLANZAPINE (Sus                     | spected)          | 15.0 Milligram |          | Oral       |                    |
|  |  | OLANZAPINE (Sus<br>Tablet           | spected)          |                |          |            |                    |
|  |  | DLANZAPINE (Sus<br>Tablet           | spected)          |                |          |            |                    |
| aboratory Investigations:  | ory Investigations:  | OLANZAPINE (Sus<br>Tablet<br>Batch: |                   |                |          |            |                    |
| aboratory Investigations:  | ory Investigations:  | OLANZAPINE (Sus<br>Tablet<br>Batch: |                   |                |          |            |                    |
| aboratory Investigations:  | ory Investigations:  | OLANZAPINE (Sus<br>Tablet<br>Batch: |                   |                |          |            |                    |
| aboratory Investigations:  | ory Investigations:  | OLANZAPINE (Sus<br>Tablet<br>Batch: |                   |                |          |            |                    |
| aboratory Investigations:  | ory Investigations:  | OLANZAPINE (Sus<br>Tablet<br>Batch: |                   |                |          |            |                    |
| aboratory Investigations:  | ory Investigations:  | OLANZAPINE (Sus<br>Tablet<br>Batch: |                   |                |          |            |                    |
| aboratory Investigations:  | ory Investigations:  | OLANZAPINE (Sus<br>Tablet<br>Batch: |                   |                |          |            |                    |
| _aboratory Investigations:   | ory Investigations:  | OLANZAPINE (Sus<br>Tablet<br>Batch: |                   |                |          |            |                    |
| aboratory Investigations:  | ory Investigations:  | OLANZAPINE (Sus<br>Tablet<br>Batch: |                   |                |          |            |                    |
|  |  | OLANZAPINE (Sus<br>Tablet<br>Batch: | vestigations:     |                |          |            |                    |
|  |  | OLANZAPINE (Sus<br>Tablet<br>Batch: | vestigations:     |                |          |            |                    |
|  |  | OLANZAPINE (Sus<br>Tablet<br>Batch: | vestigations:     |                |          |            |                    |
|  |  | OLANZAPINE (Sus<br>Tablet<br>Batch: | vestigations:     |                |          |            |                    |
| Laboratory Investigations:  Additional Information:  |  | OLANZAPINE (Sus<br>Tablet<br>Batch: | vestigations:     |                |          |            |                    |

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Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

Case Number: 217652 Seq: 1 Gender: F

Reported: 24/04/2006 Weight: 0.00 Hospitalisation: Age: 66

Onset Date: 16/02/2006 DOB: 13/12/1939

Outcome: Recovered 17/02/2006 Causality: Causality possible

**Reaction Details:** 

| 1 | eaction Details.      |          |   |           |   |
|---|-----------------------|----------|---|-----------|---|
|   | Preferred Term        | Severity | Report Description  | Treatment | 1 |
|   | Hallucination, visual |          | Patient experienced visual hallucinations. Symptoms included seeing moving objects and spinning surroundings. |           |   |

### **Medicine Details:**

Batch:

PARNATE (Interaction) Reason:

Tablet Oral

**Batch: Started:** 15/06/1965 **Stopped:** 01/03/2006

STELAZINE (Interaction) Reason:

Oral **Started**: 15/06/1965 **Stopped**:

XENICAL (Interaction) Reason: Obesity other than endoc origin

Capsule 120.0 Milligram 1 time Oral

**Batch: Started:** 16/02/2006 **Stopped:** 17/02/2006

DILTIAZEM HYDROCHLORIDE (Other drug) Reason:

Batch: Started: Stopped:

## **Laboratory Investigations:**

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
|      |      |       |             |        |         |

### **Additional Information:**

Report Run: 06/06/2007 08:47AM Database: pusime02 ADRS004 Page 191 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Report Details:   |          |            |          |      |
|---|----------|------------|----------|------|
| Case Number: 217652 Reported: 24/04/2006 Hospitalisation: Onset Date: 16/02/2006 Outcome: Recovered Reaction Details: | Seq: 1   | 17/02/2006 |          | 0.00 |
|   |          |            |          |      |
| Medicine Details: PRAVACHOL (Other drug)  |          | Reason:    |          |      |
| Batch:  | Started: |            | Stopped: |      |
| DIAFORMIN (Other drug)  | Starteu. | Reason:    | Stopped. |      |
| Batch:  | Started: |            | Stopped: |      |
| Laboratory Investigations:  |          |            |          |      |
| Additional Information:   |          |            |          |      |

