



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 55702

Seq: 1

Gender: F

Reported: 26/08/1988

Weight: 72.00

Hospitalisation:

Age: 33Y

Onset Date: 26/08/1988

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------|--|
| Affect lability Dyspnoea | | | Phenergan 12.5mg given, complete resolution within 3 minutes. reaction occurred 5mins after droperidol given and 50mins after omnopon. |
| Tongue discolouration Tongue oedema | | | |

Medicine Details:

| | | | |
|-------------------------------|------------------------------|-----------------|---------------|
| DROPERIDOL (Suspected) | Reason: | | |
| Injection | 5.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 26/08/1988 | Stopped: | |
| OMNOPON (Suspected) | Reason: Premedication | | |
| Injection | 20.0 Milligram | 1 time | Intramuscular |
| Batch: | Started: 26/08/1988 | Stopped: | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 56929

Seq: 1

Gender: F

Reported: 13/10/1988

Weight: 57.00

Hospitalisation:

Age: 52Y

Onset Date: 15/08/1988

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

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

Medicine Details:

| DROPERIDOL (Suspected) | | Reason: | |
|---------------------------------|---------------------|----------|-------------|
| Injection, intravenous infusion | 10.0 Milligram | Total | Intravenous |
| Batch: | Started: 14/08/1988 | Stopped: | 15/08/1988 |

| PETHIDINE HYDROCHLORIDE (Suspected) | | Reason: | |
|-------------------------------------|---------------------|----------|-------------|
| Injection, intravenous infusion | 500.0 Milligram | Total | Intravenous |
| Batch: | Started: 14/08/1988 | Stopped: | 15/08/1988 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 58196

Seq: 1

Gender: F

Reported: 25/01/1989

Weight: 57.00

Hospitalisation:

Age: 34Y

Onset Date: 23/01/1989

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------------------|
| Dystonia | | | Cogentin & valium ivi |

Medicine Details:

| | | | |
|-------------------------------|------------------------------------|-----------------|---------------|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting | | |
| Injection | 10.0 Milligram | 1 time | Intramuscular |
| Batch: | Started: 23/01/1989 | Stopped: | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 59253 **Seq:** 1 **Gender:** F
Reported: 17/03/1989 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: 14/03/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|------------------------|----------|--------------------|--------------|
| Dysarthria Dystonia | | | 2mg cogentin |

Medicine Details:

| | |
|-------------------------------|--|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection | 75.0 Milligram Daily Intravenous |
| Batch: | Started: 14/03/1989 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 59524 **Seq:** 1 **Gender:** F
Reported: 29/03/1989 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 13/02/1989 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|------------------------|----------|--------------------|---|
| Anaphylactoid reaction | | | Adrenaline 1:1000 1ml sc, hydrocortisone 100mg im, promethazine 25mg im |

Medicine Details:

| | |
|--|---|
| DIPRIVAN (Other drug) | Reason: Other disturbance of sensation |
| Injection 220.0 Milligram Total Intravenous | |
| Batch: | Started: 13/02/1989 Stopped: |
| FENTANYL CITRATE (Other drug) | Reason: Other disturbance of sensation |
| Injection 50.0 Microgram Total Intravenous | |
| Batch: | Started: 13/02/1989 Stopped: |
| SYNTOCINON (Other drug) | Reason: |
| Injection 10.0 International Unit Total Intravenous | |
| Batch: | Started: 13/02/1989 Stopped: |
| DROLEPTAN (Suspected) | Reason: Other disturbance of sensation |
| Injection 2.5 Milligram Total Intravenous | |
| Batch: | Started: 13/02/1989 Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|---|
| | Immunology | | | | Skin testing performed on 29/3/89 positive for droperidol (droleptan) |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 61376

Seq: 1

Gender: F

Reported: 13/07/1989

Weight: 50.00

Hospitalisation:

Age: 57Y

Onset Date: 05/07/1989

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------|-----------------|
| Dry mouth Dystonia Speech disorder | | | l.m.i. cogentin |

Medicine Details:

| | | | |
|-------------------------------|------------------------------------|----------------------------|---------------|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting | | |
| Injection | 5.0 Milligram | Daily | Intramuscular |
| Batch: | Started: 04/07/1989 | Stopped: 05/07/1989 | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 62150 | Seq: 1 | Gender: M |
| Reported: 28/08/1989 | | Weight: |
| Hospitalisation: | | Age: 53Y |
| Onset Date: 23/08/1989 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--------------------|
| Dystonia | | | Cogentin iv/valium |

Medicine Details:

| | | | |
|-------------------------------|----------------------------|------------------------------------|------|
| DROPERIDOL (Suspected) | | Reason: Nausea and vomiting | |
| Tablet | 30.0 Milligram | Daily | Oral |
| Batch: | Started: 22/08/1989 | Stopped: 23/08/1989 | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 62472 **Seq:** 1 **Gender:** M
Reported: 31/08/1989 **Weight:**
Hospitalisation: **Age:** 53Y
Onset Date: 23/08/1989 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 64103 | Seq: 1 | Gender: M |
| Reported: 25/10/1989 | | Weight: |
| Hospitalisation: | | Age: 58Y |
| Onset Date: 26/09/1989 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------|-----------|
| Abdominal pain | | | |
| Blood amylase increased | | | |
| Jaundice | | | |

Medicine Details:

| | | |
|-------------------------------------|----------------------------|---|
| DIPRIVAN (Suspected) | 0.0 | Reason: Other disturbance of sensation |
| Batch: | Started: 26/09/1989 | Stopped: |
| FENTANYL CITRATE (Suspected) | 0.0 | Reason: Other disturbance of sensation |
| Batch: | Started: 26/09/1989 | Stopped: |
| DROPERIDOL (Suspected) | 0.0 | Reason: Other disturbance of sensation |
| Batch: | Started: 26/09/1989 | Stopped: |
| ISOFLURANE (Suspected) | 0.0 | Reason: Other disturbance of sensation |
| Batch: | Started: 26/09/1989 | Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------------|-------|-------------|--------|--|
| | Biochemistry | | | | 30/8/89 26/9/89 27/9/89 28/9/89 16/10/89 ref range bili: 23 90 32 28 15 (0-20 umol/l) alk phos: 75 68 56 60 48 (35-115 u/l) ld: 176 718 572 467 252 (120-250 u/l) ast: 21 61 41 31 29 (0-40 u/l) |
| | Misclassified at | | | | Amylase: - 283 - 77 101 (20-100 u/l) |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 64316

Seq: 1

Gender: F

Reported: 08/02/1990

Weight: 51.00

Hospitalisation:

Age: 21Y

Onset Date: 07/02/1990

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---------------------------|
| Oculogyration | | | Benztropine 2 mg iv stat. |

Medicine Details:

| | | | |
|-------------------------------|---|----------------------------|---------------|
| DROPERIDOL (Suspected) | Reason: Otr intestne&peritoneum dsease | | |
| Injection | 15.0 Milligram | Total | Intramuscular |
| Batch: | Started: 06/02/1990 | Stopped: 07/02/1990 | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 64696

Seq: 1

Gender: F

Reported: 02/03/1990

Weight: 56.00

Hospitalisation:

Age: 34Y

Onset Date: 02/03/1990

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

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

Medicine Details:

| | | | |
|-------------------------------|------------------------------------|----------------------------|---------------|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting | | |
| Injection | 10.0 Milligram | As necessary | Intramuscular |
| Batch: | Started: 01/03/1990 | Stopped: 02/03/1990 | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 65043 | Seq: 1 | Gender: F |
| Reported: 04/04/1990 | | Weight: |
| Hospitalisation: | | Age: 46Y |
| Onset Date: 03/04/1990 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--|
| Pruritus | | | Ceased omnopon infusion. pethidine 100 mg im was used. |
| Rash | | | |

Medicine Details:

| | |
|---------------------------------------|---|
| OMNOPON (Suspected) | Reason: Other disturbance of sensation |
| Injection, intravenous infusion | 100.0 Millilitre Total Intravenous |
| Batch: | Started: 03/04/1990 Stopped: 04/04/1990 |
| THIOPENTONE SODIUM (Suspected) | Reason: |
| | 300.0 Milligram Daily |
| Batch: | Started: Stopped: |
| VECURONIUM BROMIDE (Suspected) | Reason: |
| | 6.0 Milligram Daily |
| Batch: | Started: Stopped: |
| MORPHINE NOS (Suspected) | Reason: |
| | 5.0 Milligram Daily |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 65043

Seq: 1

Gender: F

Reported: 04/04/1990

Weight:

Hospitalisation:

Age: 46Y

Onset Date: 03/04/1990

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

DROPERIDOL (Suspected)

Reason:

4.0 Milligram

Daily

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 65534

Seq: 1

Gender: M

Reported: 17/05/1990

Weight: 60.00

Hospitalisation:

Age: 18Y

Onset Date: 16/05/1990

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--------------------|
| Dystonia | | | lv benztropine 2mg |

Medicine Details:

| | | |
|--|---|----------------------------|
| PANADEINE (Other drug) | Reason: Pain | |
| 2.0 Dose Unspecified As necessary | | |
| Batch: | Started: 14/05/1990 | Stopped: |
| FLOXAPEN (Other drug) | Reason: Otr&nos infec¶sit diseases | |
| Injection 4.0 Gram Daily Intravenous | | |
| Batch: | Started: 14/05/1990 | Stopped: |
| PENICILLIN NOS (Other drug) | Reason: Otr&nos infec¶sit diseases | |
| Injection 4.0 Dose Unspecified Daily Intravenous | | |
| Batch: | Started: 14/05/1990 | Stopped: |
| DROLEPTAN (Suspected) | Reason: Nausea and vomiting | |
| Injection 10.0 Milligram Daily Intravenous | | |
| Batch: | Started: 15/05/1990 | Stopped: 16/05/1990 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 65534

Seq: 1

Gender: M

Reported: 17/05/1990

Weight: 60.00

Hospitalisation:

Age: 18Y

Onset Date: 16/05/1990

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|-----------------------------|------------------------------------|-----------------|---------------|
| STEMETIL (Suspected) | Reason: Nausea and vomiting | | |
| Injection | 50.0 Milligram | Daily | Intramuscular |
| Batch: | Started: 15/05/1990 | Stopped: | |
| MAXOLON (Suspected) | Reason: Nausea and vomiting | | |
| Injection | 40.0 Milligram | Daily | Intramuscular |
| Batch: | Started: 15/05/1990 | Stopped: | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 65964 | Seq: 1 | Gender: F |
| Reported: 07/06/1990 | | Weight: 59.00 |
| Hospitalisation: | | Age: 35Y |
| Onset Date: | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Hot flush | | | |
| Palpitations | | | |
| Tremor | | | |

Medicine Details:

| | |
|---|---|
| TEMAZEPAM (Suspected) | Reason: Anxiety neurosis |
| 1.0 Dose Unspecified As necessary | |
| Batch: | Started: 04/06/1990 Stopped: |
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: Other disturbance of sensation |
| Injection 10.0 Milligram As necessary Intramuscular | |
| Batch: | Started: 04/06/1990 Stopped: |
| PANADEINE (Suspected) | Reason: Other disturbance of sensation |
| 2.0 Dose Unspecified As necessary | |
| Batch: | Started: 04/06/1990 Stopped: |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection 1.0 Milligram As necessary Intravenous | |
| Batch: | Started: 05/06/1990 Stopped: 05/06/1990 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 65964

Seq: 1

Gender: F

Reported: 07/06/1990

Weight: 59.00

Hospitalisation:

Age: 35Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

HEPARIN SODIUM (Suspected)

Reason: Other coagulation defects

Injection

10.0 Thousand Internal Daily

Subcutaneous

Batch:

Started: 04/06/1990

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 66411 | Seq: 1 | Gender: F |
| Reported: 27/06/1990 | | Weight: 57.00 |
| Hospitalisation: | | Age: 24Y |
| Onset Date: 26/06/1990 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--------------------|
| Myalgia | | | |
| Oculogyration | | | Benztropine img iv |

Medicine Details:

| | | | |
|-------------------------------|----------------------------|------------------------------------|-------------|
| DROPERIDOL (Suspected) | | Reason: Nausea and vomiting | |
| Injection | 4.0 Milligram | Total | Intravenous |
| Batch: | Started: 25/06/1990 | Stopped: | 26/06/1990 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 67715 | Seq: 1 | Gender: F |
| Reported: 02/10/1990 | | Weight: 60.00 |
| Hospitalisation: | | Age: 45Y |
| Onset Date: 25/06/1990 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------|-------------------------|
| Injection site reaction | | | Dmsso, vitamin e cream. |

Medicine Details:

| | | |
|---|----------------------------|--|
| EPIRUBICIN HYDROCHLORIDE (Suspected) | | Reason: Malignant neoplasm of ovary |
| Injection | 100.0 Milligram | 1 time Intravenous |
| Batch: | Started: 25/06/1990 | Stopped: |
| CYCLOPHOSPHAMIDE (Suspected) | | Reason: Malignant neoplasm of ovary |
| Injection | 1.2 Gram | 1 time Intravenous |
| Batch: | Started: 25/06/1990 | Stopped: |
| DEXAMETHASONE (Suspected) | | Reason: Malignant neoplasm of ovary |
| Injection | 10.0 Milligram | 1 time Intravenous |
| Batch: | Started: 25/06/1990 | Stopped: |
| PROCHLORPERAZINE MALEATE (Suspected) | | Reason: Malignant neoplasm of ovary |
| Injection | 12.0 Milligram | 1 time Intravenous |
| Batch: | Started: 25/06/1990 | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 67715

Seq: 1

Gender: F

Reported: 02/10/1990

Weight: 60.00

Hospitalisation:

Age: 45Y

Onset Date: 25/06/1990

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

DROPERIDOL (Suspected)

Reason: Malignant neoplasm of ovary

Injection

10.0 Milligram

1 time

Intravenous

Batch:

Started: 25/06/1990

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 69071 **Seq:** 1 **Gender:** M
Reported: 09/01/1991 **Weight:**
Hospitalisation: **Age:** 6M
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------------|
| Oculogyration | | | Cogentin 0.02mg/kg 1gm |

Medicine Details:

| | | | |
|---------------------------------|------------------------------|-----------------|---------------|
| DROLEPTAN (Suspected) | Reason: Premedication | | |
| Injection | 1.0 Milligram | Daily | Intramuscular |
| Batch: | Started: | Stopped: | |
| MORPHINE NOS (Suspected) | Reason: Premedication | | |
| Injection | 1.0 Milligram | Daily | Intramuscular |
| Batch: | Started: | Stopped: | |
| ATROPINE (Suspected) | Reason: Premedication | | |
| Injection | 0.5 Milligram | Daily | Intramuscular |
| Batch: | Started: | Stopped: | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 69072 | Seq: 1 | Gender: M |
| Reported: 09/01/1991 | | Weight: 8.00 |
| Hospitalisation: | | Age: 7M |
| Onset Date: | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-------------------------|
| Oculogyration | | | Cogentin 0.02mg/kg, 1gm |

Medicine Details:

| | |
|---------------------------------|-----------------------------------|
| DROLEPTAN (Suspected) | Reason: Premedication |
| Injection | 1.0 Milligram Daily Intramuscular |
| Batch: | Started: Stopped: |
| MORPHINE NOS (Suspected) | Reason: Premedication |
| Injection | 1.0 Milligram Daily Intramuscular |
| Batch: | Started: Stopped: |
| ATROPINE (Suspected) | Reason: Premedication |
| Injection | 0.1 Milligram Daily Intramuscular |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 69738

Seq: 1

Gender: F

Reported: 27/02/1991

Weight: 40.00

Hospitalisation:

Age: 28Y

Onset Date: 21/02/1991

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------|------------------|
| Hallucination Thinking abnormal Visual disturbance | | | Imi cogentin 2mg |

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| Injection | 2.0 Milligram Total Intravenous |
| Batch: | Started: 21/02/1991 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 69739 | Seq: 1 | Gender: M |
| Reported: 26/02/1991 | | Weight: |
| Hospitalisation: | | Age: 19Y |
| Onset Date: 26/02/1991 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-------------------|
| Opisthotonus | | | Imi cogentin 2mg. |

Medicine Details:

| | | | |
|-------------------------------|----------------------------|---|-------------|
| DROPERIDOL (Suspected) | | Reason: Other disturbance of sensation | |
| Injection | 2.5 Milligram | Total | Intravenous |
| Batch: | Started: 26/02/1991 | Stopped: | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 69935 | Seq: 1 | Gender: F |
| Reported: 08/02/1991 | | Weight: |
| Hospitalisation: | | Age: 26Y |
| Onset Date: 31/12/1990 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|--------------------|-----------|
| Grand mal convulsion | | | |
| Muscle twitching | | | |
| Nausea | | | |

Medicine Details:

| | | |
|-------------------------------|---|-----------------|
| LORAZEPAM (Suspected) | Reason: | |
| Tablet | 0.0 | Oral |
| Batch: | Started: | Stopped: |
| DIAZEPAM (Suspected) | Reason: | |
| Tablet | 0.0 | Oral |
| Batch: | Started: | Stopped: |
| OMNOPON (Suspected) | Reason: Other disturbance of sensation | |
| | 0.0 | |
| Batch: | Started: | Stopped: |
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation | |
| | 0.0 | |
| Batch: | Started: | 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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 69935

Seq: 1

Gender: F

Reported: 08/02/1991

Weight:

Hospitalisation:

Age: 26Y

Onset Date: 31/12/1990

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|------------------------------|---|
| MIDAZOLAM (Suspected) | Reason: Other disturbance of sensation |
| 0.0 | |
| Batch: | Started: Stopped: |
| PROPOFOL (Suspected) | Reason: Other disturbance of sensation |
| 120.0 Milligram | Daily |
| Batch: | Started: Stopped: |

Laboratory Investigations:

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 70325 | Seq: 1 | Gender: F |
| Reported: 10/12/1990 | | Weight: |
| Hospitalisation: | | Age: 17 |
| Onset Date: 08/07/1988 | | DOB: 19/09/1970 |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---|
| Rash | | | Promethazine commenced, cephalothin ceased. |

Medicine Details:

| | | |
|--|----------------------------|------------------------|
| ENFLURANE (Suspected) | | Reason: Surgery |
| Inhalation | 0.0 | Inhalation |
| Batch: | Started: 08/07/1988 | Stopped: |
| THIOPENTONE SODIUM (Suspected) | | Reason: Surgery |
| Injection | 0.0 | Intravenous |
| Batch: | Started: 08/07/1988 | Stopped: |
| SUXAMETHONIUM BROMIDE (Suspected) | | Reason: Surgery |
| Injection | 100.0 Milligram | Total Intravenous |
| Batch: | Started: 08/07/1988 | Stopped: |
| PANCURONIUM BROMIDE (Suspected) | | Reason: Surgery |
| Injection | 6.0 Milligram | Total Intravenous |
| Batch: | Started: 08/07/1988 | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 70325

Seq: 1

Gender: F

Reported: 10/12/1990

Weight:

Hospitalisation:

Age: 17

Onset Date: 08/07/1988

DOB: 19/09/1970

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|---------------------------------------|----------------------------|----------------------------|-------------|
| MORPHINE NOS (Suspected) | Reason: Surgery | | |
| Injection | 15.0 Milligram | Total | Intravenous |
| Batch: | Started: 08/07/1988 | Stopped: | |
| DROPERIDOL (Suspected) | Reason: Surgery | | |
| Injection | 10.0 Milligram | Total | Intravenous |
| Batch: | Started: 08/07/1988 | Stopped: | |
| CEPHALOTHIN SODIUM (Suspected) | Reason: | | |
| Injection, intravenous infusion | 4.0 Gram | Daily | Intravenous |
| Batch: | Started: 08/07/1988 | Stopped: 08/07/1988 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 71230 | Seq: 1 | Gender: F |
| Reported: 15/05/1991 | | Weight: |
| Hospitalisation: | | Age: 36Y |
| Onset Date: 07/11/1990 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|---------------------|----------|--------------------|-----------|
| Apnoea Paralysis | | | |

Medicine Details:

| | | |
|---------------------------------------|-----------------|---|
| PROPOFOL (Suspected) | 0.0 | Reason: Other disturbance of sensation |
| Batch: | Started: | Stopped: |
| SUXAMETHONIUM NOS (Suspected) | 0.0 | Reason: Other disturbance of sensation |
| Batch: | Started: | Stopped: |
| VECURONIUM BROMIDE (Suspected) | 0.0 | Reason: Other disturbance of sensation |
| Batch: | Started: | Stopped: |
| NITROUS OXIDE (Suspected) | 0.0 | Reason: Other disturbance of sensation |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 71230 **Seq:** 1 **Gender:** F
Reported: 15/05/1991 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: 07/11/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

| | |
|-------------------------------------|---|
| FENTANYL CITRATE (Suspected) | Reason: Other disturbance of sensation |
| 0.0 | |
| Batch: | Started: Stopped: |
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| 0.0 | |
| Batch: | Started: Stopped: |
| ENFLURANE (Suspected) | Reason: Other disturbance of sensation |
| 0.0 | |
| Batch: | Started: Stopped: |
| TEMAZEPAM (Suspected) | Reason: Premedication |
| 20.0 Milligram | 1 time |
| Batch: | Started: 07/11/1990 Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 72219 **Seq:** 1 **Gender:** M
Reported: 09/08/1991 **Weight:** 63.00
Hospitalisation: **Age:** 19Y
Onset Date: 29/07/1991 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Agitation | | | |
| Fatigue | | | |
| Insomnia | | | |

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| Injection | 2.5 Milligram 1 time Intravenous |
| Batch: | Started: 29/07/1991 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 72472 | Seq: 1 | Gender: M |
| Reported: 07/08/1991 | | Weight: 65.00 |
| Hospitalisation: | | Age: |
| Onset Date: 16/06/1991 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|--|----------------------------|
| Dystonia Tremor | Severe | Dystonic reaction affecting mouth/tongue Whole body tremors | Settled with 6 mg cogentin |

Medicine Details:

| | |
|-----------------------------|--|
| NILSTAT (Other drug) | Reason: |
| Mouthwash | 40.0 Millilitre |
| Batch: | Started: |
| | Stopped: |
| ZANTAC (Other drug) | Reason: Other diseases of esophagus |
| Tablet | 300.0 Milligram |
| Batch: | Started: 12/06/1991 |
| | Stopped: |
| LASIX (Other drug) | Reason: |
| Injection | 20.0 Milligram |
| Batch: | Started: 11/06/1991 |
| | Stopped: 17/06/1991 |
| ZOFRAN (Other drug) | Reason: Nausea and vomiting |
| Oral application | 24.0 Milligram |
| Batch: | Started: 12/06/1991 |
| | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 72472

Seq: 1

Gender: M

Reported: 07/08/1991

Weight: 65.00

Hospitalisation:

Age:

Onset Date: 16/06/1991

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|------------------------------|---|
| DROLEPTAN (Suspected) | Reason: Nausea and vomiting |
| | 1.0 Milligram Per hour |
| Batch: | Started: 15/06/1991 Stopped: 16/06/1991 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 74464 | Seq: 1 | Gender: M |
| Reported: 27/11/1991 | | Weight: 88.00 |
| Hospitalisation: | | Age: 31Y |
| Onset Date: 22/11/1991 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------|-----------|
| Dystonia Torticollis | | | Cogentin |

Medicine Details:

| | | |
|-------------------------------|----------------------------|------------------------------------|
| DROPERIDOL (Suspected) | | Reason: Nausea and vomiting |
| Injection | 15.0 Milligram | 3 times Intramuscular |
| Batch: | Started: 21/11/1991 | Stopped: 22/11/1991 |
| OMNOPON (Suspected) | | Reason: |
| Injection | 20.0 Milligram | 1 time Intramuscular |
| Batch: | Started: 21/11/1991 | Stopped: 22/11/1991 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 74501 | Seq: 1 | Gender: F |
| Reported: 02/12/1991 | | Weight: 80.00 |
| Hospitalisation: | | Age: 46Y |
| Onset Date: 29/11/1991 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Cardiac arrest | | Cardiac asystole. | |

Medicine Details:

| | | | |
|-------------------------------|----------------------------|------------------------------|---------------|
| DROPERIDOL (Suspected) | | Reason: Premedication | |
| Injection | 10.0 Milligram | 1 time | Intramuscular |
| Batch: | Started: 29/11/1991 | Stopped: | |

Laboratory Investigations:

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

Additional Information:

Patient history: diazepam - dystonic reaction clindamycin - pseudomembranous colitis brufen - vomiting.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 75462 | Seq: 1 | Gender: M |
| Reported: 06/02/1992 | | Weight: |
| Hospitalisation: | | Age: 21Y |
| Onset Date: | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|------------------------|----------|--------------------|-----------|
| Abdominal pain | | | |
| Renal tubular necrosis | | | |

Medicine Details:

| | | |
|------------------------------|----------|--|
| NITROUS OXIDE (Suspected) | 0.0 | Reason: Other disturbance of sensation |
| Batch: | Started: | Stopped: |
| ISOFLURANE (Suspected) | 0.0 | Reason: Other disturbance of sensation |
| Batch: | Started: | Stopped: |
| DROPERIDOL (Suspected) | 0.0 | Reason: Other disturbance of sensation |
| Batch: | Started: | Stopped: |
| FENTANYL CITRATE (Suspected) | 0.0 | Reason: Other disturbance of sensation |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|----------------|-------|-------------|--------|-------------------------|
| | Creatinine | | 03/12/1991 | 0.22 | Acute tubular necrosis. |
| | Creatinine | | 05/12/1991 | 0.29 | |
| | Creatinine | | 07/12/1991 | 0.24 | |
| | Renal biopsy = | | | | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 75462

Seq: 1

Gender: M

Reported: 06/02/1992

Weight:

Hospitalisation:

Age: 21Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

PROPOFOL (Suspected)

Reason: Other disturbance of sensation

0.0

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 75751 | Seq: 1 | Gender: F |
| Reported: 27/02/1992 | | Weight: |
| Hospitalisation: | | Age: 33Y |
| Onset Date: 26/02/1992 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Details:

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

Medicine Details:

| | | | |
|---|----------------------------|------------------------------------|--------------|
| MORPHINE NOS (Other drug) | | Reason: | |
| Injection | 5.0 Milligram | As necessary | Subcutaneous |
| Batch: | Started: | Stopped: | |
| MIANSERIN HYDROCHLORIDE (Other drug) | | Reason: | |
| | 20.0 Milligram | Daily | |
| Batch: | Started: | Stopped: | |
| DROPERIDOL (Suspected) | | Reason: Nausea and vomiting | |
| Injection | 2.5 Milligram | As necessary | Intravenous |
| Batch: | Started: 25/02/1992 | Stopped: 26/02/1992 | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 76088 | Seq: 1 | Gender: M |
| Reported: 20/03/1992 | | Weight: 80.00 |
| Hospitalisation: | | Age: 42Y |
| Onset Date: 20/03/1992 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|-----------------------|-----------|
| Convulsion | | Tonic clonic reaction | |

Medicine Details:

| | |
|-------------------------------------|------------------------------|
| PROPOFOL (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: |
| Batch: | Stopped: |
| TEMAZEPAM (Suspected) | Reason: Premedication |
| 20.0 Milligram | Daily |
| Batch: | Started: 20/03/1992 |
| Batch: | Stopped: |
| MAXOLON (Suspected) | Reason: Premedication |
| 10.0 Milligram | Daily |
| Batch: | Started: 20/03/1992 |
| Batch: | Stopped: |
| FENTANYL CITRATE (Suspected) | Reason: Premedication |
| 50.0 Microgram | Daily |
| Batch: | Started: 20/03/1992 |
| Batch: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 76088

Seq: 1

Gender: M

Reported: 20/03/1992

Weight: 80.00

Hospitalisation:

Age: 42Y

Onset Date: 20/03/1992

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

DROPERIDOL (Suspected)

Reason: Premedication

1.2 Milligram

Daily

Batch:

Started: 20/03/1992

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 77057 **Seq:** 1 **Gender:** F
Reported: 18/05/1992 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: 04/05/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|----------------------------|-----------|
| Convulsion | | Post operative convulsions | |

Medicine Details:

| |
|---|
| DROPERIDOL (Suspected) Injection 2.5 Milligram Reason: Other disturbance of sensation Batch: Started: Stopped: Intravenous |
| NITROUS OXIDE (Suspected) 0.0 Reason: Other disturbance of sensation Batch: Started: Stopped: |
| PROPOFOL (Suspected) Injection 150.0 Milligram Reason: Other disturbance of sensation Batch: Started: Stopped: Daily Intravenous |
| MIDAZOLAM (Suspected) Injection 5.0 Milligram Reason: Other disturbance of sensation Batch: Started: Stopped: Daily Intravenous |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 77459 **Seq:** 1 **Gender:** F
Reported: 07/05/1992 **Weight:**
Hospitalisation: **Age:** 28Y
Onset Date: 07/03/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---|
| Dystonia | | | Cogentin 2mg imi to reverse droperidol. |

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: |
| Injection | 5.0 Milligram 5 times Intramuscular |
| Batch: | Started: 04/03/1992 Stopped: 07/03/1992 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 77471 | Seq: 1 | Gender: M |
| Reported: 05/06/1992 | | Weight: |
| Hospitalisation: | | Age: 32Y |
| Onset Date: 05/06/1992 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|------------------------------------|-----------|
| Rash | | Red blotchy rash on trunk and arms | |

Medicine Details:

| | | |
|---------------------------------|----------------------------|------------------------------------|
| MORPHINE NOS (Suspected) | | Reason: Pain |
| Injection, intravenous infusion | 50.0 Milligram | Daily Intravenous |
| Batch: | Started: 05/06/1992 | Stopped: 05/06/1992 |
| DROPERIDOL (Suspected) | | Reason: Nausea and vomiting |
| Injection, intravenous infusion | 5.0 Milligram | Daily Intravenous |
| Batch: | Started: 05/06/1992 | Stopped: 05/06/1992 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 78254 | Seq: 1 | Gender: F |
| Reported: 03/10/1991 | | Weight: 75.00 |
| Hospitalisation: | | Age: 45Y |
| Onset Date: 30/08/1991 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Details:

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

Medicine Details:

| | | | |
|--------------------------------------|----------------------------|---|---------------|
| SODIUM VALPROATE (Other drug) | | Reason: Other&unspecified epilepsy | |
| Oral application | 600.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | CONTIN |
| THYROXINE SODIUM (Other drug) | | Reason: Myxedema | |
| Tablet | 150.0 Microgram | Daily | Oral |
| Batch: | Started: | Stopped: | CONTIN |
| OXAZEPAM (Other drug) | | Reason: | |
| Tablet | 90.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | CONTIN |
| DROPERIDOL (Suspected) | | Reason: Nausea and vomiting | |
| Injection | 10.0 Milligram | 1 time | Intramuscular |
| Batch: | Started: 29/08/1991 | Stopped: | |

Laboratory Investigations:

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

Additional Information:

Oculogyric crisis previously experienced with maxolon and stemetil (phenothiazines) 29/10/82.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 78661 | Seq: 1 | Gender: F |
| Reported: 10/08/1992 | | Weight: 55.00 |
| Hospitalisation: | | Age: 22Y |
| Onset Date: 06/08/1992 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Dystonia | | | Cogentin |

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection | 2.5 Milligram Daily Intramuscular |
| Batch: | Started: 05/08/1992 Stopped: 06/08/1992 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|--|---------------|--------------------------------------|
| Case Number: 79494 | Seq: 1 | Gender: M |
| Reported: 16/09/1992 | | Weight: |
| Hospitalisation: Admitted to hospital | | Age: 15Y |
| Onset Date: 11/09/1992 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|------------------------------------|-------------------|
| Tremor | | Tremor in lower, then upper limbs. | |
| Dystonia | | | |
| Extrapyramidal disorder | | | Congentin 1mg im. |

Medicine Details:

| | | | |
|-------------------------------|----------------------------|------------------------|-------------|
| MAXOLON (Suspected) | | Reason: Surgery | |
| Injection | 10.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 11/09/1992 | Stopped: | |
| DROPERIDOL (Suspected) | | Reason: | |
| Injection | 2.5 Milligram | 1 time | Intravenous |
| Batch: | Started: 11/09/1992 | Stopped: | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 80557 **Seq:** 1 **Gender:** F
Reported: 16/10/1992 **Weight:** 57.00
Hospitalisation: **Age:** 32Y
Onset Date: 14/10/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--------------------|
| Oculogyration | | | Benztropine 2mg iv |

Medicine Details:

| | |
|--|---|
| RANITIDINE (Other drug) | Reason: |
| Oral application 300.0 Milligram Daily Oral | |
| Batch: | Started: L TERM Stopped: CONTIN |
| OMNOPON (Suspected) | Reason: Other disturbance of sensation |
| Injection 20.0 Milligram 1 time Intravenous | |
| Batch: | Started: 14/10/1992 Stopped: 14/10/1992 |
| STEMETIL (Suspected) | Reason: |
| Injection 12.5 Milligram 1 time Intravenous | |
| Batch: | Started: 14/10/1992 Stopped: 14/10/1992 |
| DROLEPTAN (Suspected) | Reason: |
| Injection 2.5 Milligram 1 time Intravenous | |
| Batch: | Started: 14/10/1992 Stopped: 14/10/1992 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 80557

Seq: 1

Gender: F

Reported: 16/10/1992

Weight: 57.00

Hospitalisation:

Age: 32Y

Onset Date: 14/10/1992

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|--|----------------------------|-----------------|---------------|
| PETHIDINE HYDROCHLORIDE (Suspected) | | Reason: | |
| Injection | 50.0 Milligram | 1 time | Intramuscular |
| Batch: | Started: 13/10/1992 | Stopped: | 13/10/1992 |
| MAXOLON (Suspected) | | Reason: | |
| Injection | 10.0 Milligram | 1 time | Intramuscular |
| Batch: | Started: 13/10/1992 | Stopped: | 13/10/1992 |
| HEPARIN SODIUM (Suspected) | | Reason: | |
| Injection, intravenous infusion | 1.0 Thousand Internal | Per hour | Intravenous |
| Batch: | Started: 14/10/1992 | Stopped: | CONTIN |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 80923 | Seq: 1 | Gender: F |
| Reported: 12/11/1992 | | Weight: 70.00 |
| Hospitalisation: | | Age: 33 |
| Onset Date: 11/11/1992 | | DOB: 27/01/1959 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------|
| Tremor | | | Cogentin iv 2mg. |

Medicine Details:

| | |
|---|---|
| MAXOLON (Suspected) | Reason: Hyperemes gravidar w/o neurits |
| Injection | 20.0 Milligram 2 times Intravenous |
| Batch: | Started: 11/11/1992 Stopped: 11/11/1992 |
| STEMETIL (Suspected) | Reason: Hyperemes gravidar w/o neurits |
| Suppository | 25.0 Milligram As necessary Rectal |
| Batch: | Started: 03/11/1992 Stopped: 10/11/1992 |
| PYRIDOXINE HYDROCHLORIDE (Suspected) | Reason: Hyperemes gravidar w/o neurits |
| Injection | 50.0 Milligram Daily Intramuscular |
| Batch: | Started: 11/11/1992 Stopped: |
| DROPERIDOL (Suspected) | Reason: Hyperemes gravidar w/o neurits |
| Injection | 7.5 Milligram Daily Intramuscular |
| Batch: | Started: 10/11/1992 Stopped: 11/11/1992 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 81751 | Seq: 1 | Gender: M |
| Reported: 24/12/1992 | | Weight: |
| Hospitalisation: | | Age: 12 |
| Onset Date: 19/12/1992 | | DOB: 10/09/1980 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------|
| Dystonia | | | 8mg cogentin iv. |

Medicine Details:

| | | |
|-------------------------------|---------------------------------------|----------------------------|
| DROPERIDOL (Suspected) | Reason: | |
| Injection | 3.0 Milligram | 4 times Intramuscular |
| Batch: | Started: 18/12/1992 | Stopped: 19/12/1992 |
| PANADOL (Suspected) | Reason: Pain | |
| | 750.0 Milligram | As necessary |
| Batch: | Started: 19/12/1992 | Stopped: 21/12/1992 |
| CODEINE (Suspected) | Reason: Pain | |
| | 20.0 Milligram | As necessary |
| Batch: | Started: 19/12/1992 | Stopped: 19/12/1992 |
| BRICANYL (Suspected) | Reason: Bronchitis,unqualified | |
| Inhalation | 2.0 Dose Unspecified | As necessary Inhalation |
| Batch: | Started: 16/12/1992 | Stopped: 21/12/1992 |

Laboratory Investigations:

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

Additional Information:

Patient appears to be sensitive to narcotics.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 81751

Seq: 1

Gender: M

Reported: 24/12/1992

Weight:

Hospitalisation:

Age: 12

Onset Date: 19/12/1992

DOB: 10/09/1980

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

PETHIDINE HYDROCHLORIDE (Suspected)

Reason: Pain

Injection, intravenous infusion

6.5 Milligram

Per hour

Intravenous

Batch:

Started: 16/12/1992

Stopped: 19/12/1992

Laboratory Investigations:

Additional Information:

Patient appears to be sensitive to narcotics.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 82184

Seq: 1

Gender: F

Reported: 28/01/1993

Weight: 60.00

Hospitalisation:

Onset Date: 27/01/1993

Age: 30Y

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|---------------------|-------------|
| Bronchospasm | | Bronchoconstriction | Salbutamol. |

Medicine Details:

| | | | |
|--|----------------------------|----------------------------|---------------|
| ATRACURIUM BESYLATE (Suspected) | Reason: | | |
| Injection | 50.0 Milligram | Daily | Intravenous |
| Batch: | Started: | Stopped: | |
| SUXAMETHONIUM BROMIDE (Suspected) | Reason: | | |
| Injection | 100.0 Milligram | Daily | Intravenous |
| Batch: | Started: | Stopped: | |
| PROPOFOL (Suspected) | Reason: | | |
| Injection | 200.0 Milligram | Daily | Intravenous |
| Batch: | Started: | Stopped: | |
| TORADOL (Suspected) | Reason: | | |
| Injection | 30.0 Milligram | Daily | Intramuscular |
| Batch: | Started: 27/01/1993 | Stopped: 27/01/1993 | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 82184

Seq: 1

Gender: F

Reported: 28/01/1993

Weight: 60.00

Hospitalisation:

Age: 30Y

Onset Date: 27/01/1993

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|-------------------------------------|----------------------------|----------------------------|---------------|
| DROLEPTAN (Suspected) | Reason: | | |
| Injection | 5.0 Milligram | Daily | Intravenous |
| Batch: | Started: 27/01/1993 | Stopped: 27/01/1993 | |
| MAXOLON (Suspected) | Reason: | | |
| Injection | 10.0 Milligram | Daily | Intramuscular |
| Batch: | Started: 27/01/1993 | Stopped: 27/01/1993 | |
| MEFOXIN (Suspected) | Reason: | | |
| Injection | 1.0 Gram | Daily | Intravenous |
| Batch: | Started: 27/01/1993 | Stopped: 27/01/1993 | |
| FENTANYL CITRATE (Suspected) | Reason: | | |
| Injection | 100.0 Microgram | Daily | Intravenous |
| Batch: | Started: 27/01/1993 | Stopped: 27/01/1993 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 82184

Seq: 1

Gender: F

Reported: 28/01/1993

Weight: 60.00

Hospitalisation:

Age: 30Y

Onset Date: 27/01/1993

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ATROPINE (Suspected)

Reason:

Injection

600.0 Microgram

Daily

Intravenous

Batch:

Started: 27/01/1993

Stopped: 27/01/1993

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 83315 | Seq: 1 | Gender: F |
| Reported: 19/03/1993 | | Weight: 55.00 |
| Hospitalisation: | | Age: 41Y |
| Onset Date: 23/02/1993 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------|-----------|
| Agitation Hyperkinesia Paraesthesia Thinking abnormal | | | Cogentin |

Medicine Details:

| | |
|-------------------------------------|---|
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| 5.0 Microgram | 1 time |
| Batch: | Started: 23/02/1993 Stopped: |
| MAXOLON (Suspected) | Reason: Other disturbance of sensation |
| 10.0 Milligram | 1 time |
| Batch: | Started: 23/02/1993 Stopped: |
| FENTANYL CITRATE (Suspected) | Reason: Other disturbance of sensation |
| 80.0 Milligram | 1 time |
| Batch: | Started: 23/02/1993 Stopped: |
| DIPRIVAN (Suspected) | Reason: Other disturbance of sensation |
| 50.0 Milligram | 1 time |
| Batch: | Started: 23/02/1993 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 83315

Seq: 1

Gender: F

Reported: 19/03/1993

Weight: 55.00

Hospitalisation:

Age: 41Y

Onset Date: 23/02/1993

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|------------------------------|---|
| MIDAZOLAM (Suspected) | Reason: Other disturbance of sensation |
| | 3.5 Milligram 1 time |
| Batch: | Started: 23/02/1993 Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 84248

Seq: 1

Gender: F

Reported: 27/04/1993

Weight: 72.00

Hospitalisation:

Age: 38

Onset Date: 19/03/1993

DOB: 31/10/1954

Outcome: Unknown

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--|
| Oculogyration | | | Valium 10mg, cogentin 2mg im, observation for 3 hours. |

Medicine Details:

| | |
|-------------------------------|---|
| PANADEINE (Other drug) | Reason: Pain |
| Oral application | 2.0 Dose Unspecified Daily Oral |
| Batch: | Started: 17/03/1993 Stopped: 20/03/1993 |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection | 1.2 Milligram Daily Intravenous |
| Batch: | Started: 18/03/1993 Stopped: 19/03/1993 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 84781 | Seq: 1 | Gender: F |
| Reported: 31/05/1993 | | Weight: |
| Hospitalisation: | | Age: 18Y |
| Onset Date: 09/04/1993 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

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

Medicine Details:

| | |
|-------------------------------|---|
| TEMAZEPAM (Other drug) | Reason: Specific disorders of sleep |
| Capsule | 20.0 Milligram Daily Oral |
| Batch: | Started: 06/04/1993 Stopped: 12/04/1993 |
| PANADEINE (Other drug) | Reason: Pain |
| Oral application | 12.0 Dose Unspecified Daily Oral |
| Batch: | Started: 06/04/1993 Stopped: 13/04/1993 |
| VALIUM (Suspected) | Reason: Abnormal involuntary movement |
| | 5.0 Milligram 1 time |
| Batch: | Started: 09/04/1993 Stopped: |
| MAXOLON (Suspected) | Reason: Nausea and vomiting |
| Injection | 40.0 Milligram Daily Intramuscular |
| Batch: | Started: 06/04/1993 Stopped: 08/04/1993 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 84781

Seq: 1

Gender: F

Reported: 31/05/1993

Weight:

Hospitalisation:

Age: 18Y

Onset Date: 09/04/1993

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

DROPERIDOL (Suspected)

Reason: Nausea and vomiting

20.0 Milligram

Daily

Batch:

Started: 08/04/1993

Stopped: 09/04/1993

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 87046 **Seq:** 1 **Gender:** F
Reported: 25/08/1993 **Weight:** 57.00
Hospitalisation: **Age:** 45Y
Onset Date: 12/08/1993 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|---|-----------|
| Dermatitis bullous Pruritus Rash | | Blue/black blisters on r thumb & finger. Itchy at nape, breasts & extremities. | |

Medicine Details:

| | |
|---|---|
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: Other disturbance of sensation |
| Injection 75.0 Milligram As necessary Intramuscular | |
| Batch: Started: 11/08/1993 Stopped: 13/08/1993 | |
| PANADEINE (Suspected) | Reason: |
| Oral application 2.0 Dose Unspecified Daily Oral | |
| Batch: Started: 10/08/1993 Stopped: 14/08/1993 | |
| MONOPRIL (Suspected) | Reason: Essential benign hypertension |
| Tablet 10.0 Milligram Daily Oral | |
| Batch: Started: 10/08/1993 Stopped: 14/08/1993 | |
| ADALAT (Suspected) | Reason: Essential benign hypertension |
| Tablet 10.0 Milligram Daily Oral | |
| Batch: Started: 10/08/1993 Stopped: 13/08/1993 | |

Laboratory Investigations:

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

Additional Information:

Patient has had a previous reaction in penicillin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 87046

Seq: 1

Gender: F

Reported: 25/08/1993

Weight: 57.00

Hospitalisation:

Age: 45Y

Onset Date: 12/08/1993

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|-----------------------------------|---|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection | 2.0 Milligram Daily Intramuscular |
| Batch: | Started: 11/08/1993 Stopped: 13/08/1993 |
| HEPARIN SODIUM (Suspected) | Reason: |
| Injection | 10.0 Thousand Internal Daily Subcutaneous |
| Batch: | Started: 11/08/1993 Stopped: 13/08/1993 |
| MAXOLON (Suspected) | Reason: Nausea and vomiting |
| Injection | 40.0 Milligram Daily Intramuscular |
| Batch: | Started: 11/08/1993 Stopped: 14/08/1993 |

Laboratory Investigations:

Additional Information:

Patient has had a previous reaction in penicillin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 87490 | Seq: 1 | Gender: F |
| Reported: 06/09/1993 | | Weight: 59.00 |
| Hospitalisation: | | Age: 36Y |
| Onset Date: 11/06/1993 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------|-----------|
| Injection site reaction | | | |
| Urticaria | | | |

Medicine Details:

| | |
|------------------------------------|--|
| ISOFLURANE (Other drug) | Reason: Other disturbance of sensation |
| 0.0 | |
| Batch: | Started: Stopped: |
| ATROPINE (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: Stopped: |
| NEOSTIGMINE NOS (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: Stopped: |
| MORPHINE NOS (Suspected) | Reason: Other disturbance of sensation |
| Injection | 15.0 Milligram Daily Intravenous |
| Batch: | Started: 11/06/1993 Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient has had no known previous allergies.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 87490

Seq: 1

Gender: F

Reported: 06/09/1993

Weight: 59.00

Hospitalisation:

Age: 36Y

Onset Date: 11/06/1993

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|--|---|
| DROPERIDOL (Suspected) | Reason: |
| Injection 15.0 Milligram | Daily Intravenous |
| Batch: | Started: 11/06/1993 Stopped: |
| GLYCOPYRROLATE (Suspected) | Reason: |
| Injection 200.0 Microgram | Daily Intravenous |
| Batch: | Started: 11/06/1993 Stopped: |
| PROPOFOL (Suspected) | Reason: Other disturbance of sensation |
| Injection 150.0 Milligram | Daily Intravenous |
| Batch: | Started: 11/06/1993 Stopped: |
| ATRACURIUM BESYLATE (Suspected) | Reason: |
| Injection 35.0 Milligram | Daily Intravenous |
| Batch: | Started: 11/06/1993 Stopped: |

Laboratory Investigations:

Additional Information:

Patient has had no known previous allergies.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 87490

Seq: 1

Gender: F

Reported: 06/09/1993

Weight: 59.00

Hospitalisation:

Age: 36Y

Onset Date: 11/06/1993

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

Keflin Neutral (Suspected)

Reason: Prophylaxis

Injection

1.0 Gram

Daily

Intravenous

Batch:

Started: 11/06/1993

Stopped:

Laboratory Investigations:

Additional Information:

Patient has had no known previous allergies.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 87961 | Seq: 1 | Gender: F |
| Reported: 28/09/1993 | | Weight: 68.00 |
| Hospitalisation: | | Age: 39Y |
| Onset Date: 01/06/1993 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|--------------------|-----------|
| Nausea Vomiting | | | |

Medicine Details:

| | |
|--|---|
| MORPHINE NOS (Suspected) | Reason: Pain |
| Injection, intravenous infusion | 0.0 Intravenous |
| Batch: | Started: 31/05/1993 Stopped: 01/06/1993 |
| MAXOLON (Suspected) | Reason: Nausea and vomiting |
| Injection, intravenous infusion | 0.0 Intravenous |
| Batch: | Started: 31/05/1993 Stopped: 01/06/1993 |
| OMNOPON-SCOPOLAMINE (Suspected) | Reason: |
| Injection | 0.0 Intramuscular |
| Batch: | Started: 31/05/1993 Stopped: |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection | 2.5 Milligram As necessary Intravenous |
| Batch: | Started: 31/05/1993 Stopped: 01/06/1993 |

Laboratory Investigations:

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

Additional Information:

Infusion ceased and patient commenced on toradol im.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 87961

Seq: 1

Gender: F

Reported: 28/09/1993

Weight: 68.00

Hospitalisation:

Age: 39Y

Onset Date: 01/06/1993

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|------------------------------------|---|
| HEPARIN CALCIUM (Suspected) | Reason: |
| Injection | 15.0 Thousand Internal Daily Subcutaneous |
| Batch: | Started: 31/05/1993 Stopped: 01/06/1993 |

Laboratory Investigations:

Additional Information:

Infusion ceased and patient commenced on toradol im.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 88398 | Seq: 1 | Gender: U |
| Reported: 11/10/1993 | | Weight: 83.00 |
| Hospitalisation: | | Age: |
| Onset Date: 30/09/1993 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------|
| Dystonia | | Neck stiff. | Cogentin 1gm iv. |

Medicine Details:

| | | | |
|---|-----------------|------------------------------|---------------|
| MORPHINE HYDROCHLORIDE (Suspected) | | Reason: Premedication | |
| Injection | 15.0 Milligram | 1 time | Intramuscular |
| Batch: | Started: | Stopped: | |
| DROPERIDOL (Suspected) | | Reason: Premedication | |
| Injection | 1.0 Milligram | 1 time | Intramuscular |
| Batch: | Started: | Stopped: | |
| Keflin Neutral (Suspected) | | Reason: | |
| Injection | 4.0 Gram | Daily | Intravenous |
| Batch: | Started: | Stopped: | |
| FLAGYL (Suspected) | | Reason: | |
| Injection | 1.0 Gram | Daily | Intravenous |
| Batch: | Started: | Stopped: | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 88502

Seq: 1

Gender: M

Reported: 15/10/1993

Weight: 68.00

Hospitalisation:

Age: 16Y

Onset Date: 30/09/1993

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------|
| Oculogyration | | | lv cogentin 2mg. |

Medicine Details:

| DROPERIDOL (Suspected) | Reason: |
|---------------------------------|---|
| Injection, intravenous infusion | 4.0 Milligram Total Intravenous |
| Batch: | Started: 29/09/1993 Stopped: 30/09/1993 |

Laboratory Investigations:

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

Additional Information:

Patient has had no known previous allergies.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 89459

Seq: 1

Gender: F

Reported: 30/11/1993

Weight: 44.00

Hospitalisation:

Age: 38Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--------------------------|
| Hypertonia | | | Benztropine 2mg im stat. |

Medicine Details:

| | |
|---|----------------------------|
| DROPERIDOL (Suspected) | Reason: |
| Injection 10.0 Milligram | 1 time Intramuscular |
| Batch: Started: 24/11/1993 | Stopped: |
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: |
| Injection 20.0 Milligram | 1 time Intramuscular |
| Batch: Started: | Stopped: |
| PROMETHAZINE HYDROCHLORIDE (Suspected) | Reason: |
| Injection 50.0 Milligram | As necessary Intramuscular |
| Batch: Started: | Stopped: |
| DIAZEPAM (Suspected) | Reason: |
| Injection 10.0 Milligram | As necessary Intramuscular |
| Batch: Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 89459

Seq: 1

Gender: F

Reported: 30/11/1993

Weight: 44.00

Hospitalisation:

Age: 38Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | |
|------------------------|----------|----------|
| PROTHIADEN (Suspected) | Reason: | |
| 150.0 Milligram | Daily | |
| Batch: | Started: | Stopped: |
| ROHYPNOL (Suspected) | Reason: | |
| 1.0 Dose Unspecified | Daily | |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 90557 **Seq:** 1 **Gender:** F
Reported: 19/01/1994 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 12/01/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------|
| Oculogyration | | | Cogentin 5mg iv. |

Medicine Details:

| | |
|---------------------------------|---|
| DROPERIDOL (Suspected) | Reason: Premedication |
| 5.0 Milligram | 1 time |
| Batch: | Started: 12/01/1994 Stopped: 12/01/1994 |
| MORPHINE NOS (Suspected) | Reason: Premedication |
| 10.0 Milligram | 1 time |
| Batch: | Started: 12/01/1994 Stopped: 12/01/1994 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 90876 | Seq: 1 | Gender: F |
| Reported: 03/02/1994 | | Weight: 60.00 |
| Hospitalisation: | | Age: 18Y |
| Onset Date: 21/01/1994 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------------|
| Dystonia | | | Benztropine 2mg |