Report Run: 06/06/2007 08:47AM Database: pusime02 ADRS004 Page 192 of 197



Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

**Report Details:** 

 Case Number:
 220473
 Seq: 1
 Gender: M

 Reported:
 31/07/2006
 Weight:
 74.00

Hospitalisation: Age: 17

**Onset Date**: 08/07/2006 **DOB**: 03/01/1989

Outcome: Recovered 17/07/2006 Causality: Causality possible

**Reaction Details:** 

| 100000000000000000000000000000000000000 |          |  |                |
|---|----------|--|----------------|
| Preferred Term                          | Severity | Report Description   | Treatment      |
| Encephalopathy                          |          | Toxic encephalopathy, hypotonia, myoclonic jerks, hypotension, delirium and extrapyramidal symptoms, seizures and severly constipated. | Ceased Clopine |
| Constipation                            |          |  |                |
| Convulsion                              |          |  |                |
| Delirium                                |          |  |                |
| Extrapyramidal disorder                 |          |  |                |
| Hypotension                             |          |  |                |
| Myoclonus                               |          |  |                |

### **Medicine Details:**

| SODIUM VALPROATE (Other drug) | Reason: |
|-------------------------------|---------|
|                               |         |

Tablet 150.0 Milligram Oral

Batch: Started: 05/10/2005 Stopped:

DOXYCYCLINE HYDROCHLORIDE (Other drug) Reason:

Tablet 100.0 Milligram Oral

**Batch: Started:** 29/06/2006 **Stopped:** 17/07/2006

FISH OIL NOS (Other drug) Reason:

Batch: Started: Stopped:

CLOPINE (Suspected) Reason: Unspecified psychosis

Tablet 800.0 Milligram Daily Oral

Batch: Started: Stopped:

# **Laboratory Investigations:**

| Date       | Туре             | Range | Date Tested | Result | Details  |
|------------|------------------|-------|-------------|--------|--|
| 31/07/2006 | Serum drug level |       |             |        | Clozapine levels (normal range 350-900): 07/07/06 - 947 and 07/07/06 - 620.<br>Lithium levels (normal range 0.6-1.2): 07/07/06 - 0.77. |

#### **Additional Information:**

History: Alcohol and cannabis abuse since 12 years of age.

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# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number:        | 220473                    | Seq: 1           |           |         | Gende                 | r: M                  |  |
|---------------------|---------------------------|------------------|-----------|---------|-----------------------|-----------------------|--|
| Reported:           | 31/07/2006                |                  |           |         | Weight                | : 74.00               |  |
| Hospitalisation:    |                           |                  |           |         | Age                   | e: 17                 |  |
| Onset Date:         | 08/07/2006                |                  |           |         | DO                    | <b>3</b> : 03/01/1989 |  |
| Outcome:            | Recovered                 |                  | 17/07/2   | 2006    | Causality             | : Causality possible  |  |
| Reaction Detai      | ils:                      |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
| Medicine Det        | aile:                     |                  |           |         |                       |                       |  |
|                     | alis.<br>IE HYDROCHLORIDE | (Suspected)      |           | Reason: | Unspecified psychosis |                       |  |
|                     |                           |                  | Milligram | Daily   | Oral                  |                       |  |
| Batch:              |                           | Started:         | 3 -       | - ,     | Stopped:              | 0                     |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
| l abayataw. Iw      | waatiaatiaaa              |                  |           |         |                       |                       |  |
| Laboratory in       | vestigations:             |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
| Additional Inf      |                           | -i 40            |           |         |                       |                       |  |
| History: Alcohol ai | nd cannabis abuse s       | since 12 years o | ot age.   |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |
|                     |                           |                  |           |         |                       |                       |  |