Medicine Details:

| | |
|-------------------------------------|---|
| AMPICILLIN (Other drug) | Reason: |
| 0.0 | |
| Batch: | Started: Stopped: |
| FLAGYL (Other drug) | Reason: |
| Injection | 1.5 Gram Daily Intravenous |
| Batch: | Started: Stopped: |
| FENTANYL CITRATE (Suspected) | Reason: Other disturbance of sensation |
| Injection | 3.0 Millilitre 1 time Intravenous |
| Batch: | Started: 21/01/1994 Stopped: 21/01/1994 |
| DROPERIDOL (Suspected) | Reason: |
| Injection | 2.5 Milligram 1 time Intravenous |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:

Allergic to morphine, maxalon, stemetil



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 91229 | Seq: 1 | Gender: F |
| Reported: 23/02/1994 | | Weight: 68.00 |
| Hospitalisation: | | Age: 34 |
| Onset Date: 14/06/1993 | | DOB: 12/08/1958 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|-----------------------------|---|
| Dystonia | | Clenched teeth, locked jaw. | Cogentin imi 1mg stat than repeat in 30 mins. |
| Oculogyration | | | |

Medicine Details:

| | |
|---|---|
| CALCIPARINE (Other drug) | Reason: |
| Injection | 10.0 Thousand Internal Daily Subcutaneous |
| Batch: | Started: 11/06/1993 Stopped: 14/06/1993 |
| TORADOL (Other drug) | Reason: Other disturbance of sensation |
| Injection | 30.0 Milligram Daily Intramuscular |
| Batch: | Started: 11/06/1993 Stopped: 16/06/1993 |
| PETHIDINE HYDROCHLORIDE (Other drug) | Reason: Pain |
| Injection | 800.0 Milligram Daily Intramuscular |
| Batch: | Started: 11/06/1993 Stopped: 14/06/1993 |
| VALIUM (Other drug) | Reason: |
| Injection | 20.0 Milligram Daily Intravenous |
| Batch: | Started: 11/06/1993 Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient allergic to voltaren, adhesive plaster, pethidine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 91229

Seq: 1

Gender: F

Reported: 23/02/1994

Weight: 68.00

Hospitalisation:

Age: 34

Onset Date: 14/06/1993

DOB: 12/08/1958

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | |
|-------------------------------|----------------------------|------------------------------------|
| DROPERIDOL (Suspected) | | Reason: Nausea and vomiting |
| Injection | 30.0 Milligram | Daily Intramuscular |
| Batch: | Started: 10/06/1993 | Stopped: 14/06/1993 |
| STEMETIL (Suspected) | | Reason: Nausea and vomiting |
| Injection | 75.0 Milligram | Daily Intramuscular |
| Batch: | Started: 10/06/1993 | Stopped: 14/06/1993 |
| TEMAZEPAM (Suspected) | | Reason: Pain |
| Capsule | 1.0 Dose Unspecified | Daily Oral |
| Batch: | Started: 10/06/1993 | Stopped: 14/06/1993 |

Laboratory Investigations:

Additional Information:

Patient allergic to voltaren, adhesive plaster, pethidine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 91605 | Seq: 1 | Gender: F |
| Reported: 14/03/1994 | | Weight: 56.00 |
| Hospitalisation: | | Age: 16Y |
| Onset Date: 02/02/1994 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------|
| Opisthotonus | | Arching back. | |
| Dystonia | | | lv cogentin 2mg. |

Medicine Details:

| | | | |
|--|----------------------------|-----------------|-------------|
| MAXOLON (Suspected) | | Reason: | |
| Injection | 10.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 02/02/1994 | Stopped: | |
| PETHIDINE HYDROCHLORIDE (Suspected) | | Reason: | |
| Injection | 50.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 02/02/1994 | Stopped: | |
| ATROPINE (Suspected) | | Reason: | |
| Injection | 300.0 Microgram | 1 time | Intravenous |
| Batch: | Started: 02/02/1994 | Stopped: | |
| PROPOFOL (Suspected) | | Reason: | |
| Injection | 160.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 02/02/1994 | Stopped: | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 91605
Reported: 14/03/1994
Hospitalisation:
Onset Date: 02/02/1994
Outcome: Recovered

Seq: 1

Gender: F
Weight: 56.00
Age: 16Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|-------------------------------|--|
| LIGNOCAINE (Suspected) | Reason: |
| Injection 100.0 Milligram | 1 time Intravenous |
| Batch: | Started: 02/02/1994 Stopped: |
| DROPERIDOL (Suspected) | Reason: |
| Injection 4.0 Milligram | 1 time Intravenous |
| Batch: | Started: 02/02/1994 Stopped: |
| NARCAN (Suspected) | Reason: |
| Injection 400.0 Microgram | 1 time Intravenous |
| Batch: | Started: 02/02/1994 Stopped: |
| TORADOL (Suspected) | Reason: |
| Injection 30.0 Milligram | 1 time Intravenous |
| Batch: | Started: 02/02/1994 Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 91605

Seq: 1

Gender: F

Reported: 14/03/1994

Weight: 56.00

Hospitalisation:

Age: 16Y

Onset Date: 02/02/1994

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|--|----------------------------|-----------------|-------------|
| TACRINE HYDROCHLORIDE (Suspected) | Reason: | | |
| Injection | 30.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 02/02/1994 | Stopped: | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 91626 | Seq: 1 | Gender: M |
| Reported: 15/03/1994 | | Weight: |
| Hospitalisation: | | Age: 20Y |
| Onset Date: 03/02/1994 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|-----------------------------|---------------------------------|
| Dyspnoea | | Difficulty with respiration | Cogentin 2mg, admission to icu. |
| Dysphagia | | | |

Medicine Details:

| | | | |
|------------------------------------|----------------------------|------------------------------------|---------------|
| Keflin Neutral (Other drug) | | Reason: Prophylaxis | |
| Injection | 4.0 Gram | Daily | Intravenous |
| Batch: | Started: 02/02/1994 | Stopped: 04/02/1994 | |
| FLAGYL (Other drug) | | Reason: Prophylaxis | |
| Injection | 1.0 Gram | Daily | Intravenous |
| Batch: | Started: 02/02/1994 | Stopped: 04/02/1994 | |
| DROPERIDOL (Suspected) | | Reason: Nausea and vomiting | |
| Injection | 1.0 Milligram | As necessary | Intramuscular |
| Batch: | Started: 02/02/1994 | Stopped: 03/02/1994 | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 91630

Seq: 1

Gender: M

Reported: 15/03/1994

Weight: 97.00

Hospitalisation:

Onset Date: 07/07/1993

Age: 32Y

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------------------|----------|--------------------|------------------------------------|
| Dystonia Dyspnoea Laryngospasm | | Lock-jaw. | Diazepam iv 2mg, cogentin 2mg imi. |

Medicine Details:

| | |
|---|--|
| PROPOFOL (Suspected) Injection Batch: 300.0 Milligram Started: 07/07/1993 | Reason: Other disturbance of sensation 1 time Intravenous Stopped: |
| LIGNOCAINE (Suspected) Injection Batch: 60.0 Milligram Started: 07/07/1993 | Reason: Other disturbance of sensation 1 time Intravenous Stopped: |
| ATROPINE (Suspected) Injection Batch: 400.0 Microgram Started: 07/07/1993 | Reason: Other disturbance of sensation 1 time Intravenous Stopped: |
| DROPERIDOL (Suspected) Injection Batch: 4.0 Milligram Started: 07/07/1993 | Reason: Other disturbance of sensation 1 time Intravenous Stopped: |

Laboratory Investigations:

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

Additional Information:

No previous problems with anaesthetics.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 91630

Seq: 1

Gender: M

Reported: 15/03/1994

Weight: 97.00

Hospitalisation:

Age: 32Y

Onset Date: 07/07/1993

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | |
|----------------------------|----------------------------|---|
| MAXOLON (Suspected) | | Reason: Other disturbance of sensation |
| Injection | 10.0 Milligram | 1 time Intravenous |
| Batch: | Started: 07/07/1993 | Stopped: |
| THA (Suspected) | | Reason: Other disturbance of sensation |
| Injection | 30.0 Milligram | 1 time Intravenous |
| Batch: | Started: 07/07/1993 | Stopped: |
| NARCAN (Suspected) | | Reason: Other disturbance of sensation |
| Injection | 600.0 Microgram | 1 time Intravenous |
| Batch: | Started: 07/07/1993 | Stopped: |

Laboratory Investigations:

Additional Information:

No previous problems with anaesthetics.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 93067 | Seq: 1 | Gender: F |
| Reported: 17/05/1994 | | Weight: |
| Hospitalisation: | | Age: 30 |
| Onset Date: 11/08/1993 | | DOB: 03/07/1963 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|-------------------------------|--------------|
| Hypoaesthesia | | Numbness in fingers and toes. | |
| Malaise | | | |
| Nausea | | | Stemetil iv. |

Medicine Details:

| | | | |
|-------------------------------------|----------------------------|-----------------|-------------|
| DROPERIDOL (Suspected) | | Reason: | |
| Injection | 1.2 Milligram | 1 time | Intravenous |
| Batch: | Started: 11/08/1993 | Stopped: | |
| VALIUM (Suspected) | | Reason: | |
| Injection | 2.5 Milligram | 1 time | Intravenous |
| Batch: | Started: 11/08/1993 | Stopped: | |
| FENTANYL CITRATE (Suspected) | | Reason: | |
| Injection | 15.0 Microgram | 1 time | Intravenous |
| Batch: | Started: 11/08/1993 | Stopped: | |
| DIAZEPAM (Suspected) | | Reason: | |
| Tablet | 10.0 Milligram | 1 time | Oral |
| Batch: | Started: 11/08/1993 | Stopped: | |

Laboratory Investigations:

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

Additional Information:

Previous reactions to pethidine=vomiting, panadeine forte=vomiting.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 93487 | Seq: 1 | Gender: F |
| Reported: 06/06/1994 | | Weight: 57.00 |
| Hospitalisation: | | Age: 85Y |
| Onset Date: 30/03/1994 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-------------|
| Constipation | | | Nulax given |

Medicine Details:

| | |
|------------------------------------|---|
| ZOFRAN (Suspected) | Reason: Nausea and vomiting |
| Injection | 4.0 Milligram 1 time Intravenous |
| Batch: | Started: 28/03/1994 Stopped: 28/03/1994 |
| PANADEINE FORTE (Suspected) | Reason: |
| Capsule | 1.0 Dose Unspecified As necessary Oral |
| Batch: | Started: Stopped: |
| DROPERIDOL (Suspected) | Reason: |
| Injection | 1.2 Milligram As necessary Intramuscular |
| Batch: | Started: Stopped: |
| STEMETIL (Suspected) | Reason: |
| Injection | 12.0 Milligram Daily Intramuscular |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 93490 | Seq: 1 | Gender: M |
| Reported: 06/06/1994 | | Weight: 73.00 |
| Hospitalisation: | | Age: 72 |
| Onset Date: 26/05/1994 | | DOB: 12/06/1921 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|-----------|
| Arrhythmia Dizziness Nausea Pallor | | | |

Medicine Details:

| | | | |
|---|----------------------------|--|---------------|
| CLEXANE (Other drug) | | Reason: Other prophylactic procedures | |
| Injection | 40.0 Milligram | Daily | Subcutaneous |
| Batch: | Started: 25/05/1994 | Stopped: | CONTIN |
| PETHIDINE HYDROCHLORIDE (Other drug) | | Reason: Pain | |
| Injection | 800.0 Milligram | Daily | Intramuscular |
| Batch: | Started: 26/05/1994 | Stopped: | |
| DROPERIDOL (Suspected) | | Reason: | |
| Injection | 2.5 Milligram | Daily | Intramuscular |
| Batch: | Started: 26/05/1994 | Stopped: | 26/05/1994 |
| Keflin Neutral (Suspected) | | Reason: | |
| Injection | 4.0 Gram | Daily | Intravenous |
| Batch: | Started: 25/05/1994 | Stopped: | 27/05/1994 |

Laboratory Investigations:

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

Additional Information:

Allergies to penicillin and garlic.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 93663 | Seq: 1 | Gender: F |
| Reported: 10/06/1994 | | Weight: 72.00 |
| Hospitalisation: | | Age: 71 |
| Onset Date: 26/04/1994 | | DOB: 26/01/1923 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Coma | | | |
| Dystonia | | | |

Medicine Details:

| | |
|---|---|
| FLUCLOXACILLIN SODIUM (Other drug) | Reason: |
| 1.5 Gram | Daily |
| Batch: | Started: 25/04/1994 Stopped: 26/04/1994 |
| LASIX (Other drug) | Reason: Essential benign hypertension |
| 40.0 Milligram | Daily |
| Batch: | Started: 26/04/1994 Stopped: |
| OROXINE (Other drug) | Reason: |
| Tablet | 50.0 Microgram |
| Daily | Oral |
| Batch: | Started: Stopped: CONTIN |
| ISOPTIN (Other drug) | Reason: Essential benign hypertension |
| Tablet, modified release | 240.0 Milligram |
| Daily | Oral |
| Batch: | Started: Stopped: 03/05/1994 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 93663

Seq: 1

Gender: F

Reported: 10/06/1994

Weight: 72.00

Hospitalisation:

Age: 71

Onset Date: 26/04/1994

DOB: 26/01/1923

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|---------------------------------|---|----------------------------|------|
| ZANTAC (Other drug) | Reason: Diaph hern of abd cav w/o obst | | |
| Tablet | 300.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: 05/05/1994 | |
| FRAGMIN (Other drug) | Reason: Pulmonary embolism&infarction | | |
| | 10.0 Thousand Internal | Daily | |
| Batch: | Started: | Stopped: | |
| NORDIOL NOS (Other drug) | Reason: | | |
| | 15.0 Milligram | Daily | |
| Batch: | Started: | Stopped: | |
| SPAN-K (Other drug) | Reason: | | |
| | 6.0 Dose Unspecified | Daily | |
| Batch: | Started: | Stopped: | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 93663

Seq: 1

Gender: F

Reported: 10/06/1994

Weight: 72.00

Hospitalisation:

Age: 71

Onset Date: 26/04/1994

DOB: 26/01/1923

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: |
| Injection | 2.5 Milligram 1 time Intramuscular |
| Batch: | Started: 26/04/1994 Stopped: 26/04/1994 |
| KEFLEX (Suspected) | Reason: |
| | 1.5 Gram Daily |
| Batch: | Started: 25/04/1994 Stopped: 26/04/1994 |
| LOSEC (Suspected) | Reason: Diaph hern of abd cav w/o obst |
| | 40.0 Milligram Daily |
| Batch: | Started: 26/04/1994 Stopped: |
| ROHYPNOL (Suspected) | Reason: |
| | 1.0 Dose Unspecified Daily |
| Batch: | Started: 26/04/1994 Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 95095 | Seq: 1 | Gender: U |
| Reported: 16/08/1994 | | Weight: |
| Hospitalisation: | | Age: |
| Onset Date: 28/07/1994 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------------------------------|---------------------------|-----------------|
| Opisthotonus Dystonia | Required Specialist Consultation | Tightness in neck and jaw | Cogentin 1mg iv |

Medicine Details:

| | | |
|--|------------------------------------|----------------------------|
| PANADOL (Other drug) | Reason: Pain | |
| Oral application | 500.0 Milligram | Total Oral |
| Batch: | Started: 28/07/1994 | Stopped: |
| PANADEINE FORTE (Suspected) | Reason: Pain | |
| Tablet | 0.0 | Total Oral |
| Batch: | Started: 28/07/1994 | Stopped: |
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: Pain | |
| | 300.0 Milligram | Total |
| Batch: | Started: 27/07/1994 | Stopped: 28/07/1994 |
| MAXOLON (Suspected) | Reason: Nausea and vomiting | |
| Injection | 10.0 Milligram | Total Intravenous |
| Batch: | Started: 27/07/1994 | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 95095

Seq: 1

Gender: U

Reported: 16/08/1994

Weight:

Hospitalisation:

Age:

Onset Date: 28/07/1994

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|-----------------------------------|----------------------------|----------------------------|---------------|
| DROPERIDOL (Suspected) | | Reason: | |
| Injection | 2.5 Milligram | Total | Intramuscular |
| Batch: | Started: 27/07/1994 | Stopped: | |
| Keflin Neutral (Suspected) | | Reason: Prophylaxis | |
| Injection | 1.0 Gram | Daily | Intravenous |
| Batch: | Started: 27/07/1994 | Stopped: 28/07/1994 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 96405 | Seq: 1 | Gender: F |
| Reported: 10/10/1994 | | Weight: |
| Hospitalisation: | | Age: 66 |
| Onset Date: | | DOB: 08/10/1928 |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Anxiety | Severe | | Xanax |
| Hallucination | Severe | | |

Medicine Details:

| | |
|------------------------------|--|
| DROLEPTAN (Suspected) | Reason: |
| 2.0 Milligram | 1 time |
| Batch: | Started: Stopped: |
| DIPRIVAN (Suspected) | Reason: Other disturbance of sensation |
| Injection | 1.0 Dose Unspecified 1 time Intravenous |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 96932 | Seq: 1 | Gender: F |
| Reported: 07/11/1994 | | Weight: 56.00 |
| Hospitalisation: | | Age: 20Y |
| Onset Date: 22/10/1994 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------------------|----------|--------------------|---------------------|
| Dystonia Mydriasis Opisthotonus | | | Benztropine iv 2mg. |

Medicine Details:

| | | | |
|---|----------------------------|----------------------------|-------------|
| METRONIDAZOLE (Other drug) | | Reason: Prophylaxis | |
| Injection | 1.5 Gram | Total | Intravenous |
| Batch: | Started: 21/10/1994 | Stopped: | |
| AMOXYCILLIN SODIUM (Other drug) | | Reason: Prophylaxis | |
| Injection | 3.0 Gram | Total | Intravenous |
| Batch: | Started: 21/10/1994 | Stopped: | |
| PETHIDINE HYDROCHLORIDE (Other drug) | | Reason: Pain | |
| Injection | 25.0 Milligram | As necessary | Intravenous |
| Batch: | Started: 20/10/1994 | Stopped: 21/10/1994 | |
| PANADEINE (Other drug) | | Reason: Pain | |
| Oral application | 1.0 Dose Unspecified | As necessary | Oral |
| Batch: | Started: 20/10/1994 | Stopped: | CONTIN |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 96932

Seq: 1

Gender: F

Reported: 07/11/1994

Weight: 56.00

Hospitalisation:

Age: 20Y

Onset Date: 22/10/1994

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|---|---|
| BECOTIDE (Other drug) | Reason: Asthma |
| Inhalation | 2.0 Dose Unspecified Daily Inhalation |
| Batch: | Started: Stopped: CONTIN |
| METOCLOPRAMIDE HYDROCHLORIDE (Suspected) | Reason: Nausea and vomiting |
| Injection | 10.0 Milligram 2 times Intravenous |
| Batch: | Started: 21/10/1994 Stopped: 22/10/1994 |
| DROLEPTAN (Suspected) | Reason: Nausea and vomiting |
| Injection | 2.0 Milligram 1 time Intravenous |
| Batch: | Started: 22/10/1994 Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 96971 | Seq: 1 | Gender: M |
| Reported: 08/11/1994 | | Weight: |
| Hospitalisation: | | Age: 14Y |
| Onset Date: 17/08/1994 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------|----------|--------------------|-----------|
| Dystonia Meningism | | | Cogentin |

Medicine Details:

| | |
|------------------------------|---|
| DROLEPTAN (Suspected) | Reason: Nausea and vomiting |
| | 1.0 Dose Unspecified 1 time |
| Batch: | Started: 17/08/1994 Stopped: 17/08/1994 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 98098 | Seq: 1 | Gender: F |
| Reported: 03/01/1995 | | Weight: |
| Hospitalisation: | | Age: 29Y |
| Onset Date: 21/07/1993 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Details:

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

Medicine Details:

| | |
|---|--|
| TEMAZE (Other drug) | Reason: Specific disorders of sleep |
| Capsule | 10.0 Milligram |
| | As necessary Oral |
| Batch: | Started: 18/07/1993 Stopped: |
| PANADOL (Other drug) | Reason: |
| | 0.0 |
| | As necessary |
| Batch: | Started: 18/07/1993 Stopped: |
| PETHIDINE HYDROCHLORIDE (Other drug) | Reason: |
| | 75.0 Milligram |
| | As necessary |
| Batch: | Started: 19/07/1993 Stopped: |
| DRIXINE (Other drug) | Reason: |
| | 3.0 Dose Unspecified Daily |
| Batch: | Started: 20/07/1993 Stopped: |

Laboratory Investigations:

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

Additional Information:

Allergic to metoclopramide - extrapyramidal reaction.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 98098

Seq: 1

Gender: F

Reported: 03/01/1995

Weight:

Hospitalisation:

Age: 29Y

Onset Date: 21/07/1993

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| | 10.0 Milligram As necessary |
| Batch: | Started: 20/07/1993 Stopped: 21/07/1993 |

Laboratory Investigations:

Additional Information:

Allergic to metoclopramide - extrapyramidal reaction.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 98105 | Seq: 1 | Gender: F |
| Reported: 03/01/1995 | | Weight: |
| Hospitalisation: | | Age: 51Y |
| Onset Date: 17/08/1994 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

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

Medicine Details:

| | |
|--------------------------------|---|
| ROHYPNOL (Other drug) | Reason: |
| | 1.0 Dose Unspecified As necessary |
| Batch: | Started: Stopped: |
| DIHYDERGOT (Other drug) | Reason: Migraine |
| Injection | 4.0 Milligram Daily Intravenous |
| Batch: | Started: Stopped: |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| | 15.0 Milligram Daily |
| Batch: | Started: 16/08/1994 Stopped: 17/08/1994 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 99245 | Seq: 1 | Gender: F |
| Reported: 28/02/1995 | | Weight: |
| Hospitalisation: | | Age: 93 |
| Onset Date: 03/01/1995 | | DOB: 10/01/1901 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------|
| Hypoglycaemia | | | Actrapid insulin |

Medicine Details:

| | |
|------------------------------------|--|
| ISOTARD MC (Other drug) | Reason: Diabetes mellitus |
| Injection | 4.0 Unit Daily Subcutaneous |
| Batch: | Started: L TERM Stopped: |
| ASPIRIN (Other drug) | Reason: |
| Oral application | 150.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: |
| NICOTINIC ACID (Other drug) | Reason: |
| Tablet | 187.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: |
| ATENOLOL (Other drug) | Reason: Essential benign hypertension |
| Tablet | 50.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 99245

Seq: 1

Gender: F

Reported: 28/02/1995

Weight:

Hospitalisation:

Age: 93

Onset Date: 03/01/1995

DOB: 10/01/1901

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

DROPERIDOL (Suspected)

Reason: Premedication

Injection

2.5 Milligram

1 time

Intravenous

Batch:

Started: 03/01/1995

Stopped:

DIAZEPAM (Suspected)

Reason: Premedication

Injection

10.0 Milligram

1 time

Intravenous

Batch:

Started: 03/01/1995

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 99895 | Seq: 1 | Gender: M |
| Reported: 31/03/1995 | | Weight: |
| Hospitalisation: | | Age: 27Y |
| Onset Date: 09/03/1995 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|-----------------------|---------------------------|
| Haematuria | Severe | Gross haematuria | Iv fluids and panadol prn |
| Renal pain | | Loin pain both sides. | |
| Renal impairment | | Renal impairment | |
| Myoglobinuria | | | |
| Myopathy | | | |
| | | | |

Medicine Details:

| | |
|--|---|
| NITROUS OXIDE (Suspected) | Reason: Other disturbance of sensation |
| 0.0 | |
| Batch: | Started: 09/03/1995 Stopped: |
| ISOFLURANE (Suspected) | Reason: Other disturbance of sensation |
| 0.0 | |
| Batch: | Started: 09/03/1995 Stopped: |
| SUXAMETHONIUM BROMIDE (Suspected) | Reason: Other disturbance of sensation |
| Injection | 100.0 Milligram 1 time Intravenous |
| Batch: | Started: 09/03/1995 Stopped: |
| FENTANYL CITRATE (Suspected) | Reason: Other disturbance of sensation |
| Injection | 125.0 Microgram 1 time Intravenous |
| Batch: | Started: 09/03/1995 Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|-------------|-------------|--------|------------------------------------|
| | Biochemistry | <10 | | | Urine myoglobin 10/3/95 42500 ug/l |
| | Creatine | 30 - 210 | 09/03/1995 | 74 | |
| | Creatine | 30 - 210 | 10/03/1995 | 160 | |
| | Creatine | 30 - 210 | 12/03/1995 | 281 | |
| | Creatine | 30 - 210 | 11/03/1995 | 102 | |
| | Creatine | 30 - 210 | 13/03/1995 | - | |
| | Creatinine | 0.06 - 0.12 | 09/03/1995 | 0.13 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 99895
Reported: 31/03/1995
Hospitalisation:
Onset Date: 09/03/1995
Outcome: Recovered

Seq: 1

Gender: M
Weight:
Age: 27Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|-------------------------------|---|-----------------|---------------|
| TORADOL (Suspected) | Reason: Pain | | |
| Injection | 30.0 Milligram | 1 time | Intramuscular |
| Batch: | Started: 09/03/1995 | Stopped: | |
| PROPOFOL (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 40.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 09/03/1995 | Stopped: | |
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 1.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 09/03/1995 | Stopped: | |
| HYPNOVEL (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 1.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 09/03/1995 | Stopped: | |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------------|-------------|--------|---------|
| | Creatinine | 0.06 - 0.12 | 10/03/1995 | 0.13 | |
| | Creatinine | 0.06 - 0.12 | 11/03/1995 | 0.13 | |
| | Creatinine | 0.06 - 0.12 | 13/03/1995 | 0.12 | |
| | Creatinine | 0.06 - 0.12 | 12/03/1995 | 0.14 | |
| | Urea | 3 - 7.5 | 09/03/1995 | 8.0 | |
| | Urea | 3 - 7.5 | 10/03/1995 | 8.4 | |
| | Urea | 3 - 7.5 | 11/03/1995 | 9.2 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 99895

Seq: 1

Gender: M

Reported: 31/03/1995

Weight:

Hospitalisation:

Age: 27Y

Onset Date: 09/03/1995

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

AMOXIL (Suspected)

Reason: Prophylaxis

Injection

1.0 Gram

1 time

Intravenous

Batch:

Started: 09/03/1995

Stopped:

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------|---------|-------------|--------|---------|
| | Urea | 3 - 7.5 | 12/03/1995 | 8.3 | |
| | Urea | 3 - 7.5 | 13/03/1995 | 8.0 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 102085

Seq: 1

Gender: F

Reported: 10/07/1995

Weight: 74.00

Hospitalisation:

Age: 27

Onset Date:

DOB: 14/03/1968

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|-----------|
| Brain oedema Hyponatraemia Nausea Vomiting | | | |

Medicine Details:

| | | | |
|-------------------------------|------------------------------------|-----------------|---------------|
| LARGACTIL (Suspected) | Reason: Nausea and vomiting | | |
| Injection | 25.0 Milligram | As necessary | Intravenous |
| Batch: | Started: | Stopped: | |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting | | |
| Injection | 2.0 Milligram | As necessary | Intravenous |
| Batch: | Started: | Stopped: | |
| STEMETIL (Suspected) | Reason: | | |
| Injection | 12.5 Milligram | As necessary | Intramuscular |
| Batch: | Started: | Stopped: | |
| ZOFRAN (Suspected) | Reason: | | |
| Injection | 4.0 Milligram | Daily | Intravenous |
| Batch: | Started: | Stopped: | |

Laboratory Investigations:

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

Additional Information:

Patient was not well controlled epileptic, who after surgery was hyponatraemic and vomiting, died of cerebral oedema.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 102085 **Seq:** 1

Gender: F

Reported: 10/07/1995

Weight: 74.00

Hospitalisation:

Age: 27

Onset Date:

DOB: 14/03/1968

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|--|-----------------------|---|---------------|
| DILANTIN (Suspected) | | Reason: Other&unspecified epilepsy | |
| Tablet | 300.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |
| PETHIDINE HYDROCHLORIDE (Suspected) | | Reason: | |
| Injection | 400.0 Milligram | Daily | Intramuscular |
| Batch: | Started: | Stopped: | |
| PANADEINE FORTE (Suspected) | | Reason: | |
| Tablet | 12.0 Dose Unspecified | Daily | Oral |
| Batch: | Started: | Stopped: | |

Laboratory Investigations:

Additional Information:

Patient was not well controlled epileptic, who after surgery was hyponatraemic and vomiting, died of cerebral oedema.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 103115 **Seq:** 1 **Gender:** F
Reported: 28/08/1995 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: 17/07/1995 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Tremor | | | Cogentin |

Medicine Details:

| | | |
|--|------------------------------------|----------------------------|
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: | |
| | 1.0 Dose Unspecified 1 time | |
| Batch: | Started: | Stopped: |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting | |
| | 2.5 Milligram Daily | |
| Batch: | Started: 17/07/1995 | Stopped: 17/07/1995 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 105062

Seq: 1

Gender: F

Reported: 04/12/1995

Weight: 69.00

Hospitalisation:

Age: 61Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--|---------------------------------|
| Dystonia | | Mouth appeared tight,lips pursed,can't communicate | Cogentin 2mg iv, midazolam 10mg |

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: 28/11/1995 Stopped: 29/11/1995 |
| MAXOLON (Suspected) | Reason: Nausea and vomiting |
| Injection | 10.0 Milligram Daily Intramuscular |
| Batch: | Started: 29/11/1995 Stopped: 29/11/1995 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 105289 **Seq:** 1 **Gender:** U
Reported: 11/12/1995 **Weight:** 63.00
Hospitalisation: **Age:**
Onset Date: 16/11/1995 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|---------------------|----------|---------------------|-------------------------|
| Rash maculo-papular | | Over trunk and arms | Phenergan 25mg imi once |

Medicine Details:

| | | |
|-------------------------------|----------------------------|----------------------------|
| DIPRIVAN (Suspected) | Reason: Surgery | |
| Injection | 0.0 | Intravenous |
| Batch: | Started: 15/11/1995 | Stopped: 15/11/1995 |
| MAXOLON (Suspected) | Reason: Surgery | |
| Injection | 0.0 | Intravenous |
| Batch: | Started: 15/11/1995 | Stopped: 15/11/1995 |
| DROPERIDOL (Suspected) | Reason: Surgery | |
| Injection | 0.0 | Intravenous |
| Batch: | Started: 15/11/1995 | Stopped: |
| CLAFORAN (Suspected) | Reason: Surgery | |
| | 2.0 Gram | 1 time |
| Batch: | Started: 15/11/1995 | Stopped: 15/11/1995 |

Laboratory Investigations:

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

Additional Information:

See original report for other drugs



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 105289 **Seq:** 1

Gender: U

Reported: 11/12/1995

Weight: 63.00

Hospitalisation:

Age:

Onset Date: 16/11/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|--|---|
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: Pain |
| Injection 15.0 Milligram | Daily Intravenous |
| Batch: | Started: 15/11/1995 Stopped: 17/11/1995 |
| TEMAZEPAM (Suspected) | Reason: |
| Oral application 20.0 Milligram | Daily Oral |
| Batch: | Started: 15/11/1995 Stopped: 15/11/1995 |
| RANITIDINE (Suspected) | Reason: |
| Oral application 150.0 Milligram | Daily Oral |
| Batch: | Started: 15/11/1995 Stopped: 15/11/1995 |

Laboratory Investigations:

Additional Information:

See original report for other drugs



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 105628 | Seq: 1 | Gender: F |
| Reported: 02/01/1996 | | Weight: 55.00 |
| Hospitalisation: | | Age: 22Y |
| Onset Date: 18/12/1995 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--|---------------------|
| Hypertonia | Severe | Mainly in back, neck, legs and abdomen | 7mg diazepam orally |

Medicine Details:

| | |
|-----------------------------------|---|
| BECONASE (Other drug) | Reason: Hay fever |
| Inhalation | 4.0 Dose Unspecified Daily Inhalation |
| Batch: | Started: 01/01/1980 Stopped: |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| | 10.0 Milligram As necessary |
| Batch: | Started: 17/12/1995 Stopped: 18/12/1995 |
| STEMETIL (Suspected) | Reason: Nausea and vomiting |
| Injection | 12.5 Milligram As necessary Intramuscular |
| Batch: | Started: 17/12/1995 Stopped: 18/12/1995 |
| Keflin Neutral (Suspected) | Reason: Othr diseases of urinary tract |
| | 4.0 Gram Daily |
| Batch: | Started: 17/12/1995 Stopped: 18/12/1995 |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 105693 **Seq:** 1 **Gender:** F
Reported: 04/01/1996 **Weight:**
Hospitalisation: **Age:** 0
Onset Date: 03/12/1995 **DOB:** 11/08/1995
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---------------|
| Oculogyration | | | Bentztropine. |

Medicine Details:

| | |
|---|---|
| PETHIDINE HYDROCHLORIDE (Other drug) | Reason: Pain |
| Injection 200.0 Milligram Daily Intravenous | |
| Batch: Started: 30/11/1995 Stopped: 06/12/1995 | |
| DOXYCYCLINE HYDROCHLORIDE (Other drug) | Reason: Female pelvic inflammatory dis |
| Oral application 200.0 Milligram Daily Oral | |
| Batch: Started: 30/11/1995 Stopped: | |
| METRONIDAZOLE (Other drug) | Reason: Female pelvic inflammatory dis |
| Injection 1.5 Gram Daily Intravenous | |
| Batch: Started: 30/11/1995 Stopped: | |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection 10.0 Milligram Daily Intravenous | |
| Batch: Started: 02/12/1995 Stopped: 03/12/1995 | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 105693

Seq: 1

Gender: F

Reported: 04/01/1996

Weight:

Hospitalisation:

Age: 0

Onset Date: 03/12/1995

DOB: 11/08/1995

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|-----------------------------|------------------------------------|
| MAXOLON (Suspected) | Reason: Nausea and vomiting |
| 40.0 Milligram | Daily |
| Batch: | Started: 30/11/1995 |
| | Stopped: 01/12/1995 |
| STEMETIL (Suspected) | Reason: Nausea and vomiting |
| Injection | 50.0 Milligram |
| | Daily |
| | Intramuscular |
| Batch: | Started: 01/12/1995 |
| | Stopped: 02/12/1995 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|---|---------------|--------------------------------------|
| Case Number: 105768 | Seq: 1 | Gender: M |
| Reported: 03/01/1996 | | Weight: |
| Hospitalisation: | | Age: 36Y |
| Onset Date: | | DOB: |
| Outcome: Recovered with sequelae | | Causality: Causality possible |

Reaction Details:

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

Medicine Details:

| | |
|--|--|
| DIAZEPAM (Suspected) | Reason: |
| Injection | 0.0 Intravenous |
| Batch: | Started: Stopped: |
| DROPERIDOL (Suspected) | Reason: |
| | 0.0 |
| Batch: | Started: Stopped: |
| TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) | Reason: Unspecified schizophrenia |
| | 50.0 Milligram Total |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:

Overdose with 50mg trifluoperazine



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 105919 **Seq:** 1 **Gender:** F
Reported: 18/01/1996 **Weight:**
Hospitalisation: **Age:** 22
Onset Date: 30/10/1995 **DOB:** 25/01/1973
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------------------|----------|--------------------|------------------|
| Agitation Anxiety Palpitations | | | Midazolam iv 2mg |

Medicine Details:

| | |
|--|---|
| DROPERIDOL (Suspected) | Reason: |
| Injection 2.5 Milligram | 1 time Intramuscular |
| Batch: | Started: 30/10/1995 Stopped: 30/10/1995 |
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: Other disturbance of sensation |
| Injection 100.0 Milligram | 1 time Intramuscular |
| Batch: | Started: 30/10/1995 Stopped: 30/10/1995 |
| BETAMETHASONE (Suspected) | Reason: |
| Injection 11.0 Milligram | 1 time Intramuscular |
| Batch: | Started: 30/10/1995 Stopped: 30/10/1995 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 108250 | Seq: 1 | Gender: F |
| Reported: 03/05/1996 | | Weight: |
| Hospitalisation: | | Age: |
| Onset Date: 20/03/1996 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

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

Medicine Details:

| | |
|---|---|
| PANCREASE (Other drug) | Reason: Acute pancreatitis |
| 20.0 Milligram | Daily |
| Batch: | Started: L TERM Stopped: |
| TEMAZE (Other drug) | Reason: |
| 10.0 Milligram | Daily |
| Batch: | Started: 19/03/1996 Stopped: |
| PANADEINE FORTE (Other drug) | Reason: Pain |
| 20.0 Milligram | Daily |
| Batch: | Started: 19/03/1996 Stopped: |
| GENTAMICIN SULPHATE (Other drug) | Reason: Unspecified septicemia |
| Oral application | 240.0 Milligram |
| | Daily |
| Batch: | Started: 19/03/1996 Stopped: 24/03/1996 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 108250
Reported: 03/05/1996

Seq: 1

Gender: F

Weight:

Hospitalisation:

Onset Date: 20/03/1996

Age:

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|--|---------------------------------------|----------------------------|---------------|
| AMOXYCILLIN SODIUM (Other drug) | Reason: Unspecified septicemia | | |
| Injection | 3.0 Gram | Daily | Intravenous |
| Batch: | Started: 19/03/1996 | Stopped: 25/03/1996 | |
| METRONIDAZOLE (Other drug) | Reason: Unspecified septicemia | | |
| Injection | 1.5 Gram | Daily | Intravenous |
| Batch: | Started: 19/03/1996 | Stopped: 25/03/1996 | |
| MORPHINE NOS (Other drug) | Reason: Pain | | |
| Injection | 60.0 Milligram | Daily | Intramuscular |
| Batch: | Started: 19/03/1996 | Stopped: 27/03/1996 | |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting | | |
| Injection | 15.0 Milligram | Daily | Intravenous |
| Batch: | Started: 20/03/1996 | Stopped: 21/03/1996 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 108350 | Seq: 1 | Gender: F |
| Reported: 08/05/1996 | | Weight: |
| Hospitalisation: | | Age: 48Y |
| Onset Date: 12/04/1996 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|--------------------|-----------|
| Bronchospasm | | | |
| Flushing | | | |
| Lacrimal disorder | | | |
| Periorbital oedema | | | |

Medicine Details:

| | |
|------------------------------------|---|
| HEPARIN SODIUM (Other drug) | Reason: |
| Injection | 0.0 Thousand Internal 5 times Subcutaneous |
| Batch: | Started: 10/04/1996 Stopped: |
| ZANTAC (Other drug) | Reason: |
| Tablet | 150.0 Milligram 1 time Oral |
| Batch: | Started: 08/04/1996 Stopped: |
| ATROPINE (Other drug) | Reason: Otr&nos disord of heart rhythm |
| | 600.0 Microgram 1 time |
| Batch: | Started: 09/04/1996 Stopped: |
| MEFOXIN (Other drug) | Reason: |
| Injection | 4.0 Gram Total Intravenous |
| Batch: | Started: 09/04/1996 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 108350
Reported: 08/05/1996
Hospitalisation:
Onset Date: 12/04/1996
Outcome: Recovered

Seq: 1

Gender: F
Weight:
Age: 48Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|---------------------------------|--|
| EPHEDRINE (Other drug) | Reason: Hypotension |
| Injection | 12.0 Milligram Total Intravenous |
| Batch: | Started: 10/04/1996 Stopped: |
| MORPHINE NOS (Suspected) | Reason: |
| | 2.0 Milligram 1 time |
| Batch: | Started: 12/04/1996 Stopped: |
| DROPERIDOL (Suspected) | Reason: |
| | 83.0 Microgram 1 time |
| Batch: | Started: 12/04/1996 Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 108934 | Seq: 1 | Gender: F |
| Reported: 03/06/1996 | | Weight: |
| Hospitalisation: | | Age: 23Y |
| Onset Date: | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------------|----------|----------------------------|-----------|
| Oculogyration | | Eyes rolling up | |
| Hypertonia | | Rigidity and spasms in leg | |
| Abdominal pain | | | |
| Bronchospasm | | | |
| Dyspnoea | | | |
| Dystonia | | | |
| Extrapyramidal disorder | | | |
| Neuroleptic malignant syndrome | | | |
| Paraesthesia | | | |
| Tachycardia | | | |

Medicine Details:

| | |
|--|---|
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: Pain |
| 200.0 Milligram | Total |
| Batch: | Started: 29/11/1995 Stopped: 30/11/1995 |
| DROLEPTAN (Suspected) | Reason: Nausea and vomiting |
| 10.0 Milligram | Daily |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient known as 'vomiter'.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 109165 | Seq: 1 | Gender: F |
| Reported: 17/06/1996 | | Weight: 97.00 |
| Hospitalisation: | | Age: 43 |
| Onset Date: 28/05/1996 | | DOB: 15/03/1953 |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------|-------------|
| Drug ineffective Nausea Vomiting | | | Ondansetron |

Medicine Details:

| | | |
|-------------------------------------|-----------------|----------|
| ISOFLURANE (Suspected) | 0.0 | Reason: |
| Batch: | Started: | Stopped: |
| FENTANYL CITRATE (Suspected) | 100.0 Milligram | 1 time |
| Batch: | Started: | Stopped: |
| DROPERIDOL (Suspected) | 500.0 Microgram | 1 time |
| Batch: | Started: | Stopped: |
| PETHIDINE HYDROCHLORIDE (Suspected) | 75.0 Milligram | 1 time |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 109165

Seq: 1

Gender: F

Reported: 17/06/1996

Weight: 97.00

Hospitalisation:

Age: 43

Onset Date: 28/05/1996

DOB: 15/03/1953

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|---------------------------------------|---------------------------------|
| MAXOLON (Suspected) | Reason: |
| 10.0 Milligram | 1 time |
| Batch: | Started: Stopped: |
| DIPRIVAN (Suspected) | Reason: |
| 200.0 Milligram | 1 time |
| Batch: | Started: Stopped: |
| VECURONIUM BROMIDE (Suspected) | Reason: |
| 5.0 Milligram | 1 time |
| Batch: | Started: Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 109297 **Seq:** 1 **Gender:** F
Reported: 17/06/1996 **Weight:** 58.00
Hospitalisation: **Age:** 36
Onset Date: 23/05/1996 **DOB:** 28/10/1959
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-------------------|
| Nausea | | | Maxolon, stemetil |

Medicine Details:

| | |
|---------------------------------------|---|
| FENTANYL CITRATE (Suspected) | Reason: Other disturbance of sensation |
| 0.0 | |
| Batch: | Started: 23/05/1996 Stopped: 23/05/1996 |
| VECURONIUM BROMIDE (Suspected) | Reason: Other disturbance of sensation |
| 0.0 | |
| Batch: | Started: 23/05/1996 Stopped: 23/05/1996 |
| ISOFLURANE (Suspected) | Reason: Other disturbance of sensation |
| 0.0 | |
| Batch: | Started: 23/05/1996 Stopped: 23/05/1996 |
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| 2.5 Milligram 1 time | |
| Batch: | Started: 23/05/1996 Stopped: 23/05/1996 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 109297

Seq: 1

Gender: F

Reported: 17/06/1996

Weight: 58.00

Hospitalisation:

Age: 36

Onset Date: 23/05/1996

DOB: 28/10/1959

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

PETHIDINE HYDROCHLORIDE (Suspected)

Reason: Pain

50.0 Milligram

1 time

Batch:

Started: 23/05/1996

Stopped: 23/05/1996

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 109309

Seq: 1

Gender: F

Reported: 17/06/1996

Weight: 81.00

Hospitalisation:

Onset Date: 20/05/1996

Age: 58

Outcome: Recovered

DOB: 02/04/1938

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Headache | | | |
| Nausea | | | Maxolon |

Medicine Details:

| | | |
|-------------------------------------|----------------------------|---|
| ISOFLURANE (Suspected) | | Reason: Other disturbance of sensation |
| | 0.0 | |
| Batch: | Started: 20/05/1996 | Stopped: 20/05/1996 |
| FENTANYL CITRATE (Suspected) | | Reason: Other disturbance of sensation |
| Injection | 100.0 Milligram | 1 time Intravenous |
| Batch: | Started: 20/05/1996 | Stopped: 20/05/1996 |
| OMNOPON (Suspected) | | Reason: Other disturbance of sensation |
| Injection | 20.0 Milligram | 1 time Intramuscular |
| Batch: | Started: 20/05/1996 | Stopped: 20/05/1996 |
| DIPRIVAN (Suspected) | | Reason: Other disturbance of sensation |
| Injection | 200.0 Milligram | 1 time Intravenous |
| Batch: | Started: 20/05/1996 | Stopped: 20/05/1996 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 109309

Seq: 1

Gender: F

Reported: 17/06/1996

Weight: 81.00

Hospitalisation:

Age: 58

Onset Date: 20/05/1996

DOB: 02/04/1938

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|-------------------------------|---|----------------------------|-------------|
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 5.0 Milligram | Daily | Intravenous |
| Batch: | Started: 20/05/1996 | Stopped: 20/05/1996 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 109310 **Seq:** 1 **Gender:** F
Reported: 17/06/1996 **Weight:** 71.00
Hospitalisation: **Age:** 64
Onset Date: 20/05/1996 **DOB:** 14/10/1931
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Nausea | | | Maxolon |

Medicine Details:

| | | |
|-------------------------------------|----------------------------|---|
| ISOFLURANE (Suspected) | | Reason: Other disturbance of sensation |
| | 0.0 | |
| Batch: | Started: 20/05/1996 | Stopped: 20/05/1996 |
| FENTANYL CITRATE (Suspected) | | Reason: Other disturbance of sensation |
| Injection | 100.0 Milligram | 1 time Intravenous |
| Batch: | Started: 20/05/1996 | Stopped: |
| DROPERIDOL (Suspected) | | Reason: Other disturbance of sensation |
| Injection | 2.5 Milligram | 1 time Intravenous |
| Batch: | Started: 20/05/1996 | Stopped: 20/05/1996 |
| DIPRIVAN (Suspected) | | Reason: Other disturbance of sensation |
| Injection | 200.0 Milligram | 1 time Intravenous |
| Batch: | Started: 20/05/1996 | Stopped: 20/05/1996 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 109310 **Seq:** 1
Reported: 17/06/1996

Gender: F
Weight: 71.00

Hospitalisation:

Onset Date: 20/05/1996
Outcome: Not yet recovered

Age: 64
DOB: 14/10/1931
Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|--|---|----------------------------|-------------|
| SUXAMETHONIUM BROMIDE (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 50.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 20/05/1996 | Stopped: 20/05/1996 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 109720 **Seq:** 1 **Gender:** M
Reported: 04/07/1996 **Weight:**
Hospitalisation: **Age:** 12
Onset Date: 14/06/1996 **DOB:** 24/04/1984
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---------------------------------|
| Dystonia | | Jaw tightness | Benztropine 0.7mg ivi stat only |
| Hypertonia | | Neck stiffness | |

Medicine Details:

| | | | |
|---|---|--|----------------------------|
| BISACODYL (Other drug) Suppository Batch: | 5.0 Milligram Started: 11/06/1996 | Reason: 1 time Rectal | Stopped: |
| IBUPROFEN (Other drug) Batch: | 200.0 Milligram Started: 11/06/1996 | Reason: Pain As necessary | Stopped: CONTIN |
| CEFACLOR MONOHYDRATE (Other drug) Batch: | 750.0 Milligram Started: 11/06/1996 | Reason: Daily | Stopped: 14/06/1996 |
| DROPERIDOL (Suspected) Injection, intravenous infusion Batch: | 0.0 Started: 13/06/1996 | Reason: Pain As necessary Intravenous | Stopped: 14/06/1996 |

Laboratory Investigations:

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

Additional Information:

Droperidol 5mg into pca with morphine 60mg 1mg/ml. see original report for other drugs.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 109720

Seq: 1

Gender: M

Reported: 04/07/1996

Weight:

Hospitalisation:

Age: 12

Onset Date: 14/06/1996

DOB: 24/04/1984

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|--------------------------------------|---|
| MORPHINE NOS (Suspected) | Reason: |
| Injection, intravenous infusion | 0.0 As necessary Intravenous |
| Batch: | Started: Stopped: |
| CEPHAZOLIN SODIUM (Suspected) | Reason: |
| Injection | 1.5 Gram Daily Intravenous |
| Batch: | Started: 13/06/1996 Stopped: 2D |

Laboratory Investigations:

Additional Information:

Droperidol 5mg into pca with morphine 60mg 1mg/ml. see original report for other drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 109798

Seq: 1

Gender: U

Reported: 05/07/1996

Weight: 72.00

Hospitalisation:

Onset Date: 16/12/1995

Age:

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|--------------------|-----------|
| Dizziness | | | |
| Visual disturbance | | | |

Medicine Details:

| | |
|------------------------------------|---|
| PANADOL (Other drug) | Reason: Other disturbance of sensation |
| Oral application | 2.0 Dose Unspecified Daily Oral |
| Batch: | Started: 14/12/1995 Stopped: |
| PANADEINE FORTE (Suspected) | Reason: Other disturbance of sensation |
| Tablet | 2.0 Dose Unspecified As necessary Oral |
| Batch: | Started: 15/12/1995 Stopped: 16/12/1995 |
| MAXOLON (Suspected) | Reason: |
| Injection | 10.0 Milligram As necessary Intramuscular |
| Batch: | Started: Stopped: |
| PREMARIN (Suspected) | Reason: Menopausal symptoms |
| Tablet | 625.0 Microgram Daily Oral |
| Batch: | Started: 16/12/1995 Stopped: 17/12/1995 |

Laboratory Investigations:

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

Additional Information:

Premarin recommenced on 18/12/95 without any further dizziness or blurred vision.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 109798

Seq: 1

Gender: U

Reported: 05/07/1996

Weight: 72.00

Hospitalisation:

Age:

Onset Date: 16/12/1995

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|--|------------------------------------|
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: |
| 20.0 Milligram | Daily |
| Batch: | Started: 13/12/1995 |
| | Stopped: 15/12/1995 |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection | 3.0 Milligram |
| | Daily |
| | Intramuscular |
| Batch: | Started: 14/12/1995 |
| | Stopped: 15/12/1995 |

Laboratory Investigations:

Additional Information:

Premarin recommenced on 18/12/95 without any further dizziness or blurred vision.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 110509 **Seq:** 1 **Gender:** F
Reported: 06/08/1996 **Weight:** 100.00
Hospitalisation: **Age:** 38Y
Onset Date: 30/07/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--------------------|---------------------------------------|
| Pruritus | | | Promethazine 25mg imi six hourly prn. |
| Rash erythematous | | | |

Medicine Details:

| | |
|---------------------------------|---|
| DROLEPTAN (Suspected) | Reason: Nausea and vomiting |
| Injection | 2.5 Milligram As necessary Intramuscular |
| Batch: | Started: 30/07/1996 Stopped: |
| PANADEINE (Suspected) | Reason: Pain |
| | 2.0 Dose Unspecified As necessary |
| Batch: | Started: 30/07/1996 Stopped: |
| FORTRAL (Suspected) | Reason: Pain |
| | 45.0 Milligram As necessary |
| Batch: | Started: 30/07/1996 Stopped: |
| PAPAVERETUM (Suspected) | Reason: Pain |
| Injection, intravenous infusion | 4.0 Milligram Per hour Intravenous |
| Batch: | Started: 30/07/1996 Stopped: 30/07/1996 |

Laboratory Investigations:

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

Additional Information:

Patient has previous allergy to pethidine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 110509

Seq: 1

Gender: F

Reported: 06/08/1996

Weight: 100.00

Hospitalisation:

Age: 38Y

Onset Date: 30/07/1996

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|-----------------------------|------------------------------------|-----------------|--------|
| NAPROSYN (Suspected) | Reason: Pain | | |
| Suppository | 1.0 Gram | Daily | Rectal |
| Batch: | Started: 30/07/1996 | Stopped: | |
| ESTIGYN (Suspected) | Reason: Menopausal symptoms | | |
| | 20.0 Microgram | Daily | |
| Batch: | Started: 30/07/1996 | Stopped: | |

Laboratory Investigations:

Additional Information:

Patient has previous allergy to pethidine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 110815 **Seq:** 1 **Gender:** M
Reported: 13/08/1996 **Weight:** 80.00
Hospitalisation: **Age:** 57
Onset Date: 29/07/1996 **DOB:** 31/10/1938
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---------------------------|
| Vomiting | | Post-op emesis | Maxolon 10mg im at 5:10pm |