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Case Number: 225356

Reported: 04/02/2007

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

Gender: F

**Weight:** 80.00

| Hospitalisatio  | on:            |              |                         |   |                                |                                  | <b>Age:</b> 45 | 5Y            |        |
|-----------------|----------------|--------------|-------------------------|---|--------------------------------|----------------------------------|----------------|---------------|--------|
| Onset Da        |                |              | DOB:                    |   |                                |                                  |                |               |        |
|                 | ne: Unknown    |              |                         |   |                                | Cau                              | usality: C     | ausality poss | ible   |
| Reaction De     |                | <b>I</b> .   |                         |   |                                |                                  | <u> </u>       |               |        |
|                 | ferred Term    | Se           | verity                  | •   | ort Descripti                  |                                  |                | Treatmer      | nt     |
| Depression      |                |              | de<br>to                | so very dry mo<br>epression. The<br>xin than a ther<br>ulled the mind | drug became apeutic thing      | & some<br>e more of<br>. It also | ·a             |               |        |
| Weight increa   | ased           |              | C<br>br                 | aused weight greats became  | gain - about 2<br>much larger, | 20 kg or n                       | nore,          |               |        |
| Dyspnoea        |                |              | dı                      | ne main proble<br>ue to difficulty l<br>ose & sinus wa                | oreathing - bl                 | ocked up                         |                |               |        |
| Dry mouth       |                |              |                         |   |                                |                                  |                |               |        |
| Insomnia        |                |              |                         |   |                                |                                  |                |               |        |
| Rhinitis        |                |              |                         |   |                                |                                  |                |               |        |
|                 |                |              |                         |   |                                |                                  |                |               |        |
| Medicine I      |                |              |                         |   |                                |                                  |                |               |        |
| STELAZINE (S    |                |              | 0.0 14                  |   | son:                           |                                  | 1              |               |        |
| Tablet<br>Batch |                | -            | 2.0 Mi<br>arted: 01/01/ | _   | Daily                          |                                  | ral            |               |        |
| Datei           | l•             |              | artea. 01/01/           | 1505  |                                | opped: 0                         | 170 17 1330    |               |        |
| Laboratory      | / Investigati  | ons:         |                         |   |                                |                                  |                |               |        |
| Date            | Type           | Range        | Date Tested             | Result  |                                |                                  | Details        |               |        |
|                 |                | <u> </u>     |                         |   |                                |                                  |                |               |        |
| Additional      | Information    | 1:           |                         |   |                                |                                  |                |               |        |
| eport Run: 06/0 | 6/2007 08:47AM | Database: pu | sime02                  | Å   | ADRS004                        |                                  |                | Page 195      | of 197 |



# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE, STELAZINE, TERFLUZIN, TRIFLUOPERAZINE HYDROCHLORIDE

| Case Number: 225356                      | Seq: 1              | Gend                   | ler: F                  |
|--|---------------------|------------------------|-------------------------|
| Reported: 04/02/2007                     |                     | Weig                   | ht: 80.00               |
| Hospitalisation:                         |                     | A                      | <b>je:</b> 45Y          |
| Onset Date:                              |                     | DO                     | DB:                     |
| Outcome: Unknown                         |                     | Causal                 | ity: Causality possible |
| Reaction Details:                        |                     |                        |                         |
| Preferred Term                           | Severity            | Report Description     | Treatment               |
| Sinusitis                                |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
| Medicine Details:                        |                     |                        |                         |
| STELAZINE (Suspected)                    |                     | Reason:                |                         |
| Tablet                                   | 2.0 Milligram       | Daily Oral             |                         |
| Batch:                                   | Started: 01/01/1983 | <b>Stopped:</b> 01/01/ | 1998                    |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
| <b>Laboratory Investigations:</b>        |                     |                        |                         |
| _assumery in recingulations.             |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
| Additional Information:                  |                     |                        |                         |
| Additional information.                  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
|  |                     |                        |                         |
| onart Pun : 06/06/2007 - 08:47AM - Datal |                     | ADDS004                | Dama 400 of 407         |

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**Hospitalisation:** 

Case Number: 227847

Reported: 23/04/2007

Seq: 1

# THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Range: 11 Jul 1988 To 31 Dec 2059 Case Range: 000000 To 999999 Unclear causality excluded GM medicines Only Tradenames: CALMAZINE,STELAZINE,TERFLUZIN,TRIFLUOPERAZINE HYDROCHLORIDE

Gender: F

Weight: 0.00

**Age:** 32Y

| Onset Date: 03/12/2006                                |   | DOB:   |  |                                    |
|---|---|--|--|------------------------------------|
| Outcome: Recovered                                    |   | 03/12/2006 Causa                             |  | ity: Causality probable            |
| eaction Details:                                      |   |  |  |                                    |
| Preferred Term  | Severity                                      | Report De                                    |  | Treatment                          |
| Oculogyration   | Caused or prolonged inpatient hospitalisation | Patient experienced a dystonic reaction, una | n oculogyric crisis,<br>ble to open jaw. | 1mg cogentin I/M, 2mg cogentin IV. |
| Dystonia  | Caused or prolonged inpatient hospitalisation |  |  |                                    |
| Medicine Details: TEGRETOL (Other drug)               |   | Reason:                                      |  |                                    |
|   |   |  |  |                                    |
| Batch:  | Started:                                      |  | Stopped:                                 |                                    |
| STELAZINE (Suspected)                                 |   | Reason:                                      |  |                                    |
|   |   |  |  |                                    |
| Batch:  | Started: 28/1                                 | 1/2006                                       | Stopped:                                 |                                    |
| Laboratory Investigation<br>Date Type                 | <b>1S:</b> Range Date Teste                   | ed Result                                    | Ţ  | Details                            |
|   |   |  |  |                                    |
| Additional Information:<br>Patient history: Epilepsy. |   |  |  |                                    |
|   |   |  |  |                                    |