Medicine Details:

| | |
|-------------------------------------|---|
| OMNOPON (Suspected) | Reason: Pain |
| Injection 20.0 Milligram | 1 time Intramuscular |
| Batch: | Started: 29/07/1996 Stopped: |
| DIPRIVAN (Suspected) | Reason: Other disturbance of sensation |
| Injection 200.0 Milligram | 1 time Intravenous |
| Batch: | Started: 29/07/1996 Stopped: |
| FENTANYL CITRATE (Suspected) | Reason: Other disturbance of sensation |
| Injection 100.0 Microgram | 1 time Intravenous |
| Batch: | Started: 29/07/1996 Stopped: |
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| Injection 5.0 Milligram | 1 time Intravenous |
| Batch: | Started: 29/07/1996 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|--|---------------|--------------------------------------|
| Case Number: 110818 | Seq: 1 | Gender: F |
| Reported: 13/08/1996 | | Weight: 90.00 |
| Hospitalisation: Admitted to hospital | | Age: 53 |
| Onset Date: 24/07/1996 | | DOB: 04/10/1942 |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------------------|----------|--------------------|-----------|
| Nausea Pain Vomiting | | Post-op nausea | |

Medicine Details:

| | | | |
|--|----------------------------|---|---------------|
| PETHIDINE HYDROCHLORIDE (Suspected) | | Reason: | |
| Injection | 100.0 Milligram | 2 times | Intramuscular |
| Batch: | Started: 24/07/1996 | Stopped: | |
| MAXOLON (Suspected) | | Reason: | |
| Injection | 10.0 Milligram | 2 times | Intramuscular |
| Batch: | Started: 24/07/1996 | Stopped: | |
| THIOPENTONE SODIUM (Suspected) | | Reason: Other disturbance of sensation | |
| Injection | 300.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 24/07/1996 | Stopped: | |
| FENTANYL CITRATE (Suspected) | | Reason: Other disturbance of sensation | |
| Injection | 100.0 Microgram | 1 time | Intravenous |
| Batch: | Started: 24/07/1996 | Stopped: | |

Laboratory Investigations:

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

Additional Information:

See original report for other drugs



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 110818 **Seq:** 1 **Gender:** F
Reported: 13/08/1996 **Weight:** 90.00
Hospitalisation: Admitted to hospital **Age:** 53
Onset Date: 24/07/1996 **DOB:** 04/10/1942
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

| | |
|---|---|
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| Injection 1.5 Milligram 1 time Intravenous | |
| Batch: | Started: 24/07/1996 Stopped: |
| ATROPINE (Suspected) | Reason: Other disturbance of sensation |
| Injection 1.2 Milligram 1 time Intravenous | |
| Batch: | Started: 24/07/1996 Stopped: |

Laboratory Investigations:

Additional Information:

See original report for other drugs



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 110827 | Seq: 1 | Gender: F |
| Reported: 13/07/1996 | | Weight: 63.00 |
| Hospitalisation: | | Age: 36 |
| Onset Date: 10/07/1996 | | DOB: 14/08/1959 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--------------------------|
| Nausea | | Post-op nausea | Maxolon 10mg imi 10:20am |

Medicine Details:

| | |
|-------------------------------------|---|
| NEOSTIGMINE NOS (Other drug) | Reason: Other disturbance of sensation |
| 2.5 Milligram | 1 time |
| Batch: | Started: 10/07/1996 Stopped: |
| ATROPINE (Other drug) | Reason: Other disturbance of sensation |
| 1.0 Milligram | 1 time |
| Batch: | Started: 10/07/1996 Stopped: |
| NITROUS OXIDE (Other drug) | Reason: |
| 1.0 Dose Unspecified | 1 time |
| Batch: | Started: Stopped: |
| FENTANYL CITRATE (Suspected) | Reason: Other disturbance of sensation |
| Injection | 100.0 Microgram |
| | 1 time |
| | Intravenous |
| Batch: | Started: 10/07/1996 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 110827
Reported: 13/07/1996
Hospitalisation:
Onset Date: 10/07/1996
Outcome: Recovered

Seq: 1

Gender: F
Weight: 63.00
Age: 36
DOB: 14/08/1959
Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|---------------------------------------|---|-----------------|-------------|
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 500.0 Microgram | 1 time | Intravenous |
| Batch: | Started: 10/07/1996 | Stopped: | |
| DIPRIVAN (Suspected) | Reason: Other disturbance of sensation | | |
| | 150.0 Milligram | 1 time | |
| Batch: | Started: 10/07/1996 | Stopped: | |
| VECURONIUM BROMIDE (Suspected) | Reason: Other disturbance of sensation | | |
| | 4.0 Milligram | 1 time | |
| Batch: | Started: 10/07/1996 | Stopped: | |
| ISOFLURANE (Suspected) | Reason: Other disturbance of sensation | | |
| | 0.0 | 1 time | |
| Batch: | Started: 10/07/1996 | Stopped: | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 110827

Seq: 1

Gender: F

Reported: 13/07/1996

Weight: 63.00

Hospitalisation:

Age: 36

Onset Date: 10/07/1996

DOB: 14/08/1959

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

PETHIDINE HYDROCHLORIDE (Suspected)

Reason: Pain

Injection

100.0 Milligram

Total

Intramuscular

Batch:

Started: 10/07/1996

Stopped: 10/07/1996

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 110832

Seq: 1

Gender: F

Reported: 13/08/1996

Weight: 54.00

Hospitalisation:

Age: 36Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Dizziness | | | |
| Nausea | | | |
| Somnolence | | | |

Medicine Details:

| | |
|-------------------------------------|---|
| FENTANYL CITRATE (Suspected) | Reason: Other disturbance of sensation |
| 100.0 Microgram | 1 time |
| Batch: | Started: 01/09/1995 Stopped: |
| PROPOFOL (Suspected) | Reason: Other disturbance of sensation |
| 200.0 Milligram | 1 time |
| Batch: | Started: 01/09/1995 Stopped: |
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| 2.0 Milligram | 1 time |
| Batch: | Started: 01/09/1995 Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|--|
| | Immunology | | | | Skin tests done and show reactivity to droperidol. |

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.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 110914 **Seq:** 1 **Gender:** U
Reported: 16/08/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: 13/08/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|-------------------------------|--------------------------------------|
| Dystonia | | Unable to speak, jaw "locked" | iv cogentin 1.5ml, iv midazolam 3mg, |
| Torticollis | | | |

Medicine Details:

| | |
|---|-------------------------------------|
| PETHIDINE HYDROCHLORIDE (Other drug) | Reason: Pain |
| Injection 75.0 Milligram As necessary Intramuscular | |
| Batch: Started: 09/08/1996 Stopped: CONTIN | |
| PANADEINE FORTE (Other drug) | Reason: Pain |
| 1.0 Dose Unspecified As necessary | |
| Batch: Started: 11/08/1996 Stopped: CONTIN | |
| FLAGYL (Other drug) | Reason: Gastritis&duodenitis |
| Suppository 2.0 Gram Daily Rectal | |
| Batch: Started: 12/08/1996 Stopped: 13/08/1996 | |
| BUSCOPAN (Other drug) | Reason: Pain |
| Injection 60.0 Milligram Daily Intramuscular | |
| Batch: Started: 09/08/1996 Stopped: CONTIN | |

Laboratory Investigations:

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

Additional Information:

One previous dose of droperidol 12/8/96 with no reaction observed.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 110914

Seq: 1

Gender: U

Reported: 16/08/1996

Weight:

Hospitalisation:

Age:

Onset Date: 13/08/1996

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|-------------------------------|------------------------------------|-----------------|---------------|
| MAXOLON (Other drug) | Reason: Nausea and vomiting | | |
| Injection | 40.0 Milligram | Daily | Intramuscular |
| Batch: | Started: 09/08/1996 | Stopped: | CONTIN |
| DROPERIDOL (Suspected) | Reason: | | |
| Injection | 5.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 13/08/1996 | Stopped: | |

Laboratory Investigations:

Additional Information:

One previous dose of droperidol 12/8/96 with no reaction observed.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 110992 | Seq: 1 | Gender: F |
| Reported: 20/08/1996 | | Weight: 65.00 |
| Hospitalisation: | | Age: 26Y |
| Onset Date: 13/08/1996 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|---|----------------------|
| Dystonia | | Locked jaw unable to open mouth + neck stiffness. | Cogentin, midazolam. |
| Extrapyramidal disorder | | | |

Medicine Details:

| | |
|--|---|
| BUSCOPAN (Other drug) | Reason: Abdominal pain |
| 80.0 Milligram | Total |
| Batch: | Started: 09/08/1996 Stopped: 12/08/1996 |
| STEMETIL (Suspected) | Reason: Nausea and vomiting |
| 1.0 Dose Unspecified | 1 time |
| Batch: | Started: Stopped: |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| 10.0 Milligram | Total |
| Batch: | Started: 12/08/1996 Stopped: 13/08/1996 |
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: Pain |
| 75.0 Milligram | As necessary |
| Batch: | Started: 09/08/1996 Stopped: 13/08/1996 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 110992
Reported: 20/08/1996

Seq: 1

Gender: F
Weight: 65.00

Hospitalisation:

Onset Date: 13/08/1996
Outcome: Recovered

Age: 26Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|------------------------------------|---|
| PANADEINE (Suspected) | Reason: Pain |
| | 1.0 Dose Unspecified As necessary |
| Batch: | Started: 11/08/1996 Stopped: 13/08/1996 |
| PANADEINE FORTE (Suspected) | Reason: Pain |
| | 2.0 Dose Unspecified As necessary |
| Batch: | Started: 12/08/1996 Stopped: 15/08/1996 |
| MAXOLON (Suspected) | Reason: Nausea and vomiting |
| | 40.0 Milligram Daily |
| Batch: | Started: 09/08/1996 Stopped: 12/08/1996 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 112232 | Seq: 1 | Gender: F |
| Reported: 14/10/1996 | | Weight: |
| Hospitalisation: | | Age: 44Y |
| Onset Date: 01/10/1996 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---------------|
| Dystonia | | | Bentztropine. |

Medicine Details:

| | |
|---|---|
| TEMAZEPAM (Other drug) | Reason: |
| Oral application | 10.0 Milligram As necessary Oral |
| Batch: | Started: 26/09/1996 Stopped: 02/10/1996 |
| SEREVENT (Other drug) | Reason: Asthma |
| Inhalation | 2.0 Dose Unspecified As necessary Inhalation |
| Batch: | Started: Stopped: |
| VENTOLIN (Other drug) | Reason: Asthma |
| | 20.0 Milligram Daily |
| Batch: | Started: 26/09/1996 Stopped: 02/10/1996 |
| ONDANSETRON HYDROCHLORIDE DIHYDRATE (Other drug) | Reason: Nausea and vomiting |
| Injection | 16.0 Milligram Daily Intravenous |
| Batch: | Started: 26/09/1996 Stopped: 02/10/1996 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 112232
Reported: 14/10/1996
Hospitalisation:
Onset Date: 01/10/1996
Outcome: Recovered

Seq: 1

Gender: F
Weight:
Age: 44Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|------------------------------------|---|
| HEPARIN SODIUM (Other drug) | Reason: Other prophylactic procedures |
| Injection | 10.0 Thousand Internal Daily Subcutaneous |
| Batch: | Started: 26/09/1996 Stopped: 02/10/1996 |
| THEO-DUR (Other drug) | Reason: Asthma |
| Tablet | 600.0 Milligram Daily Oral |
| Batch: | Started: Stopped: |
| PREDNISONE (Other drug) | Reason: Asthma |
| Oral application | 10.0 Milligram Daily Oral |
| Batch: | Started: Stopped: |
| ROCALTROL (Other drug) | Reason: |
| Capsule | 250.0 Microgram Daily Oral |
| Batch: | Started: Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 112232
Reported: 14/10/1996
Hospitalisation:
Onset Date: 01/10/1996
Outcome: Recovered

Seq: 1

Gender: F
Weight:
Age: 44Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|-------------------------------|---------------------------------------|
| FLIXOTIDE (Other drug) | Reason: Asthma |
| Inhalation | 2.0 Dose Unspecified Daily Inhalation |
| Batch: | Started: Stopped: |
| CAPADEX (Other drug) | Reason: |
| Capsule | 8.0 Dose Unspecified Daily Oral |
| Batch: | Started: Stopped: |
| DROPERIDOL (Suspected) | Reason: |
| Injection | 2.5 Milligram 1 time Intravenous |
| Batch: | Started: Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 112341 | Seq: 1 | Gender: F |
| Reported: 17/10/1996 | | Weight: |
| Hospitalisation: | | Age: 45Y |
| Onset Date: 09/10/1995 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|----------------------------|-----------|
| Paraesthesia | | Tingles in hands and toes. | |

Medicine Details:

| | | |
|--|----------------------------|-----------------|
| MIDAZOLAM (Suspected) | Reason: | 0.0 |
| Batch: | Started: 09/10/1995 | Stopped: |
| FENTANYL CITRATE (Suspected) | Reason: | 0.0 |
| Batch: | Started: 09/10/1995 | Stopped: |
| DROPERIDOL (Suspected) | Reason: | 0.0 |
| Batch: | Started: 09/10/1995 | Stopped: |
| METOCLOPRAMIDE HYDROCHLORIDE (Suspected) | Reason: | 0.0 |
| Batch: | Started: 09/10/1995 | Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|-------------------------------|
| | Other data | | | | All tests and mri scan normal |

Additional Information:

Reaction started when patient woke from anaesthetic.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 112341 **Seq:** 1
Reported: 17/10/1996

Gender: F

Weight:

Hospitalisation:

Age: 45Y

Onset Date: 09/10/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|--|--|
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: 09/10/1995 Stopped: |
| TRACRIUM INJECTABLE (Suspected) | Reason: |
| 35.0 Milligram | Total |
| Batch: | Started: 09/10/1995 Stopped: |

Laboratory Investigations:

Additional Information:

Reaction started when patient woke from anaesthetic.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 112803 | Seq: 1 | Gender: M |
| Reported: 01/11/1996 | | Weight: |
| Hospitalisation: | | Age: 8 |
| Onset Date: 05/10/1994 | | DOB: 06/11/1985 |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|-------------------------------------|--------------------|
| Rash erythematous | | Spreading red areas chest/neck/face | Cepahazolin ceased |

Medicine Details:

| | | |
|---------------------------------|----------|-----------------------|
| MIDAZOLAM (Suspected) | 0.0 | Reason: Premedication |
| Batch: | Started: | Stopped: |
| THIOPENTONE SODIUM (Suspected) | 0.0 | Reason: |
| Batch: | Started: | Stopped: |
| ATRACURIUM BESYLATE (Suspected) | 0.0 | Reason: |
| Batch: | Started: | Stopped: |
| MORPHINE NOS (Suspected) | 0.0 | Reason: |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 112803

Seq: 1

Gender: M

Reported: 01/11/1996

Weight:

Hospitalisation:

Age: 8

Onset Date: 05/10/1994

DOB: 06/11/1985

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|--------------------------------------|----------------------------|----------------------------|-------------|
| DROPERIDOL (Suspected) | | Reason: | |
| | 0.0 | | |
| Batch: | Started: | Stopped: | |
| CEPHAZOLIN SODIUM (Suspected) | | Reason: | |
| Injection | 500.0 Milligram | 2 times | Intravenous |
| Batch: | Started: 05/10/1994 | Stopped: 06/10/1994 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 113748 | Seq: 1 | Gender: F |
| Reported: 06/12/1996 | | Weight: 50.00 |
| Hospitalisation: | | Age: 62Y |
| Onset Date: | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|--------------------|-----------|
| Coma | | | |
| Grand mal convulsion | | | |

Medicine Details:

| | | |
|-------------------------------------|-----------------|-----------------|
| NAROPIN (Suspected) | Reason: | |
| 400.0 Milligram | 1 time | |
| Batch: | Started: | Stopped: |
| MIDAZOLAM (Suspected) | Reason: | |
| Injection 1.0 Milligram | 1 time | Intravenous |
| Batch: | Started: | Stopped: |
| FENTANYL CITRATE (Suspected) | Reason: | |
| Injection 50.0 Microgram | 1 time | Intravenous |
| Batch: | Started: | Stopped: |
| DROPERIDOL (Suspected) | Reason: | |
| Injection 5.0 Milligram | 1 time | Intravenous |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 113947 **Seq:** 1 **Gender:** M
Reported: 16/12/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

| | | | |
|-------------------------------|-----------------|-----------------|----|
| DROPERIDOL (Suspected) | Reason: | | |
| 0.0 | | | |
| Batch: | Started: | Stopped: | 5D |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 113968 | Seq: 1 | Gender: F |
| Reported: 16/12/1996 | | Weight: 62.00 |
| Hospitalisation: | | Age: 22Y |
| Onset Date: 04/09/1996 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|---|---|
| Hypoxia Shock | | Oxygen saturation dropped to about 60 Peripheral circulatory failure | Ceased minomycin; resuscitation; iv fluids (haemaccel); iv ephedrine 10mg; iv adrenaline 1:1000 diluted to 10ml - 5ml given; iv dexamethasone 4mg; iv lignocaine 50mg |
| Extrasystoles Ventricular tachycardia | | | |

Medicine Details:

| | | |
|-------------------------------------|----------------------------|-----------------|
| INDOCID (Suspected) | Reason: | |
| Suppository | 0.0 | Rectal |
| Batch: | Started: | Stopped: |
| PROPOFOL (Suspected) | Reason: Surgery | |
| | 130.0 Milligram | 1 time |
| Batch: | Started: | Stopped: |
| FENTANYL CITRATE (Suspected) | Reason: Surgery | |
| | 100.0 Microgram | 1 time |
| Batch: | Started: 04/09/1996 | Stopped: |
| DROPERIDOL (Suspected) | Reason: Surgery | |
| | 2.5 Milligram | 1 time |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:

Minomycin 100mg in 500mls of normal saline over 1/2 hour.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 113968
Reported: 16/12/1996

Seq: 1

Gender: F
Weight: 62.00

Hospitalisation:

Onset Date: 04/09/1996
Outcome: Recovered

Age: 22Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|--|--|
| ATRACURIUM BESYLATE (Suspected) | Reason: Surgery |
| 30.0 Milligram | 1 time |
| Batch: | Started: 04/09/1996 Stopped: |
| MINOMYCIN (Suspected) | Reason: |
| Injection, intravenous infusion | 100.0 Milligram Total Intravenous |
| Batch: | Started: 04/09/1996 Stopped: |

Laboratory Investigations:

Additional Information:

Minomycin 100mg in 500mls of normal saline over 1/2 hour.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 113992 | Seq: 1 | Gender: M |
| Reported: 18/12/1996 | | Weight: 71.00 |
| Hospitalisation: | | Age: 16Y |
| Onset Date: 21/11/1996 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------------------|----------|------------------------|-----------|
| Oculogyration Diplopia Tremor | | Upper rotation of eyes | |

Medicine Details:

| | | | |
|---------------------------------|----------------------------|------------------------------------|-------------|
| ZOFRAN (Suspected) | | Reason: | |
| Injection | 4.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 21/11/1996 | Stopped: | |
| DROLEPTAN (Suspected) | | Reason: Nausea and vomiting | |
| Injection, intravenous infusion | 5.0 Milligram | Total | Intravenous |
| Batch: | Started: 20/11/1996 | Stopped: 21/11/1996 | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 114424 | Seq: 1 | Gender: F |
| Reported: 08/01/1997 | | Weight: 65.00 |
| Hospitalisation: | | Age: 19Y |
| Onset Date: 25/08/1996 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------------------------|-------------------------------------|
| Extrapyramidal disorder | | Extrapyramidal disorder | Benztropine 2mg 9v 2230 25/8/96. |
| Rash maculo-papular | | Maculo-papular rash on neck and back | |

Medicine Details:

| | |
|------------------------------|---|
| PANADOL (Other drug) | Reason: |
| 0.0 | |
| Batch: | Started: Stopped: |
| ATIVAN (Other drug) | Reason: |
| Tablet | 1.0 Milligram As necessary Sublingual |
| Batch: | Started: Stopped: |
| ZYCLIR (Other drug) | Reason: |
| Injection | 750.0 Milligram Daily Intravenous |
| Batch: | Started: 16/08/1996 Stopped: |
| DIFLUCAN (Other drug) | Reason: Prophylaxis |
| Injection | 400.0 Milligram Daily Intravenous |
| Batch: | Started: 16/08/1996 Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 114424

Seq: 1

Gender: F

Reported: 08/01/1997

Weight: 65.00

Hospitalisation:

Age: 19Y

Onset Date: 25/08/1996

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| STEMETIL (Suspected) | | Reason: | |
|----------------------|----------------------------|-----------------|-------------|
| Injection | 12.5 Milligram | 2 times | Intravenous |
| Batch: | Started: 24/08/1996 | Stopped: | 25/08/1996 |

| DROLEPTAN (Suspected) | | Reason: | |
|-----------------------|----------------------------|-----------------|-------------|
| Injection | 2.5 Milligram | 1 time | Intravenous |
| Batch: | Started: 19/08/1996 | Stopped: | 25/08/1996 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 115265 **Seq:** 1 **Gender:** F
Reported: 14/02/1997 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: 25/07/1996 **DOB:** 07/02/1970
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---|
| Angioedema | | | Adrenaline, hydrocortisone, ventilated, intubated, paralysed & o/night icu. |

Medicine Details:

| | |
|--|------------------------------------|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection 2.5 Milligram 1 time Intramuscular | |
| Batch: Started: Stopped: | |
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: Pain |
| Injection 75.0 Milligram 1 time Intramuscular | |
| Batch: Started: Stopped: | |
| TRIMETHOPRIM (Suspected) | Reason: |
| Oral application 300.0 Milligram 1 time Oral | |
| Batch: Started: 25/07/1996 Stopped: | |

Laboratory Investigations:

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

Additional Information:

Previous history of dystonic reactions to metaclopramide, promethazine and prochlorperizine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 115266 **Seq:** 1 **Gender:** F
Reported: 14/02/1997 **Weight:**
Hospitalisation: **Age:** 24
Onset Date: 07/03/1995 **DOB:** 24/10/1970
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--|
| Oculogyration | | | Benztropine 2mg im, droperidol ceased. |

Medicine Details:

| | |
|-------------------------------|--|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection | 2.0 Milligram Total Intravenous |
| Batch: | Started: 07/03/1995 Stopped: |

Laboratory Investigations:

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

Additional Information:

Reaction occurred 165 minutes after receiving second dose. has had similar reactions to metoclopramide and prochlorperazine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 116853

Seq: 1

Gender: F

Reported: 18/04/1997

Weight: 12.00

Hospitalisation:

Age: 3Y

Onset Date: 10/04/1997

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--------------------------|
| Oculogyration | | | Benztropine 0.25mg im bd |

Medicine Details:

| | | | |
|--|---|-----------------|---------------|
| DROPERIDOL (Suspected) | Reason: Pain | | |
| Injection | 3.6 Milligram | Total | Intramuscular |
| Batch: | Started: 02/04/1997 | Stopped: | 10/04/1997 |
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 12.5 Milligram | Daily | Intravenous |
| Batch: | Started: 10/04/1997 | Stopped: | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 116915
Reported: 18/04/1997

Seq: 1

Gender: M
Weight: 31.00

Hospitalisation:

Onset Date: 21/03/1997
Outcome: Recovered

Age: 8Y
DOB:
Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Oculogyration | | | Diazepam |

Medicine Details:

| | |
|--|---|
| DROPERIDOL (Suspected) | Reason: |
| 3.0 Milligram | Daily |
| Batch: | Started: 21/03/1997 Stopped: 21/03/1997 |
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: |
| 30.0 Milligram | Daily |
| Batch: | Started: 21/03/1997 Stopped: 21/03/1997 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 116918

Seq: 1

Gender: F

Reported: 18/04/1997

Weight: 16.00

Hospitalisation:

Age: 3Y

Onset Date: 02/04/1997

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

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

Medicine Details:

| | |
|--|---|
| DROPERIDOL (Suspected) | Reason: |
| 1.5 Milligram | 1 time |
| Batch: | Started: 02/04/1997 Stopped: 02/04/1997 |
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: |
| 1.5 Milligram | 1 time |
| Batch: | Started: 02/04/1997 Stopped: 02/04/1997 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 117716 **Seq:** 1 **Gender:** M
Reported: 20/05/1997 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: 15/05/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------------------|----------|--------------------|-------------|
| Anxiety Dystonia Hypertonia | Severe | | Benztropine |

Medicine Details:

| | |
|-------------------------------|---|
| LIGNOCAINE (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: 15/05/1997 Stopped: 15/05/1997 |
| ETHRANE (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: 15/05/1997 Stopped: 15/05/1997 |
| DIPRIVAN (Suspected) | Reason: |
| 200.0 Milligram 1 time | |
| Batch: | Started: 15/05/1997 Stopped: 15/05/1997 |
| DROLEPTAN (Suspected) | Reason: |
| 1.5 Milligram 1 time | |
| Batch: | Started: 15/05/1997 Stopped: 15/05/1997 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 117716
Reported: 20/05/1997
Hospitalisation:
Onset Date: 15/05/1997
Outcome: Recovered

Seq: 1

Gender: M
Weight:
Age: 31Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|-----------------------------|---|
| ATROPINE (Suspected) | Reason: |
| 600.0 Microgram | 1 time |
| Batch: | Started: 15/05/1997 Stopped: 15/05/1997 |
| TORADOL (Suspected) | Reason: |
| 30.0 Milligram | 1 time |
| Batch: | Started: 15/05/1997 Stopped: 15/05/1997 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 117857 | Seq: 1 | Gender: M |
| Reported: 26/05/1997 | | Weight: |
| Hospitalisation: | | Age: 31 |
| Onset Date: 19/02/1997 | | DOB: 23/04/1965 |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------------------|-------------------|
| Hypertonia Anxiety Dyspnoea Tongue oedema | | Muscle spasm in neck and face. | Oxygen, diazepam. |

Medicine Details:

| | |
|----------------------------------|--|
| EPOETIN ALFA (Other drug) | Reason: Chronic nephritis |
| Injection | 8.0 Thousand Internal Weekly Subcutaneous |
| Batch: | Started: L TERM Stopped: |
| COLCHICINE (Other drug) | Reason: Gout |
| | 500.0 Microgram Daily |
| Batch: | Started: 17/02/1997 Stopped: |
| ZANTAC (Other drug) | Reason: |
| Tablet | 1.0 Gram Daily Oral |
| Batch: | Started: L TERM Stopped: |
| NORVASC (Other drug) | Reason: Essential benign hypertension |
| Tablet | 40.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient also taking tritace.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 117857
Reported: 26/05/1997

Seq: 1

Gender: M

Weight:

Hospitalisation:

Onset Date: 19/02/1997

Age: 31

Outcome: Recovered

DOB: 23/04/1965

Causality: Causality probable

Reaction Details:

Medicine Details:

| | |
|---------------------------------------|---|
| TRITACE (Other drug) | Reason: Essential benign hypertension |
| Capsule | 5.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: |
| CALTRATE (Other drug) | Reason: Other specified symptoms nec |
| Tablet | 1.0 Dose Unspecified Daily Oral |
| Batch: | Started: L TERM Stopped: |
| VITAMIN B COMPLEX (Other drug) | Reason: |
| Oral application | 2.0 Dose Unspecified Daily Oral |
| Batch: | Started: L TERM Stopped: |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection | 7.5 Milligram Daily Subcutaneous |
| Batch: | Started: 18/02/1997 Stopped: 19/02/1997 |

Laboratory Investigations:

Additional Information:

Patient also taking tritace.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 118506

Seq: 1

Gender: F

Reported: 24/06/1997

Weight: 61.00

Hospitalisation:

Age: 13Y

Onset Date: 07/06/1997

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---------------------------------|
| Dystonia | | Acute dystonia | Benztropine 1mg im given orally |
| Oculogyration | | | |
| Opisthotonus | | | |

Medicine Details:

| | | |
|-------------------------------|----------------------------|----------------------------|
| DROPERIDOL (Suspected) | | Reason: Depression |
| Injection | 0.0 | As necessary Intramuscular |
| Batch: | Started: 06/06/1997 | Stopped: 07/06/1997 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 118725 **Seq:** 1 **Gender:** F
Reported: 01/07/1997 **Weight:**
Hospitalisation: **Age:** 47Y
Onset Date: 03/06/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--------------|
| Oculogyration | | | Benztropine. |

Medicine Details:

| | | | |
|--|----------------------------|-----------------|----------------------------|
| DOMPERIDONE (Other drug) | Reason: Vertigo | | |
| Tablet | 10.0 Milligram | As necessary | Oral |
| Batch: | Started: 01/06/1997 | Stopped: | Stopped: 02/06/1997 |
| PROMETHAZINE HYDROCHLORIDE (Other drug) | Reason: | | |
| Oral application | 20.0 Milligram | As necessary | Oral |
| Batch: | Started: 31/05/1997 | Stopped: | Stopped: |
| PETHIDINE HYDROCHLORIDE (Other drug) | Reason: Pain | | |
| Injection | 100.0 Milligram | As necessary | Intramuscular |
| Batch: | Started: 31/05/1997 | Stopped: | Stopped: |
| PANADEINE FORTE (Other drug) | Reason: Pain | | |
| Tablet | 1.0 Dose Unspecified | As necessary | Oral |
| Batch: | Started: 31/05/1997 | Stopped: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 118725

Seq: 1

Gender: F

Reported: 01/07/1997

Weight:

Hospitalisation:

Onset Date: 03/06/1997

Age: 47Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | | |
|-----------------------------------|-----------------|------------------|-----------------|------------------------------|
| DUPHALAC (Other drug) | | | Reason: | |
| Oral Liquid | 30.0 | Millilitre | Daily | Oral |
| Batch: | Started: | | Stopped: | |
| PREMARIN (Other drug) | | | Reason: | |
| Tablet | 1.2 | Milligram | Daily | Oral |
| Batch: | Started: | | Stopped: | |
| CHLOROMYCETIN (Other drug) | | | Reason: | |
| | 3.0 | Dose Unspecified | Daily | |
| Batch: | Started: | 03/05/1997 | Stopped: | |
| CEFTAZIDIME (Other drug) | | | Reason: | Other cellulitis and abscess |
| Injection | 4.0 | Gram | Daily | Intravenous |
| Batch: | Started: | 31/05/1997 | Stopped: | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 118725 **Seq:** 1
Reported: 01/07/1997

Gender: F

Weight:

Hospitalisation:

Age: 47Y

Onset Date: 03/06/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|---|----------------------------|---|---------------|
| GENTAMICIN SULPHATE (Other drug) | | Reason: Other cellulitis and abscess | |
| Injection | 350.0 Milligram | Daily | Intravenous |
| Batch: | Started: 01/06/1997 | Stopped: | |
| DROPERIDOL (Suspected) | | Reason: Nausea and vomiting | |
| Injection | 2.5 Milligram | As necessary | Intramuscular |
| Batch: | Started: 01/06/1997 | Stopped: 03/06/1997 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 119047 | Seq: 1 | Gender: F |
| Reported: 14/07/1997 | | Weight: |
| Hospitalisation: | | Age: 30 |
| Onset Date: 07/07/1997 | | DOB: 01/04/1967 |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|---------------------------------|-----------|
| Nausea | Severe | Severe nausea postoperatively | |
| Vomiting | Severe | Severe vomiting postoperatively | |

Medicine Details:

| | | |
|---------------------------------|----------|----------|
| PROPOFOL (Suspected) | 0.0 | Reason: |
| Batch: | Started: | Stopped: |
| ATRACURIUM BESYLATE (Suspected) | 0.0 | Reason: |
| Batch: | Started: | Stopped: |
| DROPERIDOL (Suspected) | 0.0 | Reason: |
| Batch: | Started: | Stopped: |
| KEFZOL (Suspected) | 0.0 | Reason: |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 119047 **Seq:** 1
Reported: 14/07/1997

Gender: F

Weight:

Hospitalisation:

Onset Date: 07/07/1997
Outcome: Not yet recovered

Age: 30

DOB: 01/04/1967

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | |
|----------------------------------|----------------------------|----------------------------|
| FLAGYL (Suspected) | | Reason: |
| | 0.0 | |
| Batch: | Started: | Stopped: |
| NITROUS OXIDE (Suspected) | | Reason: |
| | 0.0 | |
| Batch: | Started: | Stopped: |
| ISOFLURANE (Suspected) | | Reason: |
| | 0.0 | |
| Batch: | Started: | Stopped: |
| MORPHINE NOS (Suspected) | | Reason: Prophylaxis |
| Injection, intravenous infusion | 48.0 Milligram | Daily Intravenous |
| Batch: | Started: 07/07/1997 | Stopped: 08/07/1997 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 119204 **Seq:** 1 **Gender:** F
Reported: 17/07/1997 **Weight:** 83.00
Hospitalisation: Hospitalisation prolonged **Age:** 32
Onset Date: 24/06/1997 **DOB:** 23/08/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Nausea | | | Sleep. |

Medicine Details:

| | |
|---|---|
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| Injection 0.0 Intravenous | |
| Batch: Started: 24/06/1997 Stopped: 24/06/1997 | |
| SEVORANE (Suspected) | Reason: Other disturbance of sensation |
| Injection 0.0 Intravenous | |
| Batch: Started: 24/06/1997 Stopped: 24/06/1997 | |
| PANADEINE FORTE (Suspected) | Reason: Pain |
| Tablet 2.0 Dose Unspecified 1 time Oral | |
| Batch: Started: 24/06/1997 Stopped: 24/06/1997 | |
| FENTANYL CITRATE (Suspected) | Reason: Other disturbance of sensation |
| Injection 100.0 Milligram 1 time Intravenous | |
| Batch: Started: 24/06/1997 Stopped: 24/06/1997 | |

Laboratory Investigations:

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

Additional Information:

Oral analgesia given on an empty stomach



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 119204 **Seq:** 1

Reported: 17/07/1997

Hospitalisation: Hospitalisation prolonged

Onset Date: 24/06/1997

Outcome: Recovered

Gender: F

Weight: 83.00

Age: 32

DOB: 23/08/1964

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|-----------------------------|---|----------------------------|-------------|
| DIPRIVAN (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 180.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 24/06/1997 | Stopped: 24/06/1997 | |

Laboratory Investigations:

Additional Information:

Oral analgesia given on an empty stomach



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 119210 **Seq:** 1 **Gender:** F
Reported: 17/07/1997 **Weight:** 97.00
Hospitalisation: Hospitalisation prolonged **Age:** 46
Onset Date: 12/06/1997 **DOB:** 25/11/1950
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|----------------------|
| Vomiting | | Post op emesis | Maxolon, ondansetron |

Medicine Details:

| | | |
|-------------------------------------|----------------------------|---|
| SEVOFLURANE (Suspected) | | Reason: Other disturbance of sensation |
| | 0.0 | |
| Batch: | Started: 12/06/1997 | Stopped: 12/06/1997 |
| NEOSTIGMINE NOS (Suspected) | | Reason: Other disturbance of sensation |
| Injection | 0.0 | Intravenous |
| Batch: | Started: 12/06/1997 | Stopped: 12/06/1997 |
| FENTANYL CITRATE (Suspected) | | Reason: Other disturbance of sensation |
| Injection | 100.0 Milligram | 1 time Intravenous |
| Batch: | Started: 12/06/1997 | Stopped: 12/06/1997 |
| DROPERIDOL (Suspected) | | Reason: Other disturbance of sensation |
| Injection | 500.0 Microgram | 1 time Intravenous |
| Batch: | Started: 12/06/1997 | Stopped: 12/06/1997 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 119210 **Seq:** 1 **Gender:** F
Reported: 17/07/1997 **Weight:** 97.00
Hospitalisation: Hospitalisation prolonged **Age:** 46
Onset Date: 12/06/1997 **DOB:** 25/11/1950
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

| | |
|--|---|
| DIPRIVAN (Suspected) | Reason: Other disturbance of sensation |
| Injection 120.0 Milligram 1 time Intravenous | |
| Batch: | Started: 12/06/1997 Stopped: 12/06/1997 |
| ATROPINE (Suspected) | Reason: Other disturbance of sensation |
| Injection 1.0 Dose Unspecified 1 time Intravenous | |
| Batch: | Started: 12/06/1997 Stopped: 12/06/1997 |
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: Pain |
| Injection 75.0 Milligram Total Intravenous | |
| Batch: | Started: 12/06/1997 Stopped: 12/06/1997 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 119222 **Seq:** 1 **Gender:** F
Reported: 17/07/1997 **Weight:**
Hospitalisation: Hospitalisation prolonged **Age:** 31
Onset Date: 16/06/1997 **DOB:** 02/06/1966
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Nausea | | Post op nausea | Maxolon |

Medicine Details:

| | |
|--|---|
| ISOFLURANE (Suspected) | Reason: Other disturbance of sensation |
| 0.0 | |
| Batch: | Started: 16/06/1997 Stopped: 16/06/1997 |
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: Pain |
| Injection 75.0 Milligram 1 time Intramuscular | |
| Batch: | Started: 16/01/1997 Stopped: 16/06/1997 |
| ROCURONIUM BROMIDE (Suspected) | Reason: Other disturbance of sensation |
| Injection 40.0 Milligram 1 time Intravenous | |
| Batch: | Started: 16/06/1997 Stopped: 16/06/1997 |
| FENTANYL CITRATE (Suspected) | Reason: Other disturbance of sensation |
| Injection 75.0 Milligram 1 time Intravenous | |
| Batch: | Started: 16/06/1997 Stopped: 16/06/1997 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 119222 **Seq:** 1 **Gender:** F
Reported: 17/07/1997 **Weight:**
Hospitalisation: Hospitalisation prolonged **Age:** 31
Onset Date: 16/06/1997 **DOB:** 02/06/1966
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

| | |
|---|---|
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| Injection 1.5 Milligram 1 time Intravenous | |
| Batch: Started: 16/06/1997 Stopped: 16/06/1997 | |
| ATROPINE (Suspected) | Reason: Other disturbance of sensation |
| Injection 1.6 Milligram 1 time Intravenous | |
| Batch: Started: 16/06/1997 Stopped: 16/06/1997 | |
| NEOSTIGMINE NOS (Suspected) | Reason: Other disturbance of sensation |
| Injection 3.5 Milligram 1 time Intravenous | |
| Batch: Started: 16/06/1997 Stopped: 16/06/1997 | |
| THIOPENTONE SODIUM (Suspected) | Reason: Other disturbance of sensation |
| Injection 425.0 Milligram Daily Intravenous | |
| Batch: Started: 16/06/1997 Stopped: 16/06/1997 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 120877

Seq: 1

Gender: F

Reported: 16/09/1997

Weight: 68.00

Hospitalisation:

Age: 24Y

Onset Date: 24/12/1996

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------------|-----------|
| Dyspnoea | | Couldnt breathe properly | |

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection | 2.5 Milligram 1 time Intramuscular |
| Batch: | Started: 24/12/1996 Stopped: 24/12/1996 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 121866
Reported: 27/10/1997

Seq: 1

Gender: M
Weight: 61.00

Hospitalisation:

Onset Date: 22/10/1997
Outcome: Recovered

Age: 67Y
DOB:
Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------|---------------------------------|
| Pyrexia Confusional state Hypertonia Neuroleptic malignant syndrome | | Temp 38 oc | Iv dantrolene and bromocryptine |

Medicine Details:

| | | | |
|---|---|-----------------|-------------|
| ISOFLURANE (Suspected) | Reason: | | |
| 0.0 | | | |
| Batch: | Started: | Stopped: | |
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 1.5 Milligram | 1 time | Intravenous |
| Batch: | Started: 21/10/1997 | Stopped: | |
| PROPOFOL (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 100.0 Milligram | 1 time | Intravenous |
| Batch: | Started: | Stopped: | |
| DICLOXACILLIN SODIUM (Suspected) | Reason: | | |
| Injection | 2.0 Gram | 1 time | Intravenous |
| Batch: | Started: | Stopped: | |

Laboratory Investigations:

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

Additional Information:

History of previous anaesthetics without problems, has history of hypertension



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 121866
Reported: 27/10/1997

Seq: 1

Gender: M
Weight: 61.00

Hospitalisation:

Onset Date: 22/10/1997
Outcome: Recovered

Age: 67Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|--|---|
| GENTAMICIN SULPHATE (Suspected) | Reason: |
| Injection 180.0 Milligram | 1 time Intravenous |
| Batch: | Started: Stopped: |
| FENTANYL CITRATE (Suspected) | Reason: Other disturbance of sensation |
| Injection 162.5 Milligram | Total Intravenous |
| Batch: | Started: Stopped: |
| ATRACURIUM BESYLATE (Suspected) | Reason: Other disturbance of sensation |
| Injection, intravenous infusion 10.0 Milligram | Per hour Intravenous |
| Batch: | Started: Stopped: |

Laboratory Investigations:

Additional Information:

History of previous anaesthetics without problems, has history of hypertension



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 122742 | Seq: 1 | Gender: F |
| Reported: 24/11/1997 | | Weight: |
| Hospitalisation: | | Age: 60Y |
| Onset Date: 15/10/1997 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

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

Medicine Details:

| | |
|--|---|
| MIDAZOLAM (Suspected) | Reason: Other disturbance of sensation |
| 2.5 Milligram | 2 times |
| Batch: | Started: Stopped: |
| PROPOFOL (Suspected) | Reason: Other disturbance of sensation |
| 100.0 Milligram | 1 time |
| Batch: | Started: Stopped: |
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| 15.0 Milligram | 1 time |
| Batch: | Started: Stopped: |
| BUPIVACAINE HYDROCHLORIDE (Suspected) | Reason: Other disturbance of sensation |
| 75.0 Milligram | 1 time |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 122742

Seq: 1

Gender: F

Reported: 24/11/1997

Weight:

Hospitalisation:

Age: 60Y

Onset Date: 15/10/1997

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

PETHIDINE HYDROCHLORIDE (Suspected)

Reason: Other disturbance of sensation

50.0 Milligram

1 time

Batch:

Started:

Stopped:

ISOFLURANE (Suspected)

Reason: Other disturbance of sensation

1.0 Percent

1 time

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 122744 | Seq: 1 | Gender: F |
| Reported: 25/11/1997 | | Weight: |
| Hospitalisation: | | Age: 45Y |
| Onset Date: 14/11/1997 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------------|----------|--------------------------------------|--------------------|
| Dystonia Tongue disorder | | Ocomotor spasm Tongue rolled back | Benztropine 4mg iv |

Medicine Details:

| | |
|---------------------------------|---|
| MORPHINE NOS (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: |
| | Stopped: |
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| 5.0 Milligram | Daily |
| Batch: | Started: 13/11/1997 |
| | Stopped: 14/11/1997 |

Laboratory Investigations:

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

Additional Information:

Patient has previous history to maxolon, stemetil and other drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 129669 **Seq:** 1 **Gender:** M
Reported: 28/07/1998 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 06/04/1998 **DOB:** 17/06/1976
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|---------------------|
| Dystonia Hypertonia Opisthotonus Tachycardia | | | Benztropine iv 1mg. |

Medicine Details:

| | |
|---|--|
| PANADOL (Other drug) | Reason: Pain |
| 0.0 | |
| Batch: | Started: 04/04/1998 Stopped: |
| PANADEINE (Other drug) | Reason: Pain |
| 0.0 | |
| Batch: | Started: 04/04/1998 Stopped: |
| ONDANSETRON HYDROCHLORIDE DIHYDRATE (Other drug) | Reason: Nausea and vomiting |
| Tablet 8.0 Milligram 1 time Oral | |
| Batch: | Started: 06/04/1998 Stopped: |
| VENTOLIN (Other drug) | Reason: |
| Inhalation 0.0 As necessary Inhalation | |
| Batch: | Started: 05/04/1998 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 129669
Reported: 28/07/1998

Seq: 1

Gender: M

Weight:

Hospitalisation:

Onset Date: 06/04/1998

Age: 21

Outcome: Recovered

DOB: 17/06/1976

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|--|---|----------------------------|-------------|
| CLINDAMYCIN HYDROCHLORIDE (Other drug) | Reason: Otr&nos infec¶sit diseases | | |
| Oral application | 1.2 Gram | Daily | Oral |
| Batch: | Started: 04/04/1998 | Stopped: | |
| DICLOXACILLIN SODIUM (Other drug) | Reason: Otr&nos infec¶sit diseases | | |
| Injection | 4.0 Gram | Daily | Intravenous |
| Batch: | Started: 04/04/1998 | Stopped: | |
| METOCLOPRAMIDE HYDROCHLORIDE (Other drug) | Reason: Nausea and vomiting | | |
| Injection | 40.0 Milligram | Daily | Intravenous |
| Batch: | Started: 04/04/1998 | Stopped: 05/04/1998 | |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting | | |
| | 0.0 | | |
| Batch: | Started: 03/04/1998 | Stopped: 06/04/1998 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 130780 **Seq:** 1 **Gender:** F
Reported: 03/09/1998 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: 17/08/1998 **DOB:** 05/09/1948
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|---|-----------|
| Tongue oedema | | Pulling and swelling at back of tongue. | |

Medicine Details:

| | | | |
|---------------------------------------|------------------------------------|----------------------------|-------------|
| DIHYDROERGOTAMINE (Other drug) | Reason: Migraine | | |
| Injection | 1.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 17/08/1998 | Stopped: | |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting | | |
| Injection | 500.0 Microgram | 1 time | Intravenous |
| Batch: | Started: 17/08/1998 | Stopped: 17/08/1998 | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 130789 **Seq:** 1 **Gender:** M
Reported: 03/09/1998 **Weight:**
Hospitalisation: **Age:** 2Y
Onset Date: 30/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------|------------------------|----------------------|
| Opisthotonus Dystonia | | Hyperextension of neck | Cogentin iv 2 doses. |

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| 0.0 | |
| Batch: | Started: 30/07/1998 Stopped: 30/07/1998 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 131602 | Seq: 1 | Gender: F |
| Reported: 30/09/1998 | | Weight: 98.00 |
| Hospitalisation: | | Age: 49Y |
| Onset Date: 09/07/1998 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------------------|----------|---------------------|--|
| Hypotension Cyanosis Flushing | | Extreme hypotention | Pt was resuscitated using adrenaline 0.5mg x oxygen and iv fluids. |

Medicine Details:

| | |
|--|---|
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: Other disturbance of sensation |
| 50.0 Milligram | 1 time |
| Batch: | Started: 09/07/1998 Stopped: 09/07/1998 |
| DROLEPTAN (Suspected) | Reason: |
| 1.0 Milligram | 1 time |
| Batch: | Started: 09/07/1998 Stopped: 09/07/1998 |
| HYPNOVEL (Suspected) | Reason: Other disturbance of sensation |
| 2.0 Milligram | 1 time |
| Batch: | Started: 09/07/1998 Stopped: 09/07/1998 |
| ESMERON (Suspected) | Reason: |
| 60.0 Milligram | 1 time |
| Batch: | Started: 09/07/1998 Stopped: 09/07/1998 |

Laboratory Investigations:

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

Additional Information:

Pt has allergies to penicillin, amoxil, morphine & furadantin.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 131602

Seq: 1

Gender: F

Reported: 30/09/1998

Weight: 98.00

Hospitalisation:

Age: 49Y

Onset Date: 09/07/1998

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ZOFRAN (Suspected)

Reason:

200.0 Milligram

Daily

Batch:

Started: 09/07/1998

Stopped: 09/07/1998

Laboratory Investigations:

Additional Information:

Pt has allergies to penicillin, amoxil, morphine & furadantin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 134787

Seq: 1

Gender: U

Reported: 04/01/1999

Weight: 40.00

Hospitalisation:

Onset Date: 01/07/1997

Age: 13

DOB: 03/02/1984

Outcome: Unknown

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------------------|----------|--------------------|-----------|
| Oculogyration Visual disturbance | | | |

Medicine Details:

| | | | |
|--|----------------------------|-----------------|-------------|
| PANADEINE (Other drug) | | Reason: | |
| | 0.0 | | |
| Batch: | Started: 28/06/1997 | Stopped: | |
| AMOXYCILLIN TRIHYDRATE (Other drug) | | Reason: | |
| Injection | 4.0 Gram | Daily | Intravenous |
| Batch: | Started: 28/06/1997 | Stopped: | |
| METRONIDAZOLE (Other drug) | | Reason: | |
| Injection | 900.0 Milligram | Daily | Intravenous |
| Batch: | Started: 25/06/1997 | Stopped: | |
| INDOCID (Other drug) | | Reason: | |
| Suppository | 200.0 Milligram | Daily | Rectal |
| Batch: | Started: 30/06/1997 | Stopped: | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 134787

Seq: 1

Gender: U

Reported: 04/01/1999

Weight: 40.00

Hospitalisation:

Age: 13

Onset Date: 01/07/1997

DOB: 03/02/1984

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|---|----------------------------|-----------------|-------------|
| DROPERIDOL (Suspected) | | Reason: | |
| Injection | 1.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 01/07/1997 | Stopped: | 01/07/1997 |
| PROCHLORPERAZINE MALEATE (Suspected) | | Reason: | |
| Injection | 15.0 Milligram | Daily | Intravenous |
| Batch: | Started: 29/06/1997 | Stopped: | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 134855 | Seq: 1 | Gender: F |
| Reported: 04/01/1999 | | Weight: 18.00 |
| Hospitalisation: | | Age: 8 |
| Onset Date: 22/05/1998 | | DOB: 30/01/1990 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|---------------------------------|-----------|
| Hallucination Depersonalisation Urinary retention | | Stating she was another person. | |

Medicine Details:

| | | |
|--|----------------------------|-----------------------------------|
| MORPHINE NOS (Other drug) | | Reason: Cong anom of spine |
| Injection | 10.0 Milligram | Daily Intravenous |
| Batch: | Started: 20/05/1998 | Stopped: |
| DIAZEPAM (Suspected) | | Reason: Cong anom of spine |
| Tablet | 2.0 Milligram | 1 time Oral |
| Batch: | Started: 22/05/1998 | Stopped: |
| GENTAMICIN SULPHATE (Suspected) | | Reason: |
| Injection | 50.0 Milligram | 1 time Intravenous |
| Batch: | Started: 22/05/1998 | Stopped: |
| DROPERIDOL (Suspected) | | Reason: Cong anom of spine |
| Injection | 1.2 Milligram | Daily Intravenous |
| Batch: | Started: 21/05/1998 | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 134855

Seq: 1

Gender: F

Reported: 04/01/1999

Weight: 18.00

Hospitalisation:

Age: 8

Onset Date: 22/05/1998

DOB: 30/01/1990

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|----------------------------|-----------------------------------|-----------------|--------|
| PANADOL (Suspected) | Reason: Cong anom of spine | | |
| Suppository | 1.5 Gram | Daily | Rectal |
| Batch: | Started: 20/05/1998 | Stopped: | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 135175 **Seq:** 1 **Gender:** F
Reported: 14/01/1999 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: 01/10/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|----------------------------|--|
| Rash | | Generalised rash over body | Oxygen given via hudson mask, im phenergan 25mg. |
| Hypoxia | | | |

Medicine Details:

| | |
|--|---|
| Keflin Neutral (Suspected) | Reason: |
| Injection 1.0 Gram 1 time Intravenous | |
| Batch: | Started: 01/10/1998 Stopped: |
| FENTANYL CITRATE (Suspected) | Reason: Other disturbance of sensation |
| Injection 1.0 Dose Unspecified 1 time Intravenous | |
| Batch: | Started: 01/10/1998 Stopped: |
| MIDAZOLAM (Suspected) | Reason: Other disturbance of sensation |
| Injection 1.0 Dose Unspecified 1 time Intravenous | |
| Batch: | Started: 01/10/1998 Stopped: |
| DIPRIVAN (Suspected) | Reason: Other disturbance of sensation |
| Injection 1.0 Dose Unspecified 1 time Intravenous | |
| Batch: | Started: 01/10/1998 Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|-------------------------------------|
| | Other data | | | | Saturation oxygen decreased to 89%. |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 135175

Seq: 1

Gender: F

Reported: 14/01/1999

Weight:

Hospitalisation:

Age: 30Y

Onset Date: 01/10/1998

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|------------------------------|---|
| DROLEPTAN (Suspected) | Reason: Other disturbance of sensation |
| Injection | 1.0 Dose Unspecified 1 time Intravenous |
| Batch: | Started: 01/10/1998 Stopped: |

Laboratory Investigations:

Additional Information:



**THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail**

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 137338 | Seq: 1 | Gender: M |
| Reported: 16/03/1999 | | Weight: |
| Hospitalisation: | | Age: 23 |
| Onset Date: 22/10/1998 | | DOB: 15/11/1974 |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Leukopenia | | | |
| Neutropenia | | | |

Medicine Details:

| | |
|-------------------------------|--|
| MIDAZOLAM (Suspected) | Reason: |
| Injection 10.0 Milligram | 1 time Intramuscular |
| Batch: | Started: 21/10/1998 Stopped: |
| DROPERIDOL (Suspected) | Reason: |
| Injection 10.0 Milligram | 1 time Intramuscular |
| Batch: | Started: 20/10/1998 Stopped: |
| TEMAZEPAM (Suspected) | Reason: |
| 10.0 Milligram | As necessary |
| Batch: | Started: Stopped: |
| EFEXOR (Suspected) | Reason: Depression |
| Tablet 75.0 Milligram | Daily Oral |
| Batch: | Started: 21/10/1998 Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-------------------|-------|-------------|--------|---------|
| | Neutrophils | | 22/10/1998 | 0.99 | |
| | White blood cells | | 22/10/1998 | 2.62 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 137338

Seq: 1

Gender: M

Reported: 16/03/1999

Weight:

Hospitalisation:

Age: 23

Onset Date: 22/10/1998

DOB: 15/11/1974

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|---|---------------------------------|----------------------------|------|
| DIAZEPAM (Suspected) | Reason: Anxiety neurosis | | |
| Tablet | 20.0 Milligram | Daily | Oral |
| Batch: | Started: 21/10/1998 | Stopped: | |
| THIAMINE (Suspected) | Reason: | | |
| Oral application | 100.0 Milligram | Daily | Oral |
| Batch: | Started: 21/10/1998 | Stopped: | |
| FLUOXETINE HYDROCHLORIDE (Suspected) | Reason: | | |
| | 40.0 Milligram | Daily | |
| Batch: | Started: 20/08/1998 | Stopped: 20/10/1998 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 138864 **Seq:** 1 **Gender:** M
Reported: 29/04/1999 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 2
Onset Date: 30/07/1998 **DOB:** 22/07/1996
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--------------------|---------------------------------------|
| Rash Dystonia | | Rash upper chest | Benztropine 0.24mg iv (0.02mg/kg). |

Medicine Details:

| | |
|-------------------------------|--|
| DROPERIDOL (Suspected) | Reason: Premedication |
| Injection | 3.0 Milligram 1 time Intramuscular |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:

No known allergies. see original report for details of other drug - paracetamol. date of recovery: 30/7/98.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 139532 **Seq:** 1 **Gender:** F
Reported: 14/05/1999 **Weight:**
Hospitalisation: **Age:** 28Y
Onset Date: 14/02/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--|
| Dystonia | | | Ceased droperidol, given benztropine iv x 4. |

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: |
| Injection | 1.0 Milligram Daily Intramuscular |
| Batch: | Started: 14/02/1999 Stopped: |

Laboratory Investigations:

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

Additional Information:

See original report for other drug details - methadone, dicloxacillin iv & dicloxacillin oral. previous allergies to metoclopramid & haloperidol. four doses of stemetil 12.5mg im given but proved ineffective.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 139883 **Seq:** 1 **Gender:** M
Reported: 24/05/1999 **Weight:**
Hospitalisation: **Age:** 21Y
Onset Date: 12/05/1999 **DOB:**
Outcome: Recovered without treatment **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Delirium | | | |
| Vomiting | | | |

Medicine Details:

| | |
|---|---|
| DROPERIDOL (Suspected) | Reason: |
| Injection 10.0 Milligram 2 times Intramuscular | |
| Batch: | Started: Stopped: |
| CLOZARIL (Suspected) | Reason: Unspecified schizophrenia |
| Tablet 350.0 Milligram Daily Oral | |
| Batch: | Started: 14/04/1999 Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:

Please see original report for details of other drugs - thioridazine. patient has a history of aggressiveness



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 142893

Seq: 1

Gender: M

Reported: 23/08/1999

Weight:

Hospitalisation:

Onset Date: 18/07/1999

Age: 26

DOB: 17/12/1972

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------------------------------|
| Dystonia | | Dystonic reaction | Treated with cogentin 2mg orally. |
| Agitation | | Motor restlessness | |

Medicine Details:

| | | | |
|---|----------------------------|-----------------|--------|
| ZUCLOPENTHIXOL DECANOATE (Suspected) | Reason: | | |
| 200.0 Milligram | Weekly | | |
| Batch: | Started: 12/07/1999 | Stopped: | CONTIN |
| THIORIDAZINE HYDROCHLORIDE (Suspected) | Reason: | | |
| 50.0 Milligram | As necessary | | |
| Batch: | Started: 16/07/1999 | Stopped: | CONTIN |
| DROPERIDOL (Suspected) | Reason: | | |
| 5.0 Milligram | As necessary | | |
| Batch: | Started: 16/07/1999 | Stopped: | CONTIN |
| DIAZEPAM (Suspected) | Reason: | | |
| 5.0 Milligram | As necessary | | |
| Batch: | Started: 16/07/1999 | Stopped: | CONTIN |

Laboratory Investigations:

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

Additional Information:

Reduced thioridazine dose to maximum 600mg/d,



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 142893

Seq: 1

Gender: M

Reported: 23/08/1999

Weight:

Hospitalisation:

Age: 26

Onset Date: 18/07/1999

DOB: 17/12/1972

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|-----------------------------|----------------------------|
| COGENTIN (Suspected) | Reason: |
| | 0.5 Milligram As necessary |
| Batch: | Started: 16/07/1999 |
| | Stopped: CONTIN |

Laboratory Investigations:

Additional Information:

Reduced thioridazine dose to maximum 600mg/d,



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 150478
Reported: 17/03/2000
Hospitalisation:
Onset Date: 22/02/2000
Outcome: Recovered

Seq: 1

Gender: F
Weight: 85.00
Age: 56Y
DOB:
Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------|-----------|
| Angina pectoris Chest pain Electrocardiogram abnormal Myocardial infarction | | | |

Medicine Details:

| | |
|-------------------------------|---------------------------------|
| DROPERIDOL (Suspected) | Reason: |
| Injection | 2.5 Milligram Daily Intravenous |
| Batch: | Started: Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|---|-------|-------------|--------|---|
| | Electrocardiograph Immunology Radiology | | | | Marked st elevation inferior lead. Troponin i = 3.3ng/l. (<0.1) Subsequent normal coronary angiogram. |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 150535
Reported: 21/03/2000
Hospitalisation:
Onset Date: 25/11/1999
Outcome: Recovered

Seq: 1

Gender: F
Weight: 56.00
Age: 22
DOB: 27/11/1976
Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|------------------|-------------------------|--|
| Flushing | Life threatening | Generalised skin flush. | Adrenaline and supportive measures. 8 hours icu. |
| Bronchospasm | Life threatening | | |
| Hypotension | Life threatening | | |
| Tachycardia | Life threatening | | |

Medicine Details:

| | |
|---------------------------------|---|
| MORPHINE NOS (Suspected) | Reason: Other disturbance of sensation |
| Injection | 1.0 Dose Unspecified 1 time Intravenous |
| Batch: | Started: 25/11/1999 Stopped: |
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| Injection | 1.0 Dose Unspecified 1 time Intravenous |
| Batch: | Started: 25/11/1999 Stopped: |
| PROPOFOL (Suspected) | Reason: Other disturbance of sensation |
| Injection | 1.0 Dose Unspecified 1 time Intravenous |
| Batch: | Started: 25/11/1999 Stopped: |
| LIGNOCAINE (Suspected) | Reason: Other disturbance of sensation |
| Injection | 1.0 Dose Unspecified 1 time Intravenous |
| Batch: | Started: 25/11/1999 Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|---|
| | Immunology | | | | Mast cell tryptase (>200). skin tests positive to rocuronium. also positive to pancuronium, vecuronium and morphine (normal). |

Additional Information:

All drugs given as single dose all within 2 minutes prior to reaction. date of recovery: 26/11/1999.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 150535

Seq: 1

Gender: F

Reported: 21/03/2000

Weight: 56.00

Hospitalisation:

Age: 22

Onset Date: 25/11/1999

DOB: 27/11/1976

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ROCURONIUM BROMIDE (Suspected)

Reason: Other disturbance of sensation

Injection

1.0 Dose Unspecified 1 time

Intravenous

Batch:

Started: 25/11/1999

Stopped: 25/11/1999

Laboratory Investigations:

Additional Information:

All drugs given as single dose all within 2 minutes prior to reaction. date of recovery: 26/11/1999.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 150746
Reported: 24/03/2000

Seq: 1

Gender: M
Weight: 118.00

Hospitalisation:

Onset Date: 25/12/1999
Outcome: Recovered

Age: 37Y
DOB:
Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--------------------|-----------|
| Agitation | | | |
| Confusional state | | | |
| Hypertension | | | |
| Hypertonia | | | |
| Tachycardia | | | |
| Tremor | | | |

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: |
| Injection 10.0 Milligram | As necessary Intramuscular |
| Batch: | Started: 23/12/1999 Stopped: 26/12/1999 |
| TIMENTIN (Suspected) | Reason: |
| Injection 18.6 Gram | Daily Intravenous |
| Batch: | Started: 17/12/1999 Stopped: 27/12/1999 |
| RANITIDINE (Suspected) | Reason: |
| Injection 150.0 Milligram | Daily Intravenous |
| Batch: | Started: 23/12/1999 Stopped: 26/12/1999 |

Laboratory Investigations:

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

Additional Information:

Patient also taking paracetamol, heparin, nystatin, vancomycin, mianserin, metoclopramide, tramadol. p/h of reaction to stemetil - tardive dyskinesia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 154154
Reported: 23/06/2000
Hospitalisation:
Onset Date: 16/06/2000
Outcome: Recovered

Seq: 1

Gender: F
Weight: 70.00
Age: 60
DOB: 29/01/1940
Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---|
| Urticaria | | | Ceased pethidine and droperidol. given phenergan. |

Medicine Details:

| | |
|--|---|
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: 15/06/2000 Stopped: 16/06/2000 |
| DROPERIDOL (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: 15/06/2000 Stopped: 16/06/2000 |

Laboratory Investigations:

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

Additional Information:

Patient was also taking voltaren, paracetamol. patient recovered 16/6/00.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 154883 **Seq:** 1 **Gender:** M
Reported: 17/07/2000 **Weight:**
Hospitalisation: **Age:** 25Y
Onset Date: 22/01/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|---|------------------|----------------------|---|
| Hypotension Cardiac arrest Respiratory depression | Life threatening | Bp dropped to 60/40. | Resuscitated. iv fluids, 5l normal saline, 500ml haemacel, 1.5 l albumin. |

Medicine Details:

| | |
|---|---|
| HYPNOVEL (Suspected) | Reason: |
| Injection 7.5 Milligram Daily Intravenous | |
| Batch: | Started: 22/01/2000 Stopped: 22/01/2000 |
| DROPERIDOL (Suspected) | Reason: |
| Injection 10.0 Milligram Daily Intravenous | |
| Batch: | Started: 22/01/2000 Stopped: 22/01/2000 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 161274

Seq: 1

Gender: U

Reported: 07/02/2001

Weight: 22.00

Hospitalisation:

Age: AC

Onset Date: 19/01/2001

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|----------|-------------------------------------|-----------|
| Consciousness fluctuating | | Less talkative, staring into space. | |

Medicine Details:

| DROPERIDOL (Suspected) | | Reason: | |
|------------------------|----------------------------|-----------------|-------------|
| Injection | 3.0 Milligram | Total | Intravenous |
| Batch: | Started: 18/01/2001 | Stopped: | 19/01/2001 |

Laboratory Investigations:

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

Additional Information:

Patient also taking fentanyl, paracetamol, maxolon, ondansetron.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 161794 **Seq:** 1 **Gender:** F
Reported: 21/02/2001 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: 18/12/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--|---|
| Malaise Hyperkinesia | | General feeling of unwell. Involuntary muscle restlessness. | Given iv cogentin 4mg and valium iv 2mg. |

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: |
| Oral Liquid | 30.0 Millilitre Total Oral |
| Batch: | Started: 18/12/2000 Stopped: 18/12/2000 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 165036 **Seq:** 1 **Gender:** F
Reported: 01/06/2001 **Weight:** 43.00
Hospitalisation: **Age:** 10
Onset Date: 25/05/2001 **DOB:** 08/03/1991
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--|--|
| Dystonia | | Hed held in extorsion, jaw clenched shut | Cogentin. date of recovery 25/05/01 |

Medicine Details:

| | |
|---|---|
| ONDANSETRON HYDROCHLORIDE DIHYDRATE (Other drug) | Reason: Nausea and vomiting |
| 4.0 Milligram | As necessary |
| Batch: | Started: 25/05/2001 Stopped: CONTIN |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| 0.2 Milligram | As necessary |
| Batch: | Started: 24/05/2001 Stopped: 25/05/2001 |

Laboratory Investigations:

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

Additional Information:

Reaction occurred 4.5 hrs post droperidol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 169227 | Seq: 1 | Gender: F |
| Reported: 17/10/2001 | | Weight: |
| Hospitalisation: | | Age: 48Y |
| Onset Date: 04/10/2001 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|-------------------------|-----------|
| Rash erythematous | | Face and chest. | |
| Tachycardia | | Increasing tachycardia. | |
| Hypertension | | | |

Medicine Details:

| | | | |
|-------------------------------|----------------------------|------------------------------------|-------------|
| DROPERIDOL (Suspected) | | Reason: Nausea and vomiting | |
| Injection | 1.2 Milligram | Daily | Intravenous |
| Batch: | Started: 04/10/2001 | Stopped: | 04/10/2001 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 171713 **Seq:** 1 **Gender:** F
Reported: 04/01/2002 **Weight:** 18.00
Hospitalisation: **Age:** 6
Onset Date: 23/12/2001 **DOB:** 08/11/1995
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---|
| Hypertonia | | | Date of recovery 23.12.01. patient already in hospital. |
| Staring | | | |

Medicine Details:

| | |
|---|------------------------------------|
| MIDAZOLAM (Other drug) | Reason: |
| Oral application 4.0 Milligram Daily Oral | |
| Batch: Started: 20/12/2001 Stopped: | |
| RANITIDINE (Other drug) | Reason: |
| Injection 54.0 Milligram Daily Intravenous | |
| Batch: Started: 22/12/2001 Stopped: CONTIN | |
| PARACETAMOL (Other drug) | Reason: |
| Oral application 1.6 Gram Daily Oral | |
| Batch: Started: 20/12/2001 Stopped: CONTIN | |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection 2.0 Milligram As necessary Intravenous | |
| Batch: Started: 22/12/2001 Stopped: 23/12/2001 | |

Laboratory Investigations:

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

Additional Information:

Patient had had 2 previous doses of droperidol before reaction. reaction occurred when giving relatively close to a dose of metoclopramide.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 171713

Seq: 1

Gender: F

Reported: 04/01/2002

Weight: 18.00

Hospitalisation:

Age: 6

Onset Date: 23/12/2001

DOB: 08/11/1995

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Suspected)

Reason: Nausea and vomiting

Injection

8.0 Milligram

Daily

Intravenous

Batch:

Started: 21/12/2001

Stopped: 23/12/2001

Laboratory Investigations:

Additional Information:

Patient had had 2 previous doses of droperidol before reaction. reaction occurred when giving relatively close to a dose of metoclopramide.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 172415
Reported: 05/02/2002
Hospitalisation:
Onset Date: 03/12/1997
Outcome: Recovered

Seq: 1

Gender: F
Weight: 85.00
Age: 43Y
DOB:
Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------|-----------|
| Flushing Hypotension Tachycardia | | Facial flushing. | |

Medicine Details:

| | | | |
|---------------------------------------|---------------------|-----------------|---------------|
| ESMERON (Suspected) | Reason: | | |
| Injection | 50.0 Milligram | Daily | Intravenous |
| Batch: | Started: | Stopped: | |
| DROPERIDOL (Suspected) | Reason: | | |
| Injection | 0.5 Milligram | Daily | Intramuscular |
| Batch: | Started: | Stopped: | |
| THIOPENTONE SODIUM (Suspected) | Reason: | | |
| Injection | 350.0 Milligram | Daily | Intravenous |
| Batch: | Started: | Stopped: | |
| FENTANYL (Suspected) | Reason: Pain | | |
| Injection | 200.0 Milligram | Daily | Intravenous |
| Batch: | Started: | Stopped: | |

Laboratory Investigations:

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

Additional Information:

Recent ga with all same agents, except droperidol, 3 months ago uneventful. vecuron used instead of esmeron.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 172415

Seq: 1

Gender: F

Reported: 05/02/2002

Weight: 85.00

Hospitalisation:

Age: 43Y

Onset Date: 03/12/1997

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|-----------------------------|---------------------------------|
| HYPNOVEL (Suspected) | Reason: |
| Injection | 2.5 Milligram Daily Intravenous |
| Batch: | Started: Stopped: |

Laboratory Investigations:

Additional Information:

Recent ga with all same agents, except droperidol, 3 months ago uneventful. vecuron used instead of esmeron.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|--|---------------|--------------------------------------|
| Case Number: 173278 | Seq: 1 | Gender: F |
| Reported: 01/03/2002 | | Weight: 98.00 |
| Hospitalisation: Admitted to hospital | | Age: 43Y |
| Onset Date: 24/01/2002 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|---|--|
| Hypotension Blood creatine phosphokinase incr Anuria Dyspnoea Generalised oedema Peripheral ischaemia | | Decreased bp. Elevated ck. Not passing urine. | Patient was hospitalised. medication was reviewed and some withdrawn with polypharmacy being the major factor. |

Medicine Details:

| | | | |
|-----------------------------|----------------------------|---|------------|
| DERALIN (Other drug) | | Reason: Anxiety neurosis | |
| Tablet | 40.0 Milligram | Daily | Oral |
| Batch: | Started: 24/01/2002 | Stopped: | CONTIN |
| DERALIN (Suspected) | | Reason: Anxiety neurosis | |
| Tablet | 80.0 Milligram | Daily | Oral |
| Batch: | Started: 17/01/2002 | Stopped: | 24/01/2002 |
| CIPRAMIL (Suspected) | | Reason: Depression | |
| Tablet | 40.0 Milligram | Daily | Oral |
| Batch: | Started: 17/01/2002 | Stopped: | 24/01/2002 |
| PAXAM (Suspected) | | Reason: Other disturbance of sensation | |
| Tablet | 4.0 Milligram | Daily | Oral |
| Batch: | Started: 17/01/2002 | Stopped: | 24/01/2002 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 173278 **Seq:** 1

Gender: F

Reported: 01/03/2002

Weight: 98.00

Hospitalisation: Admitted to hospital

Age: 43Y

Onset Date: 24/01/2002

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | |
|------------------------------|----------------------------|---|
| PAXAM (Suspected) | | Reason: Other disturbance of sensation |
| Tablet | 2.0 Milligram | Daily Oral |
| Batch: | Started: 24/01/2002 | Stopped: 24/01/2002 |
| NEURONTIN (Suspected) | | Reason: |
| Capsule | 1.8 Gram | Daily Oral |
| Batch: | Started: 21/01/2002 | Stopped: 24/01/2002 |
| NEURONTIN (Suspected) | | Reason: |
| Capsule | 300.0 Milligram | Daily Oral |
| Batch: | Started: 24/01/2002 | Stopped: 28/01/2002 |
| DROLEPTAN (Suspected) | | Reason: Otr spec symp psychopathol nec |
| Injection | 5.0 Milligram | Daily Intravenous |
| Batch: | Started: 17/01/2002 | Stopped: 26/01/2002 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 173278 **Seq:** 1 **Gender:** F
Reported: 01/03/2002 **Weight:** 98.00
Hospitalisation: Admitted to hospital **Age:** 43Y
Onset Date: 24/01/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

| | |
|---|---|
| ZYPREXA (Suspected) | Reason: Unspecified schizophrenia |
| Oral application 20.0 Milligram Daily Oral | |
| Batch: | Started: 15/01/2002 Stopped: 24/01/2002 |
| SEROQUEL (Suspected) | Reason: Unspecified schizophrenia |
| Tablet 400.0 Milligram Daily Oral | |
| Batch: | Started: 21/01/2002 Stopped: 24/01/2002 |
| SERENACE (Suspected) | Reason: Unspecified psychosis |
| Tablet 10.0 Milligram Daily Oral | |
| Batch: | Started: 21/01/2002 Stopped: 24/01/2002 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 173703 | Seq: 1 | Gender: M |
| Reported: 19/03/2002 | | Weight: |
| Hospitalisation: | | Age: 30 |
| Onset Date: 06/01/2002 | | DOB: 22/01/1971 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------------------|----------------------------------|--------------------|--|
| Pyrexia | Required Specialist Consultation | Mild fever. | |
| Blood creatine phosphokinase incr | | | |
| Confusional state | | | |
| Dystonia | | | Treated with fluids. seroquel and droperidol ceased. |
| Hypertonia | | | |

Medicine Details:

| | |
|-------------------------------|---|
| SEROQUEL (Suspected) | Reason: |
| 400.0 Milligram | Daily |
| Batch: | Started: 15/12/2001 Stopped: 06/01/2002 |
| DROPERIDOL (Suspected) | Reason: Otr spec symp psychopathol nec |
| 40.0 Milligram | Daily |
| Batch: | Started: 05/01/2002 Stopped: 06/01/2002 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 175129 **Seq:** 1 **Gender:** M
Reported: 06/05/2002 **Weight:** 0.00
Hospitalisation: **Age:** 25
Onset Date: 22/03/2002 **DOB:** 18/01/1977
Outcome: Death 22/03/2002 **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|------------------|--------------------|-----------|
| Arrhythmia | Life threatening | | |
| Sudden death | | | |

Medicine Details:

| | |
|-------------------------------|--|
| DROPERIDOL (Suspected) | Reason: |
| Injection | As necessary Intramuscular |
| Batch: | Started: Stopped: |
| CLOZARIL (Suspected) | Reason: |
| Tablet | 450.0 Milligram Daily Oral |
| Batch: | Started: 03/08/1999 Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------------|----------------|-------|-------------|--------|---------|
| 06/05/2002 | Autopsy report | | | | |

Additional Information:

Patient died approximately 2 and half years after commencing Clozaril. He had been receive droperidol for some time and had received an IM injection half an hour prior to his death.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 175870 **Seq:** 1 **Gender:** F
Reported: 03/06/2002 **Weight:** 71.00
Hospitalisation: **Age:** 39
Onset Date: 08/05/2002 **DOB:** 15/01/1963
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Bradycardia | | | |
| Cardiac arrest | | | |

Medicine Details:

| | |
|--|---|
| MORPHINE SULPHATE (Suspected) | Reason: Other disturbance of sensation |
| Injection 0.0 Intravenous | |
| Batch: Started: Stopped: | |
| MIDAZOLAM (Suspected) | Reason: Premedication |
| Injection 5.0 Milligram 1 time Intramuscular | |
| Batch: Started: 08/05/2002 Stopped: | |
| PROPOFOL (Suspected) | Reason: Other disturbance of sensation |
| Injection 1.0 Dose Unspecified 1 time Intravenous | |
| Batch: Started: 08/05/2002 Stopped: | |
| VECURONIUM BROMIDE (Suspected) | Reason: Other disturbance of sensation |
| Injection 1.0 Dose Unspecified 1 time Intravenous | |
| Batch: Started: 08/05/2002 Stopped: | |

Laboratory Investigations:

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

Additional Information:

No reaction to previous anaesthetics.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 175870
Reported: 03/06/2002

Seq: 1

Gender: F
Weight: 71.00
Age: 39
DOB: 15/01/1963
Causality: Causality possible

Hospitalisation:

Onset Date: 08/05/2002
Outcome: Recovered

Reaction Details:

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation |
| Injection | 1.0 Dose Unspecified 1 time Intramuscular |
| Batch: | Started: Stopped: |
| MAXOLON (Suspected) | Reason: Nausea and vomiting |
| Injection | 1.0 Dose Unspecified 1 time Intravenous |
| Batch: | Started: Stopped: |
| DUCENE (Suspected) | Reason: |
| Tablet | 15.0 Milligram Daily Oral |
| Batch: | Started: 08/05/2002 Stopped: |

Laboratory Investigations:

Additional Information:

No reaction to previous anaesthetics.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 182338 | Seq: 1 | Gender: F |
| Reported: 04/02/2003 | | Weight: 0.00 |
| Hospitalisation: | | Age: 30 |
| Onset Date: 04/10/2002 | | DOB: 25/01/1972 |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|---|--------------------|
| Dystonia | | Patient became shakey, anxious and developed dystonia | Droperidol ceased. |
| Anxiety | | | |
| Tremor | | | |

Medicine Details:

| | |
|---------------------------------|--|
| PARACETAMOL (Other drug) | Reason: |
| 4.0 Gram | Daily |
| Batch: | Started: Stopped: contin |
| MS CONTIN (Other drug) | Reason: |
| Tablet 20.0 Milligram | Daily Oral |
| Batch: | Started: Stopped: Contin |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| 250.0 Microgram | 1 time |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient was also taking Morphine.
Previous reactions:-24/8/02-dystonic reaction to metoclopramide, requiring benztropine iv prn.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 186485 | Seq: 1 | Gender: M |
| Reported: 02/06/2003 | | Weight: 0.00 |
| Hospitalisation: | | Age: 27Y |
| Onset Date: 20/03/2003 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|---|--------------------|--|
| Neutropenia | Caused or prolonged inpatient hospitalisation | Neutropenia | Ceased Seroquel and Chlorpromazine, no further Droperidol given. |

Medicine Details:

| | |
|---|---|
| SEROQUEL (Suspected) | Reason: |
| Tablet | Oral |
| Batch: | Started: |
| | Stopped: 21/03/2003 |
| DROPERIDOL (Suspected) | Reason: Otr spec symp psychopathol nec |
| Injection | 10.0 Milligram 1 time Intramuscular |
| Batch: | Started: |
| | Stopped: |
| CHLORPROMAZINE HYDROCHLORIDE (Suspected) | Reason: Otr spec symp psychopathol nec |
| Tablet | 100.0 Milligram Daily Oral |
| Batch: | Started: 18/03/2003 |
| | Stopped: 21/03/2003 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------------|-------------------|---------|-------------|--------|---------|
| 02/06/2003 | Creatinine | | | | |
| 02/06/2003 | Neutrophils | (2-7.5) | 03/04/2003 | 1.24 | |
| 02/06/2003 | Neutrophils | (2-7.5) | 28/03/2003 | 1.09 | |
| 02/06/2003 | Neutrophils | (2-7.5) | 20/03/2003 | 1.61 | |
| 02/06/2003 | White blood cells | | 20/03/2003 | 3.5 | |
| 02/06/2003 | White blood cells | | 28/03/2003 | 2.8 | |
| 02/06/2003 | White blood cells | | 03/04/2003 | 2.7 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 190616 **Seq:** 1 **Gender:** F
Reported: 18/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 31Y
Onset Date: 12/09/2003 **DOB:**
Outcome: Recovered 12/09/2003 **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------|
| Dystonia | | Dystonic reaction | Cogentin 1 mg IV |

Medicine Details:

| | |
|-------------------------------|----------------------------|
| DROPERIDOL (Suspected) | Reason: |
| Batch: | 1.0 Dose Unspecified Daily |
| Started: | Stopped: |
| STEMETIL (Suspected) | Reason: |
| Batch: | 1.0 Dose Unspecified Daily |
| Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:

Other medications taken: Zofran, Na Heparin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 193274 | Seq: 1 | Gender: F |
| Reported: 17/12/2003 | | Weight: 0.00 |
| Hospitalisation: | | Age: 17 |
| Onset Date: 05/12/2003 | | DOB: 15/01/1986 |
| Outcome: Recovered | 05/12/2003 | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------------------------|----------|-------------------------|--|
| Depressed level of consciousness | | Consciousness impaired. | Required ICU admission, given Flumazenil 500mg iv with rapid response. |

Medicine Details:

| | |
|---------------------------------|---|
| SEROQUEL (Interaction) | Reason: Otr spec symp psychopathol nec |
| Batch: | Started: |
| Batch: | Stopped: |
| MIDAZOLAM (Interaction) | Reason: Otr spec symp psychopathol nec |
| Injection | 10.0 Milligram |
| | As necessary Intramuscular |
| Batch: | Started: |
| Batch: | Stopped: |
| DROPERIDOL (Interaction) | Reason: Otr spec symp psychopathol nec |
| Injection | 5.0 Milligram |
| | As necessary Intramuscular |
| Batch: | Started: |
| Batch: | Stopped: |
| Abilify (Interaction) | Reason: Otr spec symp psychopathol nec |
| Tablet | 15.0 Milligram |
| | Daily Oral |
| Batch: | Started: 26/11/2003 |
| Batch: | Stopped: 05/12/2003 |

Laboratory Investigations:

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

Additional Information:

Patient was also taking Levlen, Ferro-Gradmet, Nicabate, Mylanta.
 Aripiprazole commenced 1 week prior (26/11/03).
 Multiple drug interactions many have pre this event.cipitated



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 193274

Seq: 1

Gender: F

Reported: 17/12/2003

Weight: 0.00

Hospitalisation:

Age: 17

Onset Date: 05/12/2003

DOB: 15/01/1986

Outcome: Recovered

05/12/2003

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|-------------------------------|------------------|---|------|
| LAMICTAL (Interaction) | | Reason: | |
| Tablet | 137.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |
| DIAZEPAM (Interaction) | | Reason: Otr spec symp psychopathol nec | |
| Tablet | 20.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |
| EPILIM (Interaction) | | Reason: | |
| Tablet | 1000.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |

Laboratory Investigations:

Additional Information:

Patient was also taking Levlen, Ferro-Gradmet, Nicabate, Mylanta.
Aripiprazole commenced 1 week prior (26/11/03).
Multiple drug interactions many have pre this event.cipitated



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 193653 **Seq:** 1 **Gender:** F
Reported: 06/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 9
Onset Date: 13/11/2003 **DOB:** 30/03/1994
Outcome: Recovered 13/11/2003 **Causality:** Causality probable

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Oculogyration | | Oculogyric crisis. | |

Medicine Details:

| | |
|-------------------------------|----------------------------|
| DROPERIDOL (Suspected) | Reason: |
| Batch: | Dose Unspecified |
| Started: | Stopped: 13/11/2003 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 196398 **Seq:** 1 **Gender:** F
Reported: 13/04/2004 **Weight:** 50.00
Hospitalisation: **Age:** 15
Onset Date: 24/03/2004 **DOB:** 06/01/1989
Outcome: Recovered 26/03/2004 **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|----------------------|---|
| Hypotension | | Hypotensive (66/26). | Aripiprazole withheld then ceased. IV fluids given but was hard to re-establish BP. |
| Drug interaction | | | |

Medicine Details:

| | | | |
|---------------------------------|----------------------------|---|---------------|
| DROPERIDOL (Interaction) | | Reason: Otr spec symp psychopathol nec | |
| Injection | 10.0 Milligram | As necessary | Intramuscular |
| Batch: | Started: | Stopped: | |
| Abilify (Interaction) | | Reason: Anxiety neurosis | |
| Tablet | 15.0 Milligram | Daily | Oral |
| Batch: | Started: 04/03/2004 | Stopped: 24/03/2004 | |

Laboratory Investigations:

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

Additional Information:

Patient also taking Buspirone, Lamictal, Centrum and Olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 197256 **Seq:** 1 **Gender:** U
Reported: 11/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 51
Onset Date: 12/02/2004 **DOB:** 04/10/1952
Outcome: Recovered 15/02/2004 **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|---|--------------------|--|
| Diarrhoea | Caused or prolonged inpatient hospitalisation | Severe diarrhoea. | Augmentin duo forte ceased. Lomotil 1 tds prn |

Medicine Details:

| | |
|--|---|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection | 1.2 Milligram As necessary Intravenous |
| Batch: | Started: 09/02/2004 Stopped: 11/02/2004 |
| AUGMENTIN DUO FORTE (Suspected) | Reason: |
| | 2.0 Dose Unspecified Daily |
| Batch: | Started: 10/02/2004 Stopped: 11/02/2004 |
| ZOFRAN (Suspected) | Reason: Nausea and vomiting |
| Injection | 16.0 Milligram Daily |
| Batch: | Started: 09/02/2004 Stopped: 11/02/2004 |
| KEFLEX (Suspected) | Reason: |
| Capsule | 2.0 Gram Daily Oral |
| Batch: | Started: 09/02/2004 Stopped: 11/02/2004 |

Laboratory Investigations:

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

Additional Information:

Patient also taking panadol, maxolon,



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 197414 | Seq: 1 | Gender: F |
| Reported: 17/05/2004 | | Weight: 0.00 |
| Hospitalisation: | | Age: 15Y |
| Onset Date: 13/05/2004 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

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

Medicine Details:

| | | | |
|-------------------------------|----------------------------|------------------------------------|-------------|
| DROPERIDOL (Suspected) | | Reason: | |
| | | Dose Unspecified | |
| Batch: | Started: | Stopped: | |
| MAXOLON (Suspected) | | Reason: Nausea and vomiting | |
| Injection | 40.0 Milligram | Daily | Intravenous |
| Batch: | Started: 13/05/2004 | Stopped: 13/05/2004 | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 198190 | Seq: 1 | Gender: M |
| Reported: 16/06/2004 | | Weight: 0.00 |
| Hospitalisation: | | Age: 42 |
| Onset Date: 13/03/2004 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|-------------------------|--|
| Priapism | | Priapism and agitation. | Nebulised 5mg salbutamol with no effect (twice). Transferred to A & E. Withdraw blood and fluid from penile area to resolve the situation. Injected adrenaline 1:10,000 diluted 1 in 10ml. Urologist injected aramine to subside. |
| Agitation | | | |

Medicine Details:

| | | | |
|---|----------------------------|---|------|
| DROPERIDOL (Suspected) | | Reason: | |
| Injection | 10.0 Milligram | Daily | |
| Batch: | Started: 13/03/2004 | Stopped: | |
| QUETIAPINE (Suspected) | | Reason: | |
| Tablet | 300.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |
| CHLORPROMAZINE HYDROCHLORIDE (Suspected) | | Reason: Otr spec symp psychopathol nec | |
| Tablet | 200.0 Milligram | Daily | Oral |
| Batch: | Started: 13/03/2004 | Stopped: | |
| DIAZEPAM (Suspected) | | Reason: | |
| Tablet | 10.0 Milligram | Daily | Oral |
| Batch: | Started: 13/03/2004 | Stopped: | |

Laboratory Investigations:

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

Additional Information:

Large amounts of alcohol injected previous night (18 schooners). Priapism resolved but was exacerbated by chlorpromazine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 198674

Seq: 1

Gender: F

Reported: 02/07/2004

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date: 30/05/2004

DOB: 25/05/1967

Outcome: Recovered

Causality: Causality probable

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|---|------------------------------|
| Suicidal ideation | | Sad and suicidal thoughts, pain, dysphoria. | Counselling and reassurance. |
| Dysphoria | | | |
| Pain | | | |

Medicine Details:

| | |
|-------------------------------|--|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection | 625.0 Microgram 1 time Intravenous |
| Batch: | Started: 30/05/2004 Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient was also taking tramadol, Paracetamol, Metronidazole, Omeprazole, Enoxaparin, Ondansetron, Nicotine patch, Promethazine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|--|---------------|--------------------------------------|
| Case Number: 200055 | Seq: 1 | Gender: F |
| Reported: 17/08/2004 | | Weight: 0.00 |
| Hospitalisation: Admitted to hospital | | Age: 50 |
| Onset Date: 12/08/2004 | | DOB: 26/07/1954 |
| Outcome: Recovered | 12/08/2004 | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-----------------|---|--|-----------|
| Muscle rigidity | Caused or prolonged inpatient hospitalisation | Patient experienced muscle rigidity and akathisia. | |
| Akathisia | Caused or prolonged inpatient hospitalisation | | |

Medicine Details:

| | |
|-------------------------------|---|
| MAXOLON (Suspected) | Reason: Nausea and vomiting |
| 30.0 Milligram | Daily |
| Batch: | Started: 11/08/2004 Stopped: 12/08/2004 |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| | Daily |
| Batch: | Started: 11/08/2004 Stopped: 12/08/2004 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 201682 | Seq: 1 | Gender: U |
| Reported: 13/10/2004 | | Weight: 0.00 |
| Hospitalisation: | | Age: 99U |
| Onset Date: 29/06/2004 | | DOB: |
| Outcome: Recovered | 30/06/2004 | Causality: Causality probable |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--|---|
| Agitation | | Agitated behaviour, uncontrollable screaming, hallucinations | Frequent observation. Medical review - nil medical intervention. Droperidol ceased. |
| Hallucination | | | |
| Screaming | | | |

Medicine Details:

| | |
|---------------------------------|----------------------------|
| BUSCOPAN (Other drug) | Reason: |
| Injection | 60.0 Milligram |
| | Intravenous |
| Batch: | Started: |
| | Stopped: |
| PARACETAMOL (Other drug) | Reason: |
| | 4.0 Gram |
| | Oral |
| Batch: | Started: |
| | Stopped: |
| COLOXYL (Other drug) | Reason: |
| Oral Liquid | 120.0 Milligram |
| | Oral |
| Batch: | Started: |
| | Stopped: 30/06/2004 |
| AGAROL (Other drug) | Reason: |
| Oral Liquid | 20.0 Millilitre |
| | Oral |
| Batch: | Started: |
| | Stopped: 30/06/2004 |

Laboratory Investigations:

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

Additional Information:

Mother states had similar reaction x 1 before to Maxalon (Metoclopramide). Patient appeared to be hallucinating.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 201682

Seq: 1

Gender: U

Reported: 13/10/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 29/06/2004

DOB:

Outcome: Recovered

30/06/2004

Causality: Causality probable

Reaction Details:

Medicine Details:

| | | | |
|---|----------------------------|-----------------|--------------|
| ONDANSETRON HYDROCHLORIDE DIHYDRATE (Other drug) | | Reason: | |
| Injection | 12.0 Milligram | Daily | Intravenous |
| Batch: | Started: 22/06/2004 | Stopped: | 0 |
| DROPERIDOL (Suspected) | | Reason: | |
| Injection | 5.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 28/06/2004 | Stopped: | 29/06/2004 0 |

Laboratory Investigations:

Additional Information:

Mother states had similar reaction x 1 before to Maxalon (Metoclopramide). Patient appeared to be hallucinating.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 203329 **Seq:** 1 **Gender:** M
Reported: 07/12/2004 **Weight:** 8.00
Hospitalisation: Admitted to hospital **Age:** 0
Onset Date: 25/11/2004 **DOB:** 16/05/2004
Outcome: Recovered 25/11/2004 **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|---|-------------------------------|-------------------------|
| Oculogyration | Caused or prolonged inpatient hospitalisation | Oculogyric dystonic reaction. | Required IV Benztropine |
| Dystonia | Caused or prolonged inpatient hospitalisation | | |

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: |
| Injection | 1.0 Dose Unspecified 1 time Intravenous |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 203664

Seq: 1

Gender: F

Reported: 20/12/2004

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date: 30/11/2004

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|------------------------------|----------|--|-----------|
| Supraventricular tachycardia | | Patient experienced a cardiac event twenty years ago. On the 30/11/04 was administered Ondansetron HCL. At the same time, she also received Droperidol injection, almost straight after she was administered both medications, she experienced supraventricular tachycardia. | |

Medicine Details:

| | | |
|-----------------------|---------------------|------------|
| ZOFRAN (Suspected) | Reason: | |
| Batch: | Started: 30/11/2004 | Stopped: |
| DROLEPTAN (Suspected) | Reason: | |
| Batch: | Started: | Stopped: 0 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 207252 | Seq: 1 | Gender: F |
| Reported: 19/04/2005 | | Weight: 58.00 |
| Hospitalisation: | | Age: 16 |
| Onset Date: 20/02/2005 | | DOB: 10/03/1988 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|------------------|---|---|---------------------|
| Muscle twitching | Caused or prolonged inpatient hospitalisation | Twitching legs and arms after 1 dose of droperidol, vomiting. | Benztropine 1mg im. |
| Vomiting | Caused or prolonged inpatient hospitalisation | | |

Medicine Details:

| | |
|--|-------------------|
| MORPHINE SULPHATE (Other drug) | Reason: |
| Batch: | Started: Stopped: |
| OXYCODONE HYDROCHLORIDE (Other drug) | Reason: |
| Batch: | Started: Stopped: |
| TROPISETRON HYDROCHLORIDE (Other drug) | Reason: |
| Batch: | Started: Stopped: |
| AMPICILLIN (Other drug) | Reason: |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 207252

Seq: 1

Gender: F

Reported: 19/04/2005

Weight: 58.00

Hospitalisation:

Age: 16

Onset Date: 20/02/2005

DOB: 10/03/1988

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|---|----------------------------|-----------------|-------------|
| GENTAMICIN SULPHATE (Other drug) | | Reason: | |
| Batch: | Started: | Stopped: | |
| METRONIDAZOLE (Other drug) | | Reason: | |
| Batch: | Started: | Stopped: | |
| DROPERIDOL (Suspected) | | Reason: | |
| Injection | 5.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 20/02/2005 | Stopped: | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 210461 | Seq: 1 | Gender: M |
| Reported: 05/08/2005 | | Weight: 80.50 |
| Hospitalisation: | | |
| Onset Date: 18/05/2005 | | Age: 72 |
| Outcome: Recovered | 18/05/2005 | DOB: 13/11/1932 |
| | | Causality: Causality possible |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|------------------|---|---|-------------------------------|
| Dystonia | Caused or prolonged inpatient hospitalisation | Dystonic reaction, restlessness, anxiety, felt out of control, could not focus. | Treated with Cogentin IV/1mg. |
| Anxiety | Caused or prolonged inpatient hospitalisation | | |
| Feeling abnormal | Caused or prolonged inpatient hospitalisation | | |

Medicine Details:

| | |
|--------------------------------------|---|
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation As necessary |
| Batch: | Started: |
| Batch: | Stopped: |
| MORPHINE SULPHATE (Suspected) | Reason: Nausea and vomiting |
| | 30.0 Milligram Daily |
| Batch: | Started: |
| | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 210461 **Seq:** 1 **Gender:** M
Reported: 05/08/2005 **Weight:** 80.50
Hospitalisation: **Age:** 72
Onset Date: 18/05/2005 **DOB:** 13/11/1932
Outcome: Recovered 18/05/2005 **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|---|--------------------|-----------|
| Restlessness | Caused or prolonged inpatient hospitalisation | | |

Medicine Details:

| | | |
|--------------------------------------|---|-----------------|
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation As necessary | |
| Batch: | Started: | Stopped: |
| MORPHINE SULPHATE (Suspected) | Reason: Nausea and vomiting | |
| | 30.0 Milligram Daily | |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 210462 **Seq:** 1 **Gender:** M
Reported: 05/08/2005 **Weight:** 72.00
Hospitalisation: **Age:** 13
Onset Date: 18/05/2005 **DOB:** 24/10/1991
Outcome: Recovered 18/05/2005 **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|---|--|-------------------------------|
| Dystonia | Caused or prolonged inpatient hospitalisation | Dystonic reaction to Droperidol/Morphine in normal saline PCA. | Treated with Cogentin 1mg/IV. |

Medicine Details:

| | | |
|--------------------------------------|------------------------------------|----------------------------|
| MORPHINE SULPHATE (Suspected) | Reason: Pain | |
| 1.0 Milligram | Per hour | |
| Batch: | Started: | Stopped: 0 |
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting | |
| 1.0 Milligram | Per hour | |
| Batch: | Started: | Stopped: 18/05/2005 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 215059 **Seq:** 1 **Gender:** F
Reported: 18/01/2006 **Weight:** 46.00
Hospitalisation: **Age:** 12
Onset Date: 14/11/2005 **DOB:** 26/09/1993
Outcome: Recovered 14/11/2005 **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--|-----------|
| Gaze palsy | | After the first dose of Droperidol, patient had difficulty closing eyes with an upward gaze. | |

Medicine Details:

| | |
|-------------------------------|--|
| DROPERIDOL (Suspected) | Reason: |
| Injection | 0.5 Milligram 1 time Intravenous |
| Batch: | Started: 14/11/2005 Stopped: 0 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 215576 **Seq:** 1 **Gender:** M
Reported: 06/02/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 56
Onset Date: 27/01/2006 **DOB:** 22/12/1949
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|---|---|---|
| Trismus | Caused or prolonged inpatient hospitalisation | The patient developed lock jaw, thick tongue, restlessness, anxiousness and dystonic movements with arching back. | Droperidol ceased. Given oral Valium 5mg. |
| Anxiety | Caused or prolonged inpatient hospitalisation | | |
| Dystonia | Caused or prolonged inpatient hospitalisation | | |

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection | 2.5 Milligram Daily Intravenous |
| Batch: | Started: 26/01/2006 Stopped: 27/01/2006 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 215576 **Seq:** 1 **Gender:** M
Reported: 06/02/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 56
Onset Date: 27/01/2006 **DOB:** 22/12/1949
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-----------------|---|--------------------|-----------|
| Restlessness | Caused or prolonged inpatient hospitalisation | | |
| Tongue disorder | Caused or prolonged inpatient hospitalisation | | |

Medicine Details:

| | |
|-------------------------------|---|
| DROPERIDOL (Suspected) | Reason: Nausea and vomiting |
| Injection | 2.5 Milligram Daily Intravenous |
| Batch: | Started: 26/01/2006 Stopped: 27/01/2006 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 219433 | Seq: 1 | Gender: M |
| Reported: 23/06/2006 | | Weight: 44.00 |
| Hospitalisation: | | Age: 10 |
| Onset Date: 05/05/2006 | | DOB: 01/01/1996 |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--|---------------------------------|
| Muscle spasms Eye rolling Opisthotonus Pain | | Patient developed spasm of legs, fingers and neck, arching of the back, eye rolled back. | Droperidol ceased and observed. |

Medicine Details:

| | |
|---|---|
| PANADOL (Other drug) | Reason: |
| 3.5 Gram | Oral |
| Batch: | Started: 03/05/2006 Stopped: |
| TROPISETRON HYDROCHLORIDE (Other drug) | Reason: |
| Injection 2.0 Milligram | Intravenous |
| Batch: | Started: 02/05/2006 Stopped: |
| OXYCODONE HYDROCHLORIDE (Other drug) | Reason: |
| 5.0 Milligram | Oral |
| Batch: | Started: 03/05/2006 Stopped: |
| DROPERIDOL (Suspected) | Reason: |
| 500.0 Microgram | As necessary |
| Batch: | Started: 03/05/2006 Stopped: 05/05/2006 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 219441

Seq: 1

Gender: F

Reported: 23/06/2006

Weight: 50.00

Hospitalisation:

Age: 14

Onset Date: 23/12/2005

DOB: 20/07/1991

Outcome: Recovered

24/12/2006

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|---|---|
| Anxiety | | Patient became very anxious, developed spasm feeling over entire body, occasional dyskinesia movement of upper limbs. | Treated with 2 x Benztropine 1mg IV- no response 1 x Diazepam 5 mg IV-settled after 30 min. |
| Dyskinesia | | | |
| Muscle spasms | | | |

Medicine Details:

| | | |
|--------------------------------------|----------|----------|
| OXYCODONE HYDROCHLORIDE (Other drug) | Reason: | |
| Batch: | Started: | Stopped: |
| METRONIDAZOLE (Other drug) | Reason: | |
| Batch: | Started: | Stopped: |
| GENTAMICIN SULPHATE (Other drug) | Reason: | |
| Batch: | Started: | Stopped: |
| DICLOFENAC SODIUM (Other drug) | Reason: | |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 219441
Reported: 23/06/2006

Seq: 1

Gender: F
Weight: 50.00
Age: 14
DOB: 20/07/1991
Causality: Causality possible

Hospitalisation:

Onset Date: 23/12/2005
Outcome: Recovered 24/12/2006

Reaction Details:

Medicine Details:

| | | | |
|---|----------------------------|-----------------|-------------|
| PARACETAMOL (Other drug) | Reason: | | |
| Batch: | Started: | Stopped: | |
| TROPISETRON HYDROCHLORIDE (Other drug) | Reason: | | |
| Batch: | Started: | Stopped: | |
| PROMETHAZINE HYDROCHLORIDE (Suspected) | Reason: | | |
| Injection | 25.0 Milligram | As necessary | Intravenous |
| Batch: | Started: 23/12/2005 | Stopped: | 23/12/2005 |
| DROPERIDOL (Suspected) | Reason: | | |
| Injection | 500.0 Microgram | As necessary | Intravenous |
| Batch: | Started: 20/12/2005 | Stopped: | 23/12/2005 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 219583

Seq: 1

Gender: F

Reported: 30/06/2006

Weight: 0.00

Hospitalisation:

Age: 48

Onset Date: 08/04/2006

DOB: 02/08/1957

Outcome: Recovered

08/04/2006

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--|---|
| Hypotension | | Profound hypotension (BP <30mmHg with artenal line), rash and tachycardia. | IV fluid, IV increments Aramine, IV Adrenaline total 0.8mg. |
| Rash | | | |
| Tachycardia | | | |

Medicine Details:

| | | | |
|---------------------------------------|---|-----------------|-------------|
| PROPOFOL (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 200.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 08/04/2006 | Stopped: | |
| ROCURONIUM BROMIDE (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 50.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 08/04/2006 | Stopped: | |
| Keflin Neutral (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 100.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 08/04/2006 | Stopped: | |
| DROPERIDOL (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 1.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 08/04/2006 | Stopped: | |

Laboratory Investigations:

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

Additional Information:

Allergies: Sulphurs, Penicillin, Ceforoxamine, Erythromycin. Previous exposure to Cephalothin with OA in 2005- no problem.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 219583

Seq: 1

Gender: F

Reported: 30/06/2006

Weight: 0.00

Hospitalisation:

Age: 48

Onset Date: 08/04/2006

DOB: 02/08/1957

Outcome: Recovered

08/04/2006

Causality: Causality possible

Reaction Details:

Medicine Details:

| | | | |
|--------------------------------------|---|-----------------|-------------|
| DEXAMETHASONE (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 8.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 08/04/2006 | Stopped: | |
| GRANISETRON (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 1.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 08/04/2006 | Stopped: | |
| MORPHINE SULPHATE (Suspected) | Reason: Other disturbance of sensation | | |
| Injection | 5.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 08/04/2006 | Stopped: | |
| MIDAZOLAM (Suspected) | Reason: | | |
| Injection | 5.0 Milligram | 1 time | Intravenous |
| Batch: | Started: 08/04/2006 | Stopped: | |

Laboratory Investigations:

Additional Information:

Allergies: Sulphurs, Penicillin, Ceforoxamine, Erythromycin. Previous exposure to Cephalothin with OA in 2005- no problem.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 223236

Seq: 1

Gender: U

Reported: 16/11/2006

Weight: 37.00

Hospitalisation:

Age: 11

Onset Date: 10/09/2006

DOB: 19/05/1995

Outcome: Recovered

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---|
| Oculogyration | | Oculogyric crisis. | Patient required benztropine injection. |

Medicine Details:

| | |
|-------------------------------|-----------------|
| DROPERIDOL (Suspected) | Reason: |
| 0.5 Milligram | |
| Batch: | Started: |
| | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 224140

Seq: 1

Gender: F

Reported: 18/12/2006

Weight: 0.00

Hospitalisation:

Onset Date: 20/10/2006

Age: 57

Outcome: Unknown

DOB: 19/01/1949

Causality: Causality possible

Reaction Details:

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------|----------|--|---|
| Anaphylactic reaction | | Developed rash over body, acute hypotension, decreased saturation, bronchospasm. | Adrenaline, dexamethasone, fluids and promethazine. |

Medicine Details:

| | | |
|-----------------------------------|---------------------|----------|
| Desflurane (Suspected) | Reason: | |
| Batch: | Started: 20/10/2006 | Stopped: |
| ROCURONIUM BROMIDE (Suspected) | Reason: | |
| Batch: | Started: 20/10/2006 | Stopped: |
| SUXAMETHONIUM BROMIDE (Suspected) | Reason: | |
| Batch: | Started: 20/10/2006 | Stopped: |
| THIOPENTONE SODIUM (Suspected) | Reason: | |
| Batch: | Started: 20/10/2006 | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 26 Aug 1988 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames:
DROLEPTAN,DROPERIDOL

Report Details:

Case Number: 224140

Seq: 1

Gender: F

Reported: 18/12/2006

Weight: 0.00

Hospitalisation:

Age: 57

Onset Date: 20/10/2006

DOB: 19/01/1949

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

| | |
|---|--|
| DROPERIDOL (Suspected) | Reason: |
| Batch: | Started: 20/10/2006 Stopped: |
| FENTANYL (Suspected) | Reason: |
| Batch: | Started: 20/10/2006 Stopped: |
| MORPHINE HYDROCHLORIDE (Suspected) | Reason: |
| Batch: | 1 time Started: 20/10/2006 Stopped: |

Laboratory Investigations:

Additional Information: