



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 2173 **Seq:** 1 **Gender:** F
Reported: 21/08/1989 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 01/08/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------------------------|----------|--------------------|------------------------------|
| Mouth ulceration Pain Rash | | | Topical analgesics, nilstat. |

Medicine Details:

| | |
|--|---|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Rash |
| 30.0 Dose Unspecified Daily | |
| Batch: | Started: 25/07/1989 Stopped: 31/07/1989 |
| PROPYLTHIOURACIL (Suspected) | Reason: Thyrotoxicosis w/o ment goiter |
| 600.0 Milligram Daily | |
| Batch: | Started: 26/07/1989 Stopped: 08/08/1989 |

Laboratory Investigations:

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

Additional Information:

Case Sequenced to: 62758/2



THERAPEUTIC GOODS ADMINISTRATION

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 57925 **Seq:** 1 **Gender:** F
Reported: 04/01/1989 **Weight:**
Hospitalisation: **Age:** 59Y
Onset Date: 06/11/1988 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------------|
| Hepatitis | | | Feldene ceased. |

Medicine Details:

| | |
|---|--------------------------------------|
| FELDENE (Suspected) | Reason: Unspecified arthritis |
| Capsule 20.0 Milligram Daily Oral | |
| Batch: Started: 01/12/1986 Stopped: 06/11/1988 | |
| SINEQUAN (Suspected) | Reason: Disturbance of sleep |
| Capsule 50.0 Milligram Daily Oral | |
| Batch: Started: 01/01/1983 Stopped: | |
| SEREPAX (Suspected) | Reason: Disturbance of sleep |
| Tablet 30.0 Milligram Daily Oral | |
| Batch: Started: 01/01/1983 Stopped: | |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|--|
| | Biochemistry | | | | Markedly elevated liver enzyme tests return to normal except lft - by 12/12/88 - all ggt -130 (5-35) |

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



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Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 59278 | Seq: 1 | Gender: F |
| Reported: 16/03/1989 | | Weight: |
| Hospitalisation: | | Age: 19Y |
| Onset Date: 10/03/1989 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|--------------------|--|
| Grand mal convulsion | | | Phenytoin 300mg mane. sinequan reduced to 100mg |

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Depression |
| 175.0 Milligram | Daily |
| Batch: | Started: 01/03/1989 Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:

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



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Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 59564 | Seq: 1 | Gender: F |
| Reported: 03/04/1989 | | Weight: 60.00 |
| Hospitalisation: | | Age: 44Y |
| Onset Date: 09/03/1989 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------------------------|
| Alopecia | | | Withdraw epilim, changed to |

Medicine Details:

| | |
|-----------------------------|---|
| EPILIM (Suspected) | Reason: Generalizd convulsive epilepsy |
| Tablet | 1.2 Gram Daily Oral |
| Batch: | Started: 01/11/1988 Stopped: 18/03/1989 |
| SINEQUAN (Suspected) | Reason: |
| | 25.0 Milligram Daily |
| Batch: | Started: Stopped: 02/12/1988 |
| VALIUM (Suspected) | Reason: Abnormal involuntary movement |
| Tablet | 2.0 Milligram Daily Oral |
| Batch: | Started: Stopped: |
| DOLOBID (Suspected) | Reason: Other disturbance of sensation |
| | 500.0 Milligram Daily |
| Batch: | Started: 01/11/1988 Stopped: |

Laboratory Investigations:

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

Additional Information:

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



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Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 59585 | Seq: 1 | Gender: M |
| Reported: 11/04/1989 | | Weight: 89.00 |
| Hospitalisation: | | Age: 62Y |
| Onset Date: 14/12/1988 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Detail

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

Medicine Details:

| | | |
|-----------------------------------|----------------------------|----------------------------|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: | |
| 300.0 Milligram | Daily | |
| Batch: | Started: 01/01/1987 | Stopped: 14/12/1988 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: | |
| 250.0 Milligram | Daily | |
| Batch: | Started: 14/12/1988 | Stopped: 28/01/1989 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: | |
| 200.0 Milligram | Daily | |
| Batch: | Started: | Stopped: CONTIN |

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



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Report Detail

| | | |
|-----------------------------|---------------|-------------------------------------|
| Case Number: 60127 | Seq: 1 | Gender: M |
| Reported: 09/05/1989 | | Weight: 88.00 |
| Hospitalisation: | | Age: 68Y |
| Onset Date: | | DOB: |
| Outcome: Recovered | | Causality: Causality certain |

Reaction Detail

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

Medicine Details:

| | | |
|----------------------|----------------|----------|
| TOLVON (Other drug) | 0.0 | Reason: |
| Batch: | Started: | Stopped: |
| MOGADON (Other drug) | 0.0 | Reason: |
| Batch: | Started: | Stopped: |
| DEPTRAN (Suspected) | 25.0 Milligram | Daily |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 60524 **Seq:** 1 **Gender:** M
Reported: 03/05/1989 **Weight:**
Hospitalisation: **Age:** 83Y
Onset Date: 10/04/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------------|----------|--------------------|---------------------------|
| Hypertonia | | | iv kcl, normal saline iv, |
| Hypotension | | | |
| Respiratory depression | | | |

Medicine Details:

| | |
|--|--|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| Oral application | 50.0 Milligram 1 time Oral |
| Batch: | Started: 10/04/1989 Stopped: |

Laboratory Investigations:

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

Additional Information:

See original report for other drugs.



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Report Detail

Case Number: 60592 **Seq:** 1 **Gender:** F
Reported: 29/05/1989 **Weight:** 64.00
Hospitalisation: **Age:** 58Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|--------------------|-----------|
| Increased appetite | | | |
| Weight increased | | | |

Medicine Details:

| | |
|----------------------------|---|
| DEPTRAN (Suspected) | Reason: Depression |
| 50.0 Milligram | Daily |
| Batch: | Started: 23/06/1986 Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:



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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 61199 **Seq:** 1 **Gender:** F
Reported: 16/06/1989 **Weight:**
Hospitalisation: **Age:** 65Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

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

Medicine Details:

| | |
|----------------------------|--|
| DEPTRAN (Suspected) | Reason: Depression |
| 100.0 Milligram | Daily |
| Batch: | Started: 01/02/1989 Stopped: |

Laboratory Investigations:

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

Additional Information:

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 61299

Seq: 1

Gender: F

Reported: 06/07/1989

Weight: 60.00

Hospitalisation:

Age: 75Y

Onset Date: 15/05/1989

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

| | | | |
|----------------------------|----------------------------|----------------------------|------|
| DEPTRAN (Suspected) | Reason: Depression | | |
| Capsule | 50.0 Milligram | Daily | Oral |
| Batch: | Started: 15/05/1989 | Stopped: 22/06/1989 | |

Laboratory Investigations:

Additional Information:



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Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 61421 **Seq:** 1 **Gender:** F
Reported: 14/07/1989 **Weight:** 51.00
Hospitalisation: **Age:** 59Y
Onset Date: 29/04/1989 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

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

Medicine Details:

| | |
|----------------------------|---|
| DEPTRAN (Suspected) | Reason: Depression |
| | 3.0 Dose Unspecified Daily |
| Batch: | Started: 29/04/1989 Stopped: 14/07/1989 |

Laboratory Investigations:

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

Additional Information:



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Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 61562 | Seq: 1 | Gender: F |
| Reported: 19/07/1989 | | Weight: 50.00 |
| Hospitalisation: | | Age: 50Y |
| Onset Date: 17/07/1989 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|-----------|
| Agitation Coordination abnormal Hyperacusis Insomnia | | | |

Medicine Details:

| | |
|------------------------------|---|
| MIDAMOR (Other drug) | Reason: Essential benign hypertension |
| Tablet | 1.0 Dose Unspecified Daily Oral |
| Batch: | Started: 01/01/1988 Stopped: CONTIN |
| TRANDATE (Other drug) | Reason: Essential benign hypertension |
| Tablet | 400.0 Milligram Daily Oral |
| Batch: | Started: 01/01/1988 Stopped: CONTIN |
| SINEQUAN (Other drug) | Reason: Nervousness |
| Capsule | 25.0 Milligram Daily Oral |
| Batch: | Started: 01/01/1988 Stopped: 17/07/1989 |
| SEREPAX (Other drug) | Reason: Anxiety neurosis |
| Tablet | 15.0 Milligram Daily Oral |
| Batch: | Started: 01/01/1989 Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:

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Report Detail

Case Number: 61562

Seq: 1

Gender: F

Reported: 19/07/1989

Weight: 50.00

Hospitalisation:

Age: 50Y

Onset Date: 17/07/1989

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

DEPTRAN (Suspected)

Reason: Anxiety neurosis

Capsule

25.0 Milligram

1 time

Oral

Batch:

Started: 17/07/1989

Stopped: 17/07/1989

Laboratory Investigations:

Additional Information:

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



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Report Detail

| | | |
|-------------------------------|---------------|-------------------------------------|
| Case Number: 61878 | Seq: 1 | Gender: F |
| Reported: 03/08/1989 | | Weight: |
| Hospitalisation: | | Age: 56Y |
| Onset Date: 08/06/1989 | | DOB: |
| Outcome: Recovered | | Causality: Causality certain |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|--|
| Choreoathetosis Confusional state Coordination abnormal Hepatic function abnormal Speech disorder | | | Ceased lithium. recommenced on 1/4 dose (250mg mane) |

Medicine Details:

| | | |
|--|-----------------|---|
| TRANSIDERM-NITRO (Suspected) | | Reason: Essential benign hypertension |
| 0.0 | | |
| Batch: | Started: | Stopped: 13/06/1989 |
| LITHIUM CARBONATE (Suspected) | | Reason: Unspecifid affective psychosis |
| Tablet | 1.0 Gram | Daily Oral |
| Batch: | Started: | Stopped: 08/06/1989 |
| NIFEDIPINE (Suspected) | | Reason: Essential benign hypertension |
| Oral application | 40.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: 13/06/1989 |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: Depression |
| | 150.0 Milligram | Daily |
| Batch: | Started: | Stopped: 08/06/1989 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------------|-------|-------------|--------|--|
| | Pharmacokinetics | | | | 8/6/89 13/6/89 16/6/89 se lithium levels (0.6-1.2 mmol/l): 1.87 1.73 0.99 se phenytoin level (40-80 umol/l) : 2.0 |

Additional Information:



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Report Detail

| | | |
|-----------------------------|---------------|-------------------------------------|
| Case Number: 61987 | Seq: 1 | Gender: F |
| Reported: 16/08/1989 | | Weight: 92.00 |
| Hospitalisation: | | Age: 64Y |
| Onset Date: | | DOB: |
| Outcome: Recovered | | Causality: Causality certain |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--------------------------|
| Headache | | | Changed back to sinequan |
| Headache | | | |

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 62156 **Seq:** 1 **Gender:** F
Reported: 29/08/1989 **Weight:** 64.00
Hospitalisation: **Age:** 66Y
Onset Date: 07/10/1988 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Eczema | | | |
| Rash | | | |

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Neuroses |
| Capsule | 150.0 Milligram Daily Oral |
| Batch: | Started: 30/12/1987 Stopped: 14/04/1989 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|------------------------|
| | Other data | | | | 1eczema craquele acute |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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Report Detail

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 62195 | Seq: 1 | Gender: F |
| Reported: 30/08/1989 | | Weight: |
| Hospitalisation: | | Age: |
| Onset Date: | | DOB: |
| Outcome: Unknown | | Causality: Causality probable |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--------------------|-----------|
| Constipation | | | |
| Depersonalisation | | | |
| Dry mouth | | | |

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:



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Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 62292 | Seq: 1 | Gender: F |
| Reported: 03/08/1989 | | Weight: |
| Hospitalisation: | | Age: 51 |
| Onset Date: 27/06/1989 | | DOB: 09/12/1937 |
| Outcome: Death, maybe drug | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------|----------|--------------------|-----------|
| Arrhythmia | | | |
| Myocardial infarction | | | |

Medicine Details:

| | | | |
|--|----------------------------|---------------------------|-----------------|
| OESTRADIOL (Suspected) | | Reason: | |
| Nasal Drops | 0.0 | | Nasal |
| Batch: | Started: | | Stopped: |
| DI-GESIC (Suspected) | | Reason: | |
| Tablet | 0.0 | | Oral |
| Batch: | Started: | | Stopped: |
| CHOLECALCIFEROL (Suspected) | | Reason: | |
| Oral application | 10.0 | Thousand Internat Monthly | Oral |
| Batch: | Started: | | Stopped: |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | |
| Oral application | 25.0 | Milligram Daily | Oral |
| Batch: | Started: 17/04/1989 | | Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-----------|-------|-------------|--------|--|
| | Histology | | | | Suspected cause of death: arrhythmia myocardial pathology: microscopic focal necrosis. |

Additional Information:



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Report Detail

Case Number: 62292 **Seq:** 1 **Gender:** F
Reported: 03/08/1989 **Weight:**
Hospitalisation: **Age:** 51
Onset Date: 27/06/1989 **DOB:** 09/12/1937
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Medicine Details:

| | |
|--|----------------|
| PIROXICAM (Suspected) | Reason: |
| Capsule 20.0 Milligram Daily Oral | |
| Batch: Started: Stopped: | |
| OXAZEPAM (Suspected) | Reason: |
| Tablet 15.0 Milligram Daily Oral | |
| Batch: Started: Stopped: | |
| PETHIDINE HYDROCHLORIDE (Suspected) | Reason: |
| 100.0 Milligram Daily | |
| Batch: Started: Stopped: | |
| MAXOLON (Suspected) | Reason: |
| 20.0 Milligram Daily | |
| Batch: Started: Stopped: | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

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Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 62669 | Seq: 1 | Gender: M |
| Reported: 14/08/1989 | | Weight: |
| Hospitalisation: | | Age: 66Y |
| Onset Date: 11/07/1989 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------|-------------|
| Consciousness fluctuating Dehydration Hypernatraemia Renal impairment | | | Rehydration |

Medicine Details:

| | |
|--|---|
| LITHIUM CARBONATE (Suspected) | Reason: Unspecifid affective psychosis |
| Tablet | 1.0 Gram Daily Oral |
| Batch: | Started: Stopped: 17/07/1989 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Unspecifid affective psychosis |
| | 125.0 Milligram Daily |
| Batch: | Started: Stopped: 17/07/1989 |
| HALOPERIDOL (Suspected) | Reason: Unspecifid affective psychosis |
| | 0.5 Milligram Daily |
| Batch: | Started: Stopped: 17/07/1989 |
| THEO-DUR (Suspected) | Reason: Otr respiratory systm diseases |
| | 600.0 Milligram Daily |
| Batch: | Started: Stopped: 17/07/1989 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 62669

Seq: 1

Gender: M

Reported: 14/08/1989

Weight:

Hospitalisation:

Age: 66Y

Onset Date: 11/07/1989

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

MODECATE (Suspected)

Reason: Unspecifid affective psychosis

Injection

6.2 Milligram

Alternate weeks

Intramuscular

Batch:

Started:

Stopped: 17/07/1989

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 62825 **Seq:** 1 **Gender:** M
Reported: 07/10/1989 **Weight:** 75.00
Hospitalisation: **Age:** 61Y
Onset Date: 31/08/1989 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--------------------|---------------------------|
| Drug ineffective | | | Changed back to sinequan. |

Medicine Details:

| | |
|----------------------------|---|
| DEPTRAN (Suspected) | Reason: Depression |
| 0.0 | |
| Batch: | Started: 01/08/1989 Stopped: 30/09/1989 |

Laboratory Investigations:

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

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 62826 | Seq: 1 | Gender: F |
| Reported: 09/10/1989 | | Weight: 67.00 |
| Hospitalisation: | | Age: 48Y |
| Onset Date: | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|--------------------|-----------|
| Increased appetite | | | |
| Paraesthesia | | | |
| Weight increased | | | |

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Depression |
| 75.0 Milligram | Daily |
| Batch: | Started: 01/08/1989 Stopped: 09/10/1989 |
| VALIUM (Suspected) | Reason: Dependence on unspecified drugs |
| 1.0 Milligram | Daily |
| Batch: | Started: 01/01/1977 Stopped: |

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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 63208 | Seq: 1 | Gender: M |
| Reported: 13/11/1989 | | Weight: 70.00 |
| Hospitalisation: | | Age: 55Y |
| Onset Date: 29/08/1989 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--------------------|-----------|
| Rash morbilliform | | | |

Medicine Details:

| | | | |
|--|----------------------------|---------------------------------|--------|
| CARBAMAZEPINE (Suspected) | | Reason: | |
| Oral application | 600.0 Milligram | Daily | Oral |
| Batch: | Started: 01/06/1989 | Stopped: 02/09/1989 | |
| ZIDOVUDINE (Suspected) | | Reason: | |
| Oral application | 1.0 Gram | Daily | Oral |
| Batch: | Started: 21/08/1989 | Stopped: 30/08/1989 | |
| DIAZEPAM (Suspected) | | Reason: Anxiety neurosis | |
| Oral application | 20.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | CONTIN |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: Depression | |
| Oral application | 50.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: 30/08/1989 | |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 63449 | Seq: 1 | Gender: F |
| Reported: 24/11/1989 | | Weight: 55.00 |
| Hospitalisation: | | Age: 76Y |
| Onset Date: 18/11/1989 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|---|
| Bradycardia Dysphagia Sleep disorder Speech disorder Tremor | | | Cogentin im followed by cogentin 2mg tds. |

Medicine Details:

| | | | |
|------------------------------|----------------------------|---------------------------|------------|
| FELDENE (Suspected) | | Reason: | |
| Oral application | 10.0 Milligram | Daily | Oral |
| Batch: | Started: 01/11/1988 | Stopped: | CONTIN |
| SEREPAX (Suspected) | | Reason: | |
| Oral application | 30.0 Milligram | Daily | Oral |
| Batch: | Started: 01/11/1987 | Stopped: | CONTIN |
| ANATENSOL (Suspected) | | Reason: Depression | |
| Oral application | 2.0 Milligram | Daily | Oral |
| Batch: | Started: 05/10/1989 | Stopped: | 21/11/1989 |
| DEPTRAN (Suspected) | | Reason: Paranoia | |
| Oral application | 25.0 Milligram | Daily | Oral |
| Batch: | Started: 05/10/1989 | Stopped: | |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 63820 | Seq: 1 | Gender: M |
| Reported: 22/12/1989 | | Weight: 112.00 |
| Hospitalisation: | | Age: 44Y |
| Onset Date: 21/12/1989 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | |
|--|--|
| BACLOFEN (Suspected) | Reason: Abnormal involuntary movement |
| 30.0 Milligram Daily | |
| Batch: | Started: |
| Stopped: | |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| 200.0 Milligram Daily | |
| Batch: | Started: |
| Stopped: | |
| ECOTRIN (Suspected) | Reason: |
| 650.0 Milligram Daily | |
| Batch: | Started: |
| Stopped: | |
| BACTRIM DS (Suspected) | Reason: Other prophylactic procedures |
| 0.5 Dose Unspecified Daily | |
| Batch: | Started: |
| Stopped: 22/12/1989 | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 63820 **Seq:** 1

Gender: M

Reported: 22/12/1989

Weight: 112.00

Hospitalisation:

Age: 44Y

Onset Date: 21/12/1989

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | |
|---------------------------|--|-----------------|
| VALIUM (Suspected) | Reason: Abnormal involuntary movement | |
| 5.0 Milligram | Daily | |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 63885 **Seq:** 1 **Gender:** F
Reported: 05/01/1990 **Weight:** 70.00
Hospitalisation: Admitted to hospital **Age:** 48Y
Onset Date: 20/11/1989 **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------------------|----------|--------------------|---|
| Supraventricular tachycardia | | | Plendil replaced by lopresor 2 x 50 mg. |

Medicine Details:

| | |
|---|---|
| PLENDIL (Interaction) | Reason: Essential benign hypertension |
| Oral application 10.0 Milligram Daily Oral | |
| Batch: | Started: 01/04/1988 Stopped: 21/11/1989 |
| SINEQUAN (Interaction) | Reason: Depression |
| Oral application 50.0 Milligram Daily Oral | |
| Batch: | Started: 18/11/1989 Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 64091 | Seq: 1 | Gender: M |
| Reported: 16/01/1990 | | Weight: 83.00 |
| Hospitalisation: | | Age: 53Y |
| Onset Date: 02/06/1989 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | |
|--|--|
| TAGAMET (Other drug) | Reason: Ulcer of duodenum w/o ment perf |
| 800.0 Milligram | Daily |
| Batch: | Started: 01/01/1988 Stopped: |
| ZYLOPRIM (Other drug) | Reason: Gout |
| 300.0 Milligram | Daily |
| Batch: | Started: 01/01/1975 Stopped: |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| 50.0 Milligram | Daily |
| Batch: | Started: 02/06/1989 Stopped: |

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 64146 **Seq:** 1 **Gender:** F
Reported: 24/01/1990 **Weight:** 48.00
Hospitalisation: **Age:** 65Y
Onset Date: 15/12/1989 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------------------|
| Constipation | | | Manual extraction and |

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Depression |
| 25.0 Milligram | Daily |
| Batch: | Started: 14/12/1989 Stopped: 21/12/1989 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 64292 **Seq:** 1 **Gender:** F
Reported: 08/02/1990 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: 31/01/1990 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------------|
| Convulsion | | | Withdrawal of sinequan |

Medicine Details:

| | |
|--|---|
| SINEQUAN (Suspected) | Reason: Depression |
| Capsule 50.0 Milligram Daily Oral | |
| Batch: | Started: 01/01/1990 Stopped: 05D |
| DISOPYRAMIDE (Suspected) | Reason: Otr&nos disord of heart rhythm |
| Tablet 300.0 Milligram Daily Oral | |
| Batch: | Started: 01/01/1980 Stopped: CONTIN |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-----------|-------|-------------|--------|---------------|
| | Radiology | | | | Ct scan clear |

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 65085 | Seq: 1 | Gender: F |
| Reported: 11/04/1990 | | Weight: |
| Hospitalisation: | | Age: 42Y |
| Onset Date: 31/01/1990 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------|--------------------|-----------|
| Diarrhoea | | | |
| Drug withdrawal syndrome | | | |
| Headache | | | |
| Hot flush | | | |
| Insomnia | | | |
| Nausea | | | |
| Rhinitis | | | |

Medicine Details:

| | |
|--|---------------------|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: |
| | Stopped: 05Y |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 65700 | Seq: 1 | Gender: M |
| Reported: 28/05/1990 | | Weight: 73.00 |
| Hospitalisation: | | Age: 64Y |
| Onset Date: 18/05/1990 | | DOB: |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--|
| Hyperhidrosis | | | Stoped deptran and commenced prothiaden. |

Medicine Details:

| | |
|------------------------------|-------------------------------|
| VOLTAREN (Other drug) | Reason: Osteoarthritis |
| 100.0 Milligram | Daily |
| Batch: | Started: |
| Stopped: | |
| SEREPAX (Other drug) | Reason: Depression |
| 15.0 Milligram | Daily |
| Oral application | Oral |
| Batch: | Started: |
| Stopped: | |
| DEPTRAN (Suspected) | Reason: Depression |
| 50.0 Milligram | Daily |
| Batch: | Started: 18/05/1990 |
| Stopped: | 28/05/1990 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 65932 | Seq: 1 | Gender: M |
| Reported: 30/05/1990 | | Weight: 65.00 |
| Hospitalisation: | | Age: 46Y |
| Onset Date: 26/05/1990 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | |
|--|--|
| RIFAMPICIN (Suspected) | Reason: Bacterial disease nec |
| Oral application | 600.0 Milligram Daily Oral |
| Batch: | Started: 15/05/1990 Stopped: |
| CIPROFLOXACIN (Suspected) | Reason: Bacterial disease nec |
| Oral application | 1.0 Gram Daily Oral |
| Batch: | Started: 15/05/1990 Stopped: |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Bacterial disease nec |
| Oral application | 50.0 Milligram Daily Oral |
| Batch: | Started: 15/05/1990 Stopped: |
| BACTRIM DS (Suspected) | Reason: |
| Oral application | 2.0 Dose Unspecified Daily Oral |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 65932 **Seq:** 1

Gender: M

Reported: 30/05/1990

Weight: 65.00

Hospitalisation:

Age: 46Y

Onset Date: 26/05/1990

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|--|---------------------------------|
| KETOCONAZOLE (Suspected) | Reason: |
| Oral application 400.0 Milligram Daily Oral | |
| Batch: | Started: Stopped: |
| LACTOBACILLUS ACIDOPHILUS (Suspected) | Reason: |
| Tablet 3.0 Dose Unspecified Daily Oral | |
| Batch: | Started: Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 66072 **Seq:** 1 **Gender:** F
Reported: 15/06/1990 **Weight:** 92.00
Hospitalisation: **Age:** 42Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------------|----------|--------------------|--|
| Eaton-Lambert syndrome | | | Much improved myaesthesia on cessation of doxepin. |

Medicine Details:

| | | |
|--|---------------------------|----------------------------|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression | |
| 75.0 Milligram | Daily | |
| Batch: | Started: | Stopped: 28/04/1990 |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 66205 **Seq:** 1 **Gender:** M
Reported: 12/06/1990 **Weight:** 70.00
Hospitalisation: **Age:**
Onset Date: 29/03/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--|
| Dystonia | | | Intravenous benztropine (cogentin) 2mg |

Medicine Details:

| | |
|-----------------------------|--|
| SINEQUAN (Suspected) | Reason: Depression |
| Oral application | 50.0 Milligram 1 time Oral |
| Batch: | Started: 28/03/1990 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 66530 | Seq: 1 | Gender: M |
| Reported: 06/07/1990 | | Weight: |
| Hospitalisation: | | Age: 34Y |
| Onset Date: 04/04/1990 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---------------------|----------|--------------------|-----------|
| Atrial fibrillation | | | |

Medicine Details:

| | | |
|-----------------------------|-----------------|---------------------------|
| SINEQUAN (Suspected) | | Reason: Depression |
| Oral application | 150.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 67195 **Seq:** 1 **Gender:** F
Reported: 05/09/1990 **Weight:**
Hospitalisation: **Age:** 62Y
Onset Date: 05/06/1990 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | | |
|--|--|----------------------------|
| RANITIDINE (Suspected) | Reason: Other diseases of esophagus | |
| 0.0 | | |
| Batch: | Started: | Stopped: 05/06/1990 |
| PROTHIADEN (Suspected) | Reason: | |
| 75.0 Milligram | Daily | |
| Batch: | Started: | Stopped: 11/06/1990 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: | |
| 50.0 Milligram | Daily | |
| Batch: | Started: | Stopped: 05/06/1990 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 67692 **Seq:** 1 **Gender:** M
Reported: 02/10/1990 **Weight:**
Hospitalisation: **Age:** 52Y
Onset Date: 26/07/1990 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---------------|
| Glaucoma | | | Timolol drops |

Medicine Details:

| | |
|-----------------------------|--|
| SINEQUAN (Suspected) | Reason: Depression |
| Capsule | 75.0 Milligram Daily Oral |
| Batch: | Started: 12/07/1990 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 68536 | Seq: 1 | Gender: F |
| Reported: 30/11/1990 | | Weight: 76.00 |
| Hospitalisation: | | Age: 71Y |
| Onset Date: 31/10/1990 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Anxiety neurosis |
| 25.0 Milligram | Daily |
| Batch: | Started: 01/01/1980 Stopped: 28/10/1990 |
| ALCOHOL (Suspected) | Reason: |
| 1.0 Dose Unspecified | Daily |
| Batch: | Started: Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-------------|-------|-------------|--------|--|
| | Haematology | | | | 1 10/12/90 19/11 12/11 7/11 31/10 25/10 18/10 12/10 wcc: 2.5 2.0 2.5 2.7 2.1 2.7 2.1 2.2 neut: 0.7 0.6 0.4 0.4 0.4 0.6 0.3 0.4 lymph: 1.6 1.1 1.6 1.9 1.5 1.6 1.3 1.1 a bone marrow examination showed a mild decrease in granulopoietic |
| | Histology | | | | Precursors with normal morphology. red cells and megakaryocyte precursors were normal. |

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 68628 | Seq: 1 | Gender: F |
| Reported: 06/12/1990 | | Weight: 43.00 |
| Hospitalisation: | | Age: 20Y |
| Onset Date: 16/11/1990 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Detail

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

Medicine Details:

| | | |
|-----------------------------|----------------------------|----------------------------|
| SINEQUAN (Suspected) | | Reason: Depression |
| Capsule | 50.0 Milligram | Daily Oral |
| Batch: | Started: 01/11/1990 | Stopped: 21/11/1990 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-------------|-------|-------------|--------|---|
| | Haematology | | | | 1 15/10/90 16/10 17/10 16/11 21/11 22/11 26/11 5/12 range wbc: 5.0 9.7 10.2 -3.6 -2.8 -3.5 -3.8 4.7 (4.0-10.5) neut: 2.40 - - -1.69 -1.40 -1.89 2.01 2.82 (1.9-6.8) lymph: 2.00 - - 1.66 -1.18 1.30 1.48 1.55 (1.2-3.7) |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 69030 | Seq: 1 | Gender: M |
| Reported: 07/01/1991 | | Weight: 70.00 |
| Hospitalisation: | | Age: 65Y |
| Onset Date: 24/12/1990 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|----------|--------------------|--|
| Photosensitivity reaction | | | Ceased mysteclin & given oral prednisone |

Medicine Details:

| | |
|--|---|
| VENTOLIN (Other drug) | Reason: Asthma |
| 1.0 Dose Unspecified As necessary | |
| Batch: | Started: 01/01/1984 Stopped: CONTIN |
| BECOTIDE (Other drug) | Reason: Asthma |
| Inhalation 4.0 Dose Unspecified Daily Inhalation | |
| Batch: | Started: 01/01/1984 Stopped: CONTIN |
| SEREPAX (Other drug) | Reason: Specific disorders of sleep |
| Tablet 15.0 Milligram Daily Oral | |
| Batch: | Started: 01/01/1984 Stopped: CONTIN |
| MYSTECLIN V (Suspected) | Reason: Other prophylactic procedures |
| Capsule 250.0 Milligram Daily Oral | |
| Batch: | Started: 01/01/1986 Stopped: 31/12/1990 |

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 69030

Seq: 1

Gender: M

Reported: 07/01/1991

Weight: 70.00

Hospitalisation:

Age: 65Y

Onset Date: 24/12/1990

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | |
|----------------------|---------------------|---------------------|
| SINEQUAN (Suspected) | Reason: Depression | |
| 25.0 Milligram | Daily | |
| Batch: | Started: 01/01/1980 | Stopped: 02/01/1991 |

Laboratory Investigations:

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|------------------------|--------|-------------------------------|
| Case Number: 69121 | Seq: 1 | Gender: F |
| Reported: 14/01/1991 | | Weight: 63.00 |
| Hospitalisation: | | Age: 77Y |
| Onset Date: 17/09/1990 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------------------------|----------|--------------------|--|
| Coombs positive haemolytic anaemia | | | Noroxin was ceased and was transfused. |

Medicine Details:

| | |
|-----------------------------------|---|
| KOLPON (Suspected) | Reason: Pain |
| Tablet | 1.0 Dose Unspecified Weekly Vaginal |
| Batch: | Started: 12/09/1990 Stopped: CONTIN |
| NOROXIN (Suspected) | Reason: Othr diseases of urinary tract |
| | 800.0 Milligram Daily |
| Batch: | Started: 12/09/1990 Stopped: 17/09/1990 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| | 50.0 Milligram Daily |
| Batch: | Started: 01/01/1985 Stopped: CONTIN |
| CARBAMAZEPINE (Suspected) | Reason: Other&unspecified epilepsy |
| | 600.0 Milligram Daily |
| Batch: | Started: 01/01/1984 Stopped: CONTIN |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-------------|-------|-------------|--------|---|
| | Haematology | | | | 1 17/9 18/9 19/9 21/9 25/9 29/9 16/10 9/11 range erythrocytes: 2.09 1.77 1.55 2.95 3.24 2.95 5.8 6.3 (4.6-6.2) haemoglobin: 6.8 6.0 5.9 10.3 11.1 9.8 - - (13.5-18.0) reticulocytes: - 8.8 11.4 8.2 9.0 7.2 18.8 14.2 (0.1-4) direct coombs polyspecific positive |

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 69121
Reported: 14/01/1991
Hospitalisation:
Onset Date: 17/09/1990
Outcome: Recovered

Seq: 1

Gender: F
Weight: 63.00
Age: 77Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|---------------------------------|-----------------|-----------------|--------|
| ASPIRIN (Suspected) | Reason: | | |
| 150.0 Milligram | Daily | | |
| Batch: | Started: | Stopped: | CONTIN |
| DIPYRIDAMOLE (Suspected) | Reason: | | |
| 200.0 Milligram | Daily | | |
| Batch: | Started: | Stopped: | CONTIN |

Laboratory Investigations:

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 69373 | Seq: 1 | Gender: M |
| Reported: 05/02/1991 | | Weight: |
| Hospitalisation: | | Age: 54Y |
| Onset Date: 31/12/1990 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------------|----------|--------------------|-----------------|
| Haemolytic anaemia Malaise | | | Given steroids. |

Medicine Details:

| | | |
|-----------------------------|----------------------------|---|
| SINEQUAN (Suspected) | | Reason: Otr ecz&der due otr&unsp cause |
| Tablet | 10.0 Milligram | Daily Oral |
| Batch: | Started: 01/11/1990 | Stopped: |

Laboratory Investigations:

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

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 69394 | Seq: 1 | Gender: M |
| Reported: 01/02/1991 | | Weight: |
| Hospitalisation: | | Age: 49Y |
| Onset Date: 09/03/1990 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--------------------|--|
| Abdominal pain | | | I/c (drained 1.2l in 1 hr), hydration. all drugs ceased. |
| Anuria | | | |
| Constipation | | | |
| Renal impairment | | | |

Medicine Details:

| | | | |
|--|-----------------|-----------------|------------|
| LITHIUM CARBONATE (Suspected) | | Reason: | |
| 1.0 Gram | Daily | | |
| Batch: | Started: | Stopped: | 06/03/1990 |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | |
| Tablet | 150.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | 06/03/1990 |
| TRIFLUOPERAZINE HYDROCHLORIDE (Suspected) | | Reason: | |
| Tablet | 5.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | 06/03/1990 |
| BENZTROPINE MESYLATE (Suspected) | | Reason: | |
| Tablet | 10.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | 06/03/1990 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|------------------|
| | Biochemistry | | | | Creatinine - 603 |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 69930 | Seq: 1 | Gender: M |
| Reported: 12/03/1991 | | Weight: 115.00 |
| Hospitalisation: | | Age: 42Y |
| Onset Date: 01/03/1991 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Detail

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

Medicine Details:

| | |
|-------------------------------------|--|
| TRANDATE (Other drug) | Reason: |
| 600.0 Milligram | Daily |
| Batch: | Started: 01/01/1980 Stopped: |
| NAPROSYN (Other drug) | Reason: |
| Oral application 500.0 Milligram | Daily Oral |
| Batch: | Started: 01/01/1980 Stopped: |
| ZYLOPRIM (Other drug) | Reason: |
| 300.0 Milligram | Daily |
| Batch: | Started: 01/01/1988 Stopped: |
| MINIPRESS (Other drug) | Reason: |
| 30.0 Milligram | Daily |
| Batch: | Started: 01/01/1980 Stopped: |

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 69930

Seq: 1

Gender: M

Reported: 12/03/1991

Weight: 115.00

Hospitalisation:

Age: 42Y

Onset Date: 01/03/1991

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

| | | | |
|-----------------------------|----------------------------|----------------------------|------|
| SINEQUAN (Suspected) | Reason: Depression | | |
| Oral application | 25.0 Milligram | Daily | Oral |
| Batch: | Started: 01/03/1991 | Stopped: 03/03/1991 | |

Laboratory Investigations:

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 70203 | Seq: 1 | Gender: F |
| Reported: 21/03/1991 | | Weight: |
| Hospitalisation: | | Age: 92Y |
| Onset Date: | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--------------------|-------------------|
| Renal impairment | | | Enalapril ceased. |

Medicine Details:

| | | | |
|--------------------------------------|----------------------|--|------|
| ENALAPRIL MALEATE (Suspected) | | Reason: Essential benign hypertension | |
| Tablet | 10.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: 05/12/1990 | |
| FRUSEMIDE (Suspected) | | Reason: Essential benign hypertension | |
| Oral application | 40.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: 05/12/1990 | |
| SLOW-K (Suspected) | | Reason: Alkalosis | |
| Tablet | 4.0 Dose Unspecified | Daily | Oral |
| Batch: | Started: | Stopped: 05/12/1990 | |
| SINEQUAN (Suspected) | | Reason: | |
| Oral application | 2.0 Dose Unspecified | Daily | Oral |
| Batch: | Started: | Stopped: 05/12/1990 | |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|---|
| | Electrolytes | | | | 5/12/90 7/12/90 13/12/90 14/12/90 potassium 7.2 4.8 3.4 3.8 creatinine 353 312 225 195 urea 38.7 33.4 19.1 16.2 |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 70203

Seq: 1

Gender: F

Reported: 21/03/1991

Weight:

Hospitalisation:

Age: 92Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|----------------------------|--|-----------------|------------|
| ISORDIL (Suspected) | Reason: Chron isch heart dis no hyper | | |
| Tablet | 30.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | 05/12/1990 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 71597 | Seq: 1 | Gender: F |
| Reported: 19/07/1991 | | Weight: |
| Hospitalisation: | | Age: 62Y |
| Onset Date: 30/06/1991 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | |
|------------------------------------|---|
| BURINEX (Other drug) | Reason: Essential benign hypertension |
| 2.0 Milligram Daily | |
| Batch: | Started: 04/05/1991 Stopped: |
| CARDIZEM (Other drug) | Reason: Essential benign hypertension |
| 360.0 Milligram Daily | |
| Batch: | Started: 01/01/1991 Stopped: |
| CAPOTEN (Other drug) | Reason: Essential benign hypertension |
| 25.0 Milligram Daily | |
| Batch: | Started: 01/01/1986 Stopped: |
| KINIDIN DURULES (Suspected) | Reason: |
| 3.0 Dose Unspecified Daily | |
| Batch: | Started: 15/06/1991 Stopped: 04/07/1991 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|----------------|-------------|--------|---------|
| | AST = SGOT | 5-40 U/L | 03/07/1991 | 168 | |
| | AST = SGOT | 5-40 U/L | 05/07/1991 | 140 | |
| | AST = SGOT | 5-40 U/L | 09/07/1991 | 87 | |
| | AST = SGOT | 5-40 U/L | 19/07/1991 | 28 | |
| | AST = SGOT | 5-40 U/L | 07/07/1991 | 135 | |
| | AST = SGOT | 5-40 U/L | 09/08/1991 | 29 | |
| | Bilirubin | 3-20 MICRO M/L | 03/07/1991 | 13 | |

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 accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 71597

Seq: 1

Gender: F

Reported: 19/07/1991

Weight:

Hospitalisation:

Age: 62Y

Onset Date: 30/06/1991

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|-----------------------------|----------------------------|
| SINEQUAN (Suspected) | Reason: Depression |
| 50.0 Milligram | Daily |
| Batch: | Started: 04/06/1991 |
| | Stopped: 04/07/1991 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|----------------|-------------|--------|---------|
| | Bilirubin | 3-20 MICRO M/L | 05/07/1991 | 41 | |
| | Bilirubin | 3-20 MICRO M/L | 07/07/1991 | 21 | |
| | Bilirubin | 3-20 MICRO M/L | 09/07/1991 | 13 | |
| | Bilirubin | 3-20 MICRO M/L | 19/07/1991 | 11 | |
| | Bilirubin | 3-20 MICRO M/L | 09/08/1991 | 9 | |
| | GGT = SGGT = | 5-65 U/L | 03/07/1991 | 243 | |
| | GGT = SGGT = | 5-65 U/L | 09/07/1991 | 507 | |

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 accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 71597 | Seq: 1 | Gender: F |
| Reported: 19/07/1991 | | Weight: |
| Hospitalisation: | | Age: 62Y |
| Onset Date: 30/06/1991 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

Medicine Details:

| | | |
|------------------------------------|----------------------------|--|
| BURINEX (Other drug) | | Reason: Essential benign hypertension |
| 2.0 Milligram | Daily | |
| Batch: | Started: 04/05/1991 | Stopped: |
| CARDIZEM (Other drug) | | Reason: Essential benign hypertension |
| 360.0 Milligram | Daily | |
| Batch: | Started: 01/01/1991 | Stopped: |
| CAPOTEN (Other drug) | | Reason: Essential benign hypertension |
| 25.0 Milligram | Daily | |
| Batch: | Started: 01/01/1986 | Stopped: |
| KINIDIN DURULES (Suspected) | | Reason: |
| 3.0 Dose Unspecified | Daily | |
| Batch: | Started: 15/06/1991 | Stopped: 04/07/1991 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|----------|-------------|--------|--|
| | GGT = SGGT = | 5-65 U/L | 19/07/1991 | 189 | Ultrasound scan - abdomen: the liver is uniformly echogenic consistent with the presence of widespread fatty infiltration. the biliary ducts are undilated and the gallbladder appears normal. |
| | GGT = SGGT = | 5-65 U/L | 07/07/1991 | 596 | |
| | GGT = SGGT = | 5-65 U/L | 05/07/1991 | 515 | |
| | GGT = SGGT = | 5-65 U/L | 09/08/1991 | 74 | |
| | Other data | | | | |

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 accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 71597 | Seq: 1 | Gender: F |
| Reported: 19/07/1991 | | Weight: |
| Hospitalisation: | | Age: 62Y |
| Onset Date: 30/06/1991 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

Medicine Details:

| | |
|-----------------------------|----------------------------|
| SINEQUAN (Suspected) | Reason: Depression |
| 50.0 Milligram | Daily |
| Batch: | Started: 04/06/1991 |
| | Stopped: 04/07/1991 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-----------|------------|-------------|--------|---------|
| | SAP = ALP | 30-115 U/L | 03/07/1991 | 201 | |
| | SAP = ALP | 30-115 U/L | 05/07/1991 | 244 | |
| | SAP = ALP | 30-115 U/L | 07/07/1991 | 253 | |
| | SAP = ALP | 30-115 U/L | 09/07/1991 | 255 | |
| | SAP = ALP | 30-115 U/L | 19/07/1991 | 184 | |
| | SAP = ALP | 30-115 U/L | 09/08/1991 | 186 | |

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 accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 72064 | Seq: 1 | Gender: F |
| Reported: 12/07/1991 | | Weight: 64.00 |
| Hospitalisation: | | Age: 65Y |
| Onset Date: 16/04/1991 | | DOB: |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|--------------------------|--------------------|-----------|
| Oesophagitis | Required Visit to Doctor | Oesophageal pain | |
| Dyspepsia | | | |

Medicine Details:

| | |
|--|---|
| LOPID (Suspected) | Reason: Othr&unspec metabolic diseases |
| Tablet | 1.2 Gram |
| Batch: | Started: 11/03/1991 |
| | Stopped: 19/04/1991 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| Oral application | 20.0 Milligram |
| Batch: | Started: 01/01/1980 |
| | Stopped: |
| SOLPRIN (Suspected) | Reason: |
| Tablet | 125.0 Milligram |
| Batch: | Started: 01/01/1989 |
| | Stopped: |

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 73037 **Seq:** 1 **Gender:** M
Reported: 16/09/1991 **Weight:** 95.00
Hospitalisation: **Age:** 48Y
Onset Date: 31/05/1991 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|---------------------|-----------|
| Arthralgia | | Multiple arthralgia | |

Medicine Details:

| | |
|----------------------------|--|
| DEPTRAN (Suspected) | Reason: Depression |
| 50.0 Milligram | Daily |
| Batch: | Started: 01/01/1986 Stopped: |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 73376 **Seq:** 1 **Gender:** F
Reported: 09/10/1991 **Weight:** 57.00
Hospitalisation: **Age:** 61
Onset Date: 02/08/1991 **DOB:** 02/03/1930
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-----------------|----------|--------------------|-----------|
| Affect lability | | | |
| Agitation | | | |

Medicine Details:

| | |
|---------------------------------|--|
| LIPEX (Suspected) | Reason: |
| 10.0 Milligram Daily | |
| Batch: | Started: 30/07/1991 Stopped: |
| SINEQUAN (Suspected) | Reason: |
| 50.0 Milligram Daily | |
| Batch: | Started: L TERM Stopped: |
| NORMISON (Suspected) | Reason: |
| 2.0 Dose Unspecified Daily | |
| Batch: | Started: L TERM Stopped: |
| SEREPAX (Suspected) | Reason: |
| 30.0 Milligram Daily | |
| Batch: | Started: L TERM Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 73440 | Seq: 1 | Gender: F |
| Reported: 18/09/1991 | | Weight: |
| Hospitalisation: | | Age: 72Y |
| Onset Date: | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | |
|--|---------------------------------|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| 150.0 Milligram | Daily |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 74002 | Seq: 1 | Gender: F |
| Reported: 06/11/1991 | | Weight: |
| Hospitalisation: | | Age: 46Y |
| Onset Date: 28/09/1991 | | DOB: |
| Outcome: Death | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Hyponoxia | | | |
| Sudden death | | | |

Medicine Details:

| | | |
|------------------------------------|----------------------------|--------------------------------|
| ORTHOCLONE OKT3 (Suspected) | Reason: | Complicatns of transplant orgn |
| 0.0 | | |
| Batch: | Started: 28/09/1991 | Stopped: |
| IMURAN (Suspected) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: 30/09/1991 |
| SANDIMMUN (Suspected) | Reason: | Complicatns of transplant orgn |
| Solution | 5.6 Millilitre | Daily Oral |
| Batch: | Started: 18/09/1991 | Stopped: 30/09/1991 |
| PREDNISOLONE (Suspected) | Reason: | |
| Tablet | 30.0 Milligram | Daily Oral |
| Batch: | Started: 16/09/1991 | Stopped: 30/09/1991 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|---|
| | Other data | | | | Post mortem revealed pneumonic condensation. no bacteria seen. blood cultures: no growth. |

Additional Information:

Patient died on 30/09/1991.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 74002 **Seq:** 1 **Gender:** F
Reported: 06/11/1991 **Weight:**
Hospitalisation: **Age:** 46Y
Onset Date: 28/09/1991 **DOB:**
Outcome: Death **Causality:** Causality possible

Reaction Detail

Medicine Details:

| | |
|---|---|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| Capsule 100.0 Milligram Daily Oral | |
| Batch: | Started: 21/08/1991 Stopped: 30/09/1991 |
| RANITIDINE (Suspected) | Reason: |
| Tablet 150.0 Milligram Daily Oral | |
| Batch: | Started: 23/08/1991 Stopped: 30/09/1991 |
| ACICLOVIR (Suspected) | Reason: |
| 400.0 Milligram Daily | |
| Batch: | Started: 23/09/1991 Stopped: 26/09/1991 |

Laboratory Investigations:

Additional Information:

Patient died on 30/09/1991.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|--|---------------|--------------------------------------|
| Case Number: 74016 | Seq: 1 | Gender: M |
| Reported: 24/09/1991 | | Weight: |
| Hospitalisation: Admitted to hospital | | Age: 69Y |
| Onset Date: 13/05/1991 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------------|
| Abdominal pain | | | |
| Constipation | | | Pethidine and ex-prep. |

Medicine Details:

| | |
|--|---|
| THYMOL (Suspected) | Reason: |
| Mouthwash | As necessary Buccal |
| Batch: | Started: 0.0 Stopped: CONTIN |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| | 50.0 Milligram Daily |
| Batch: | Started: 01/04/1991 Stopped: 13/05/1991 |
| RANITIDINE (Suspected) | Reason: Other diseases of esophagus |
| | 600.0 Milligram Daily |
| Batch: | Started: Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 74545 | Seq: 1 | Gender: F |
| Reported: 02/12/1991 | | Weight: |
| Hospitalisation: | | Age: 38Y |
| Onset Date: 21/11/1991 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|--------------------|-----------|
| Gravitational oedema | | | |
| Urinary retention | | | |
| Weight increased | | | |

Medicine Details:

| | | |
|------------------------------|----------------------------|--|
| MS CONTIN (Suspected) | | Reason: Pain |
| Tablet | 30.0 Milligram | Daily Oral |
| Batch: | Started: 21/11/1991 | Stopped: 30/11/1991 |
| DEPTRAN (Suspected) | | Reason: Pain |
| Oral application | 150.0 Milligram | Daily Oral |
| Batch: | Started: 01/01/1990 | Stopped: |
| ZANTAC (Suspected) | | Reason: Ulcer of duodenum w/o ment perf |
| Tablet | 300.0 Milligram | Daily Oral |
| Batch: | Started: 01/01/1986 | Stopped: |
| EPILIM (Suspected) | | Reason: Pain |
| Oral application | 150.0 Milligram | Daily Oral |
| Batch: | Started: 01/07/1990 | Stopped: |

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 75120 **Seq:** 1 **Gender:** F
Reported: 16/01/1992 **Weight:** 83.00
Hospitalisation: **Age:** 37Y
Onset Date: 31/08/1991 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|---|-----------|
| Menorrhagia | Severe | Menstrual irregularity with menorrhagia | |

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Depression |
| 25.0 Milligram | Daily |
| Batch: | Started: 07/08/1991 Stopped: 09/12/1991 |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 75409 | Seq: 1 | Gender: F |
| Reported: 06/02/1992 | | Weight: |
| Hospitalisation: | | Age: 57Y |
| Onset Date: 05/11/1991 | | DOB: |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | |
|--|---|
| ENALAPRIL MALEATE (Suspected) | Reason: Essential benign hypertension |
| 5.0 Milligram Daily | |
| Batch: | Started: 05/02/1990 Stopped: CONTIN |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| 50.0 Milligram Daily | |
| Batch: | Started: Stopped: CONTIN |
| DYAZIDE (Suspected) | Reason: Essential benign hypertension |
| 1.0 Dose Unspecified Daily | |
| Batch: | Started: 01/05/1989 Stopped: 23/11/1991 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------|--------|-------------|--------|---------|
| | Sodium | MMOL/L | 05/11/1991 | 128 | |
| | Sodium | MMOL/L | 05/12/1991 | 132 | |

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 75467 | Seq: 1 | Gender: M |
| Reported: 06/02/1992 | | Weight: |
| Hospitalisation: | | Age: |
| Onset Date: 07/06/1991 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|----------------------|-----------|
| Hyperhidrosis | | Profuse diaphoresis. | |
| Tremor | | Trembling. | |

Medicine Details:

| | | |
|--|----------------------------|----------------------------|
| PARACETAMOL (Other drug) | Reason: | |
| 1.0 Gram | As necessary | |
| Batch: | Started: 03/06/1991 | Stopped: |
| LACTULOSE (Other drug) | Reason: | |
| 20.0 Millilitre | Daily | |
| Batch: | Started: 05/06/1991 | Stopped: |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: | |
| 100.0 Milligram | Total | |
| Batch: | Started: 07/06/1991 | Stopped: 09/06/1991 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 75589 | Seq: 1 | Gender: M |
| Reported: 18/02/1992 | | Weight: 99.00 |
| Hospitalisation: | | Age: 79Y |
| Onset Date: 06/04/1990 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------|----------|--------------------|-----------|
| Cataract | | | |
| Coordination abnormal | | | |
| Nausea | | | |
| Vertigo | | | |

Medicine Details:

| | |
|------------------------------|---|
| ZYLOPRIM (Suspected) | Reason: Unspecified arthritis |
| 300.0 Milligram Daily | |
| Batch: | Started: L TERM Stopped: 18/02/1992 |
| MINIPRESS (Suspected) | Reason: Essential benign hypertension |
| 2.5 Milligram Daily | |
| Batch: | Started: 01/01/1985 Stopped: |
| SLOW-K (Suspected) | Reason: Essential benign hypertension |
| 1.0 Dose Unspecified Daily | |
| Batch: | Started: 01/01/1985 Stopped: |
| ECOTRIN (Suspected) | Reason: |
| 1.0 Dose Unspecified Daily | |
| Batch: | Started: Stopped: 18/02/1992 |

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 75589

Seq: 1

Gender: M

Reported: 18/02/1992

Weight: 99.00

Hospitalisation:

Age: 79Y

Onset Date: 06/04/1990

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|------------------------------|--|
| MODURETIC (Suspected) | Reason: Essential benign hypertension |
| 1.0 Dose Unspecified Daily | |
| Batch: | Started: 01/01/1985 Stopped: |
| DEPTRAN (Suspected) | Reason: Specific disorders of sleep |
| 1.0 Dose Unspecified Daily | |
| Batch: | Started: Stopped: |

Laboratory Investigations:

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 75593 | Seq: 1 | Gender: M |
| Reported: 12/02/1992 | | Weight: |
| Hospitalisation: | | Age: 36Y |
| Onset Date: 31/01/1992 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---------------|
| Alopecia | | Loss of hair. | |
| Psoriasis | | | Betnovate gel |

Medicine Details:

| | | |
|-----------------------------|----------------------------|----------------------------|
| SINEQUAN (Suspected) | | Reason: Depression |
| Capsule | 100.0 Milligram | Daily Oral |
| Batch: | Started: 01/01/1992 | Stopped: 28/02/1992 |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 75719 | Seq: 1 | Gender: M |
| Reported: 13/02/1992 | | Weight: 85.00 |
| Hospitalisation: | | Age: 64Y |
| Onset Date: 13/02/1992 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|-----------------------|---|
| Rash | | Rash over whole body. | Calamine lotion and phenergan 20mg por daily. |
| Pruritus | | | |

Medicine Details:

| | |
|-------------------------------|---|
| STEMETIL (Suspected) | Reason: Nausea and vomiting |
| Injection | 12.5 Milligram As necessary Intramuscular |
| Batch: | Started: 10/02/1992 Stopped: |
| PANADOL (Suspected) | Reason: Other disturbance of sensation |
| Oral application | 2.0 Dose Unspecified As necessary Oral |
| Batch: | Started: 10/02/1992 Stopped: |
| BACTRIM DS (Suspected) | Reason: |
| Oral application | 2.0 Dose Unspecified Daily Oral |
| Batch: | Started: 10/02/1992 Stopped: 13/02/1992 |
| SINEQUAN (Suspected) | Reason: Specific disorders of sleep |
| Oral application | 50.0 Milligram Daily Oral |
| Batch: | Started: 10/02/1992 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 75719 **Seq:** 1

Gender: M

Reported: 13/02/1992

Weight: 85.00

Hospitalisation:

Age: 64Y

Onset Date: 13/02/1992

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|-----------------------------|--|
| NAPROSYN (Suspected) | Reason: Unspecified arthritis |
| Oral application | 500.0 Milligram Daily Oral |
| Batch: | Started: 10/02/1992 Stopped: |
| AMPRACE (Suspected) | Reason: Essential benign hypertension |
| Tablet | 5.0 Milligram Daily Oral |
| Batch: | Started: 10/02/1992 Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 75995 **Seq:** 1 **Gender:** F
Reported: 19/03/1992 **Weight:**
Hospitalisation: **Age:** 64Y
Onset Date: 26/02/1992 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|----------------------|-----------|
| Dysgeusia | | Salty, bitter taste. | |

Medicine Details:

| | |
|-----------------------------|--|
| DEPTRAN (Suspected) | Reason: |
| 100.0 Milligram | Daily |
| Batch: | Started: 19/02/1992 Stopped: |
| TEGRETOL (Suspected) | Reason: |
| 400.0 Milligram | Daily |
| Batch: | Started: 19/02/1992 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 76649 | Seq: 1 | Gender: F |
| Reported: 10/04/1992 | | Weight: 61.00 |
| Hospitalisation: | | Age: 75Y |
| Onset Date: 02/04/1992 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|------------------------------|
| Aggression Confusional state Dementia Dry mouth Tachycardia | | | Valium 10mg im, rivotril 2mg |

Medicine Details:

| | |
|---------------------------------------|---|
| TOBRAMYCIN (Other drug) | Reason: Keratitis no mention of ulcer |
| 12.0 Dose Unspecified Daily | |
| Batch: | Started: 31/03/1992 Stopped: 09/04/1992 |
| CEPHAZOLIN SODIUM (Other drug) | Reason: Keratitis no mention of ulcer |
| 12.0 Dose Unspecified Daily | |
| Batch: | Started: 31/03/1992 Stopped: 09/04/1992 |
| ATROPINE (Suspected) | Reason: Keratitis no mention of ulcer |
| 2.0 Dose Unspecified Daily | |
| Batch: | Started: 31/03/1992 Stopped: 02/04/1992 |
| PLENDIL (Suspected) | Reason: Essential benign hypertension |
| Tablet 2.5 Milligram Daily | Oral |
| Batch: | Started: 31/03/1992 Stopped: 03/04/1992 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 76649

Seq: 1

Gender: F

Reported: 10/04/1992

Weight: 61.00

Hospitalisation:

Age: 75Y

Onset Date: 02/04/1992

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|-----------------------------|--|----------------------------|------|
| RENITEC (Suspected) | Reason: Essential benign hypertension | | |
| Tablet | 5.0 Milligram | Daily | Oral |
| Batch: | Started: 31/03/1992 | Stopped: 03/04/1992 | |
| SINEQUAN (Suspected) | Reason: Anxiety neurosis | | |
| Oral application | 150.0 Milligram | Daily | Oral |
| Batch: | Started: 31/03/1992 | Stopped: 03/04/1992 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 76987 | Seq: 1 | Gender: M |
| Reported: 13/05/1992 | | Weight: 85.00 |
| Hospitalisation: | | Age: 27Y |
| Onset Date: 01/05/1992 | | DOB: |
| Outcome: Unknown | | Causality: Causality probable |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------|-----------|
| Constipation Dry mouth Fatigue Somnolence | | | |

Medicine Details:

| | |
|-------------------------------------|---------------------------|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: |
| | Stopped: |
| METHADONE HYDROCHLORIDE (Suspected) | Reason: |
| Tablet | 45.0 Milligram Daily Oral |
| Batch: | Started: |
| | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 77090 | Seq: 1 | Gender: F |
| Reported: 30/01/1992 | | Weight: |
| Hospitalisation: | | Age: 58Y |
| Onset Date: 17/01/1992 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---|
| Psoriasis | | Pustular psoriasis | Metoprolol ceased, nifedipine,20 mg twice daily |

Medicine Details:

| | | |
|--|----------------------------|--|
| PANADOL (Suspected) | | Reason: Pain |
| Tablet | 500.0 Milligram | As necessary Oral |
| Batch: | Started: | Stopped: CONTIN |
| METOPROLOL TARTRATE (Suspected) | | Reason: Essential benign hypertension |
| Oral application | 100.0 Milligram | Daily Oral |
| Batch: | Started: 20/11/1991 | Stopped: 24/01/1992 |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: Depression |
| Oral application | 25.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: CONTIN |
| F.G.F. (Suspected) | | Reason: Unspecified anemia |
| Oral application | 0.0 | Daily Oral |
| Batch: | Started: | Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 78312 | Seq: 1 | Gender: F |
| Reported: 20/07/1992 | | Weight: 55.00 |
| Hospitalisation: | | Age: 71Y |
| Onset Date: 18/05/1992 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Asthenia | | | |
| Somnolence | | | |

Medicine Details:

| | | |
|--|----------------------------|--|
| MESALAZINE (Suspected) | | Reason: Ulcerative colitis |
| Tablet | 1.5 Gram | Daily Oral |
| Batch: | Started: 18/05/1992 | Stopped: CONTIN |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: Specific disorders of sleep |
| Oral application | 25.0 Milligram | Daily Oral |
| Batch: | Started: 01/01/1991 | Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient has iron deficiency anaemia and raised esr present (consequence of colitis). the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 78786 | Seq: 1 | Gender: F |
| Reported: 14/08/1992 | | Weight: 60.00 |
| Hospitalisation: | | Age: 82Y |
| Onset Date: 06/08/1992 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|---|
| Bradycardia Hyperkalaemia Syncope | | | Iv dextrose and insulin. isoprenaline infusion |

Medicine Details:

| | | | |
|--|----------------------------|--|------------|
| TRANSIDERM-NITRO (Other drug) | | Reason: | |
| Cream | 1.0 Dose Unspecified | Daily | Topical |
| Batch: | Started: 01/05/1992 | Stopped: | CONTIN |
| RENITEC (Suspected) | | Reason: Essential benign hypertension | |
| Tablet | 10.0 Gram | Daily | Oral |
| Batch: | Started: 01/05/1992 | Stopped: | 06/08/1992 |
| VERAPAMIL HYDROCHLORIDE (Suspected) | | Reason: Essential benign hypertension | |
| Tablet | 320.0 Gram | Daily | Oral |
| Batch: | Started: 01/05/1992 | Stopped: | 06/08/1992 |
| DYAZIDE (Suspected) | | Reason: Essential benign hypertension | |
| Tablet | 2.0 Dose Unspecified | Daily | Oral |
| Batch: | Started: 01/05/1992 | Stopped: | 06/08/1992 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-----------|-------|-------------|--------|---------|
| | Potassium | | 06/08/1992 | 7.6 | |

Additional Information:

Co-existing renal impairment the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 78786

Seq: 1

Gender: F

Reported: 14/08/1992

Weight: 60.00

Hospitalisation:

Age: 82Y

Onset Date: 06/08/1992

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|--|-------------------------------------|----------------------------|------|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Disturbance of sleep | | |
| Tablet | 50.0 Milligram | Daily | Oral |
| Batch: | Started: L TERM | Stopped: 06/08/1992 | |

Laboratory Investigations:

Additional Information:

Co-existing renal impairment the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 79193 | Seq: 1 | Gender: F |
| Reported: 05/09/1992 | | Weight: 80.00 |
| Hospitalisation: | | Age: 71Y |
| Onset Date: 02/09/1992 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--------------------|-----------|
| Confusional state | | | |
| Hallucination | | | |

Medicine Details:

| | |
|------------------------------|---|
| ROHYPNOL (Other drug) | Reason: Specific disorders of sleep |
| Tablet | 2.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: CONTIN |
| ORUDIS SR (Suspected) | Reason: Osteoarthritis |
| Capsule | 200.0 Milligram Daily Oral |
| Batch: | Started: 02/09/1992 Stopped: 04/09/1992 |
| SINEQUAN (Suspected) | Reason: Depression |
| Tablet | 25.0 Milligram Daily Oral |
| Batch: | Started: 19/11/1991 Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|----------------------------|--------|-------------------------------|
| Case Number: 79279 | Seq: 1 | Gender: F |
| Reported: 04/09/1992 | | Weight: |
| Hospitalisation: | | Age: 65Y |
| Onset Date: 20/08/1992 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|----------|--------------------|-----------|
| Hepatomegaly Hepatitis | | Enlarged liver | |

Medicine Details:

| | | |
|----------------------|----------|--|
| PREMARIN (Suspected) | Reason: | |
| Batch: | Started: | L TERM Stopped: |
| | 0.0 | |
| PROVERA (Suspected) | Reason: | |
| Batch: | Started: | L TERM Stopped: |
| | 0.0 | |
| VALIUM (Suspected) | Reason: | |
| Batch: | Started: | 1.0 Dose Unspecified As necessary Stopped: |
| MOGADON (Suspected) | Reason: | |
| Batch: | Started: | 1.0 Dose Unspecified As necessary Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|---------|
| | ALT = SGPT | | 20/08/1992 | 556 | |
| | AST = SGOT | | 20/08/1992 | 665 | |
| | Bilirubin | | 20/08/1992 | 53 | |

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 79279 **Seq:** 1

Gender: F

Reported: 04/09/1992

Weight:

Hospitalisation:

Age: 65Y

Onset Date: 20/08/1992

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|------------------------------|----------------------------|-------------------------------|--------------|
| SINEQUAN (Suspected) | | Reason: | |
| | 1.0 | Dose Unspecified | As necessary |
| Batch: | Started: | Stopped: | |
| ORUDIS SR (Suspected) | | Reason: Osteoarthritis | |
| Capsule | 200.0 | Milligram | Daily |
| | | | Oral |
| Batch: | Started: 01/02/1990 | Stopped: 28/08/1992 | |

Laboratory Investigations:

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 79337 | Seq: 1 | Gender: M |
| Reported: 26/06/1992 | | Weight: 92.00 |
| Hospitalisation: | | Age: 67Y |
| Onset Date: 24/06/1992 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|------------|
| Asthenia Hypotension Pruritus Rash erythematous Urticaria Visual disturbance | | | Phenergan. |

Medicine Details:

| | | |
|----------------------------|----------------------------|---|
| CAPOTEN (Suspected) | | Reason: Congestive heart failure |
| Tablet | 50.0 Milligram | Daily Oral |
| Batch: | Started: 03/06/1992 | Stopped: CONTIN |
| LASIX (Suspected) | | Reason: Congestive heart failure |
| Tablet | 80.0 Milligram | Daily Oral |
| Batch: | Started: 03/06/1992 | Stopped: CONTIN |
| SLOW-K (Suspected) | | Reason: Congestive heart failure |
| Tablet, modified release | 2.0 Dose Unspecified | Daily Oral |
| Batch: | Started: 03/06/1992 | Stopped: CONTIN |
| DIGOXIN (Suspected) | | Reason: Otr&nos disord of heart rhythm |
| Tablet | 1.0 Dose Unspecified | Daily Oral |
| Batch: | Started: 19/06/1992 | Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 79337

Seq: 1

Gender: M

Reported: 26/06/1992

Weight: 92.00

Hospitalisation:

Age: 67Y

Onset Date: 24/06/1992

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|-----------------------------|---------------------------|-----------------|--------|
| SINEQUAN (Suspected) | Reason: Depression | | |
| Capsule | 25.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | CONTIN |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 79340 | Seq: 1 | Gender: M |
| Reported: 08/07/1992 | | Weight: |
| Hospitalisation: | | Age: 25 |
| Onset Date: 03/03/1992 | | DOB: 13/01/1967 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|------------------------|-------------------------|
| Acne | | Cystic lesions on face | Tetracycline 500 mg bd. |

Medicine Details:

| | |
|--|---|
| LITHIUM CARBONATE (Suspected) | Reason: Unspecifid affective psychosis |
| 1.0 Gram | Daily |
| Batch: | Started: |
| | Stopped: CONTIN |
| <hr/> | |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| 150.0 Milligram | Daily |
| Batch: | Started: 20/02/1992 |
| | Stopped: CONTIN |
| <hr/> | |
| THIAMINE (Suspected) | Reason: |
| 100.0 Milligram | Daily |
| Batch: | Started: 15/02/1992 |
| | Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:

Cystic lesions on face.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 80220 **Seq:** 1 **Gender:** F
Reported: 06/10/1992 **Weight:** 58.00
Hospitalisation: **Age:** 53Y
Onset Date: 31/07/1992 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|--------------------|-----------|
| Breast enlargement | | | |
| Breast pain | | | |
| Nausea | | | |

Medicine Details:

| | |
|--|---|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| Oral application | 75.0 Milligram Daily Oral |
| Batch: | Started: 16/01/1992 Stopped: 08/09/1992 |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 80227 **Seq:** 1 **Gender:** M
Reported: 08/10/1992 **Weight:** 85.00
Hospitalisation: **Age:** 36Y
Onset Date: 31/07/1992 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|--|
| SINEQUAN (Suspected) | Reason: Depression |
| 20.0 Milligram | Daily |
| Batch: | Started: 12/06/1992 Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient was rechallenged on sinequan with same result. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 80701 **Seq:** 1 **Gender:** M
Reported: 04/11/1992 **Weight:**
Hospitalisation: **Age:** 77Y
Onset Date: 01/11/1992 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------|--|
| Duodenal ulcer | | | Omeprazole, gaviscon, transfused 2 units packed cells. |
| Gastric ulcer | | | |
| Oesophagitis | | | |
| Oesophagitis ulcerative | | | |

Medicine Details:

| | | | |
|--|----------------------|---|---------------|
| KETOROLAC (Suspected) | | Reason: | |
| Injection | 30.0 Milligram | 4 times | Intramuscular |
| Batch: | Started: | Stopped: | 01/11/1992 |
| ASPIRIN SOLUBLE (Suspected) | | Reason: Transient cereb isch no hypert | |
| Tablet | 1.0 Dose Unspecified | Daily | Oral |
| Batch: | Started: | Stopped: | |
| ZYLOPRIM (Suspected) | | Reason: | |
| Tablet | 1.0 Dose Unspecified | Daily | Oral |
| Batch: | Started: | Stopped: | |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | |
| Capsule | 25.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 80701 **Seq:** 1

Gender: M

Reported: 04/11/1992

Weight:

Hospitalisation:

Age: 77Y

Onset Date: 01/11/1992

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

FRAGMIN (Suspected)

Reason:

Injection

5.0 Thousand Internat Daily

Subcutaneous

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 80863 **Seq:** 1 **Gender:** F
Reported: 11/11/1992 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Dyspepsia | | | Losec |

Medicine Details:

| | |
|---|----------------|
| PROVERA (Other drug) | Reason: |
| 10.0 Milligram Daily | |
| Batch: Started: Stopped: | |
| PREMARIN (Other drug) | Reason: |
| 625.0 Microgram Daily | |
| Batch: Started: Stopped: | |
| ZANTAC (Other drug) | Reason: |
| 300.0 Milligram Daily | |
| Batch: Started: Stopped: | |
| FELDENE (Other drug) | Reason: |
| 20.0 Milligram Daily | |
| Batch: Started: Stopped: | |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 80863

Seq: 1

Gender: F

Reported: 11/11/1992

Weight:

Hospitalisation:

Age: AD

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|---------------------|----------|----------|----|
| DEPTRAN (Suspected) | Reason: | | |
| 150.0 Milligram | Daily | | |
| Batch: | Started: | Stopped: | 2Y |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|----------------------------|--------|-------------------------------|
| Case Number: 80874 | Seq: 1 | Gender: F |
| Reported: 11/11/1992 | | Weight: 72.00 |
| Hospitalisation: | | Age: 65Y |
| Onset Date: 06/11/1992 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | | | |
|---------------------|---------------------|---------------------|----------------------------------|
| RULIDE (Suspected) | 300.0 Milligram | Daily | Reason: Unspecified arthritis |
| Batch: | Started: 28/10/1992 | Stopped: 02/11/1992 | |
| DOLOBID (Suspected) | 1.0 Gram | Daily | Reason: Unspecified arthritis |
| Batch: | Started: 01/01/1990 | Stopped: CONTIN | |
| DEPTRAN (Suspected) | 100.0 Milligram | Daily | Reason: Depression |
| Batch: | Started: 01/01/1990 | Stopped: CONTIN | |
| BURINEX (Suspected) | 1.0 Milligram | Daily | Reason: Left ventricular failure |
| Batch: | Started: 01/01/1985 | Stopped: CONTIN | |

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 80874 **Seq:** 1

Gender: F

Reported: 11/11/1992

Weight: 72.00

Hospitalisation:

Age: 65Y

Onset Date: 06/11/1992

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|---------------------------|----------------------------|
| SPAN-K (Suspected) | Reason: |
| 600.0 Milligram | Daily |
| Batch: | Started: 01/01/1985 |
| | Stopped: CONTIN |

Laboratory Investigations:

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 81071 **Seq:** 1 **Gender:** F
Reported: 23/11/1992 **Weight:** 80.00
Hospitalisation: **Age:** 65Y
Onset Date: 06/07/1992 **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|---------------------------------|
| SINEQUAN (Suspected) | Reason: Depression |
| Capsule | 1.0 Dose Unspecified Daily Oral |
| Batch: | Started: Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|--|
| | Liver biopsy | | | | Liver biopsy shows necrosis, inflammation in the portal tracts, rganulomas within the hepatic lobules - a severe form of drug reaction |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 81768 **Seq:** 1 **Gender:** M
Reported: 18/12/1992 **Weight:** 78.00
Hospitalisation: Admitted to hospital **Age:** 63Y
Onset Date: 08/12/1992 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-----------------|----------|--------------------|-----------|
| Depression | | | |
| Suicide attempt | | | |

Medicine Details:

| | |
|---|--|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| Tablet 0.0 Oral | |
| Batch: | Started: 07/12/1992 Stopped: |
| DIGOXIN (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: 07/12/1992 Stopped: |
| CIPROXIN (Suspected) | Reason: |
| Tablet 1.0 Gram Total Oral | |
| Batch: | Started: 07/12/1992 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 81808 | Seq: 1 | Gender: M |
| Reported: 06/01/1993 | | Weight: 51.00 |
| Hospitalisation: | | Age: 70Y |
| Onset Date: 22/12/1992 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Hyperkalaemia | | | |
| Hyponatraemia | | | |

Medicine Details:

| | |
|------------------------------|---|
| VALIUM (Other drug) | Reason: Anxiety neurosis |
| Tablet | 20.0 Milligram Daily Oral |
| Batch: | Started: 01/01/1980 Stopped: CONTIN |
| MODURETIC (Suspected) | Reason: Essential benign hypertension |
| Tablet | 1.0 Dose Unspecified Daily Oral |
| Batch: | Started: 16/12/1992 Stopped: 22/12/1992 |
| SINEQUAN (Suspected) | Reason: Depression |
| | 175.0 Milligram Daily |
| Batch: | Started: 15/11/1992 Stopped: 24/12/1992 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-----------|-------------|--------|---------|
| | Chloride | 96-110 | 02/07/1992 | 102 | |
| | Chloride | 96-110 | 07/12/1992 | 101 | |
| | Chloride | 96-110 | 22/12/1992 | 89 | |
| | Chloride | 96-110 | 04/01/1993 | 106 | |
| | Chloride | 96-110 | 30/07/1992 | 97 | |
| | Chloride | 96-110 | 23/12/1992 | 87 | |
| | Creatinine | 0.06-0.13 | 02/07/1992 | 0.092 | |

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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 81808

Seq: 1

Gender: M

Reported: 06/01/1993

Weight: 51.00

Hospitalisation:

Age: 70Y

Onset Date: 22/12/1992

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|------------------------------|--|-----------------|------------|
| VALIUM (Other drug) | Reason: Anxiety neurosis | | |
| Tablet | 20.0 Milligram | Daily | Oral |
| Batch: | Started: 01/01/1980 | Stopped: | CONTIN |
| MODURETIC (Suspected) | Reason: Essential benign hypertension | | |
| Tablet | 1.0 Dose Unspecified | Daily | Oral |
| Batch: | Started: 16/12/1992 | Stopped: | 22/12/1992 |
| SINEQUAN (Suspected) | Reason: Depression | | |
| | 175.0 Milligram | Daily | |
| Batch: | Started: 15/11/1992 | Stopped: | 24/12/1992 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-----------|---------|-------------|--------|---------|
| | Potassium | 3.4-4.8 | 04/01/1993 | 4.7 | |
| | Potassium | 3.4-4.8 | 30/12/1992 | 5.4 | |
| | Potassium | 3.4-4.8 | 07/12/1992 | 4.4 | |
| | Potassium | 3.4-4.8 | 22/12/1992 | 5.0 | |
| | Potassium | 3.4-4.8 | 23/12/1992 | 4.9 | |
| | Sodium | 134-144 | 02/07/1992 | 141 | |
| | Sodium | 134-144 | 07/12/1992 | 134 | |

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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 81808

Seq: 1

Gender: M

Reported: 06/01/1993

Weight: 51.00

Hospitalisation:

Age: 70Y

Onset Date: 22/12/1992

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|------------------------------|--|-----------------|------------|
| VALIUM (Other drug) | Reason: Anxiety neurosis | | |
| Tablet | 20.0 Milligram | Daily | Oral |
| Batch: | Started: 01/01/1980 | Stopped: | CONTIN |
| MODURETIC (Suspected) | Reason: Essential benign hypertension | | |
| Tablet | 1.0 Dose Unspecified | Daily | Oral |
| Batch: | Started: 16/12/1992 | Stopped: | 22/12/1992 |
| SINEQUAN (Suspected) | Reason: Depression | | |
| | 175.0 Milligram | Daily | |
| Batch: | Started: 15/11/1992 | Stopped: | 24/12/1992 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------|---------|-------------|--------|---------|
| | Sodium | 134-144 | 23/12/1992 | 122 | |
| | Sodium | 134-144 | 04/01/1993 | 137 | |
| | Sodium | 134-144 | 30/12/1992 | 133 | |
| | Sodium | 134-144 | 22/12/1992 | 123 | |
| | Urea | 3.0-8.0 | 02/07/1992 | 5.0 | |
| | Urea | 3.0-8.0 | 07/12/1992 | 4.9 | |
| | Urea | 3.0-8.0 | 22/12/1992 | 8.3 | |

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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 81808

Seq: 1

Gender: M

Reported: 06/01/1993

Weight: 51.00

Hospitalisation:

Age: 70Y

Onset Date: 22/12/1992

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|------------------------------|--|-----------------|------------|
| VALIUM (Other drug) | Reason: Anxiety neurosis | | |
| Tablet | 20.0 Milligram | Daily | Oral |
| Batch: | Started: 01/01/1980 | Stopped: | CONTIN |
| MODURETIC (Suspected) | Reason: Essential benign hypertension | | |
| Tablet | 1.0 Dose Unspecified | Daily | Oral |
| Batch: | Started: 16/12/1992 | Stopped: | 22/12/1992 |
| SINEQUAN (Suspected) | Reason: Depression | | |
| | 175.0 Milligram | Daily | |
| Batch: | Started: 15/11/1992 | Stopped: | 24/12/1992 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------|---------|-------------|--------|---------|
| | Urea | 3.0-8.0 | 23/12/1992 | 7.2 | |
| | Urea | 3.0-8.0 | 30/07/1992 | 4.6 | |
| | Urea | 3.0-8.0 | 04/01/1993 | 5.1 | |

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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|--|---------------|--------------------------------------|
| Case Number: 82395 | Seq: 1 | Gender: F |
| Reported: 02/02/1993 | | Weight: 60.00 |
| Hospitalisation: Admitted to hospital | | Age: 49Y |
| Onset Date: 06/01/1993 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------------------------|----------|--------------------|-----------|
| Flatulence Diarrhoea Ileus | | Distended abdomen. | |

Medicine Details:

| | | | |
|----------------------------|----------------------|-----------------|-----------------|
| ORUDIS (Other drug) | | Reason: | |
| Capsule | 200.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |
| OGEN (Other drug) | | Reason: | |
| Tablet | 2.0 Dose Unspecified | Daily | Oral |
| Batch: | Started: | Stopped: | |
| DEPTRAN (Suspected) | | Reason: | |
| Capsule | 25.0 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 82884 **Seq:** 1 **Gender:** M
Reported: 08/03/1993 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 77
Onset Date: 16/07/1992 **DOB:** 26/03/1915
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------|-----------------|
| Blood alkaline phosphatase incre Confusional state Neutropenia Vomiting | | | Antibiotics iv. |

Medicine Details:

| | |
|--|----------------------------|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| Batch: | 25.0 Milligram Daily |
| Started: 01/06/1992 | Stopped: 16/07/1992 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-------------|-----------|-------------|--------|---------|
| | Neutrophils | 2.0 - 7.5 | 14/05/1992 | 3.3 | |
| | Neutrophils | 2.0 - 7.5 | 16/07/1992 | 0.0 | |
| | Neutrophils | 2.0 - 7.5 | 19/07/1992 | 0.4 | |
| | Neutrophils | 2.0 - 7.5 | 27/07/1992 | 3.5 | |
| | Neutrophils | 2.0 - 7.5 | 22/07/1992 | 1.8 | |
| | SAP = ALP | 35 - 135 | 14/05/1992 | - | |
| | SAP = ALP | 35 - 135 | 16/07/1992 | 555 | |

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 82884 **Seq:** 1 **Gender:** M
Reported: 08/03/1993 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 77
Onset Date: 16/07/1992 **DOB:** 26/03/1915
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

| | |
|--|---|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| 25.0 Milligram | Daily |
| Batch: | Started: 01/06/1992 Stopped: 16/07/1992 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-------------------|--------|-------------|--------|---------|
| | White blood cells | 4 - 11 | 27/07/1992 | 6.1 | |

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 83578 | Seq: 1 | Gender: F |
| Reported: 25/03/1993 | | Weight: |
| Hospitalisation: | | Age: 69Y |
| Onset Date: 03/06/1992 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | | |
|--|----------------------------|--|
| PREDNISOLONE (Other drug) | Reason: | |
| 10.0 Milligram | Daily | |
| Batch: | Started: | Stopped: |
| DOXEPIN HYDROCHLORIDE (Suspected) | | |
| 0.0 | | |
| Batch: | Started: | Stopped: |
| OMEPRAZOLE (Suspected) | | |
| 20.0 Milligram | Daily | Reason: Other diseases of esophagus |
| Batch: | Started: 02/06/1992 | Stopped: 04/06/1992 |
| ATARAX (Suspected) | | |
| 25.0 Milligram | Daily | Reason: Other puritis conditions |
| Batch: | Started: | Stopped: 2W |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 83578

Seq: 1

Gender: F

Reported: 25/03/1993

Weight:

Hospitalisation:

Age: 69Y

Onset Date: 03/06/1992

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

CYCLOPHOSPHAMIDE (Suspected)

Reason:

50.0 Milligram

Alternate days

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|--|---------------|--------------------------------------|
| Case Number: 85194 | Seq: 1 | Gender: F |
| Reported: 09/06/1993 | | Weight: |
| Hospitalisation: Admitted to hospital | | Age: 92Y |
| Onset Date: 14/03/1993 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---------------------|----------|--------------------------------|---------------------------|
| Pyrexia | | 39.8'c | |
| Rash maculo-papular | | Rash on trunk, face and limbs. | Prednisolone 60mg for two |
| Sepsis | | | |

Medicine Details:

| | | |
|-------------------------|----------------------|------------------------|
| INDOCID (Other drug) | 25.0 Milligram | Reason: As necessary |
| Batch: | Started: | Stopped: CONTIN |
| DIGOXIN (Other drug) | 1.0 Dose Unspecified | Reason: Alternate days |
| Batch: | Started: | Stopped: CONTIN |
| ALLOPURINOL (Suspected) | 0.0 | Reason: Gout |
| Batch: | Started: 08/03/1993 | Stopped: |
| STEMETIL (Suspected) | 5.0 Milligram | Reason: As necessary |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 85194 **Seq:** 1 **Gender:** F
Reported: 09/06/1993 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 92Y
Onset Date: 14/03/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

| | |
|---------------------------------|--|
| FRUSEMIDE (Suspected) | Reason: |
| 80.0 Milligram Daily | |
| Batch: | Started: Stopped: 03/04/1993 |
| SINEQUAN (Suspected) | Reason: |
| 25.0 Milligram Daily | |
| Batch: | Started: Stopped: |
| ASPIRIN (Suspected) | Reason: |
| 150.0 Milligram Daily | |
| Batch: | Started: Stopped: |
| MOGADON (Suspected) | Reason: |
| 1.0 Dose Unspecified Daily | |
| Batch: | Started: Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 86342 | Seq: 1 | Gender: F |
| Reported: 28/07/1993 | | Weight: 80.00 |
| Hospitalisation: | | Age: 71Y |
| Onset Date: 15/07/1993 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Insomnia | | | |
| Nightmare | | | |

Medicine Details:

| | |
|-------------------------------|---|
| TEMAZEPAM (Other drug) | Reason: Specific disorders of sleep |
| 20.0 Milligram Daily | |
| Batch: | Started: 13/07/1993 Stopped: |
| APRINOX (Other drug) | Reason: Essential benign hypertension |
| 1.0 Dose Unspecified Daily | |
| Batch: | Started: 07/10/1987 Stopped: |
| MELLERIL (Other drug) | Reason: |
| 50.0 Milligram Daily | |
| Batch: | Started: 12/07/1988 Stopped: |
| SINEQUAN (Suspected) | Reason: Depression |
| 50.0 Milligram Daily | |
| Batch: | Started: 08/07/1987 Stopped: 15/07/1993 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 86342

Seq: 1

Gender: F

Reported: 28/07/1993

Weight: 80.00

Hospitalisation:

Age: 71Y

Onset Date: 15/07/1993

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PROZAC (Suspected)

Reason: Depression

20.0 Milligram

Daily

Batch:

Started: 15/07/1993

Stopped: 18/07/1993

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 87430 | Seq: 1 | Gender: F |
| Reported: 02/09/1993 | | Weight: |
| Hospitalisation: | | Age: 74Y |
| Onset Date: 16/08/1993 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------------|----------|--------------------|-----------|
| Nephritis interstitial | | | |
| Renal failure acute | | | |

Medicine Details:

| | |
|--|---|
| GENTAMICIN SULPHATE (Suspected) | Reason: Unspecified arthritis |
| 0.0 | |
| Batch: | Started: 05/08/1993 Stopped: 05/08/1993 |
| FLUCLOXACILLIN SODIUM (Suspected) | Reason: Unspecified arthritis |
| Oral application | 2.0 Gram Daily Oral |
| Batch: | Started: 05/08/1993 Stopped: 18/08/1993 |
| PREDNISOLONE (Suspected) | Reason: Otr mus rheum, fibrosit&myalgia |
| Oral application | 8.5 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: CONTIN |
| VERAPAMIL HYDROCHLORIDE (Suspected) | Reason: Otr&nos disord of heart rhythm |
| Oral application | 180.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: CONTIN |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|---------|
| | Creatinine | | 05/08/1993 | 0.09 | |
| | Creatinine | | 19/08/1993 | 0.45 | |
| | Creatinine | | 27/08/1993 | 0.38 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 87430 **Seq:** 1

Gender: F

Reported: 02/09/1993

Weight:

Hospitalisation:

Age: 74Y

Onset Date: 16/08/1993

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | |
|---|---|----------------------------|
| DIGOXIN (Suspected) | Reason: Otr&nos disord of heart rhythm | |
| 125.0 Microgram Daily | | |
| Batch: | Started: | Stopped: 10/08/1993 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Pain | |
| Oral application 50.0 Milligram Daily Oral | | |
| Batch: | Started: | Stopped: CONTIN |
| CAPADEX (Suspected) | Reason: Pain | |
| Capsule 2.0 Dose Unspecified Daily Oral | | |
| Batch: | Started: | Stopped: 19/08/1993 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 87577 **Seq:** 1 **Gender:** M
Reported: 10/09/1993 **Weight:** 63.00
Hospitalisation: **Age:** 49Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Hyperglycaemia | | | Daonil. |

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Depression |
| Oral application | 300.0 Milligram Daily Oral |
| Batch: | Started: 27/05/1993 Stopped: 02/08/1993 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|---------------|-------|-------------|--------|-----------------------|
| | Serum glucose | | | | Blood glucose - 28.5. |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 87776 **Seq:** 1 **Gender:** F
Reported: 17/09/1993 **Weight:** 42.00
Hospitalisation: **Age:** 71Y
Onset Date: 03/09/1993 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------------|----------|--------------------|-----------|
| Muscle spasms Paraesthesia | | | |

Medicine Details:

| | |
|--|---|
| SOLPRIN (Other drug) | Reason: |
| 150.0 Milligram Daily | |
| Batch: | Started: L TERM Stopped: |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Specific disorders of sleep |
| 10.0 Milligram Daily | |
| Batch: | Started: 03/09/1993 Stopped: 14/09/1993 |

Laboratory Investigations:

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

Additional Information:

Paraesthesia of hands and feet, plus cramps in legs and forearms. ceased on cessation of medication and recurred on re-challenge.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 88962 **Seq:** 1 **Gender:** F
Reported: 01/11/1993 **Weight:** 63.00
Hospitalisation: **Age:** 72Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Dyspepsia | | | |
| Flatulence | | | |

Medicine Details:

| | |
|--|--|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| 10.0 Milligram | Daily |
| Batch: | Started: 13/08/1993 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 89237 **Seq:** 1 **Gender:** M
Reported: 12/11/1993 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

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

Medicine Details:

| | |
|--|-----------------------------|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| Batch: | 25.0 Milligram 2 times |
| Started: 01/04/1990 | Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|--|
| | Bilirubin | | | | Peak recorded serum bili level for each episode was 56, 280 and 94 mmol/l (2-17), respectively. on each occasion, the peak serum alanine aminotransferase activity was greater than 1500 u/l (0-40) Active acute hepatitis with portal and acinar inflammation. |
| | Liver biopsy | | | | |

Additional Information:

Patient was rechallenged on doxepin hydrochloride 8/90 and again 3/92 with same reaction occurring. 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 89292 | Seq: 1 | Gender: M |
| Reported: 16/11/1993 | | Weight: 66.00 |
| Hospitalisation: | | Age: 74Y |
| Onset Date: 06/08/1993 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | |
|--|---|
| CLAFORAN (Suspected) | Reason: Other cellulitis and abscess |
| Injection | 4.0 Gram Daily Intravenous |
| Batch: | Started: 02/08/1993 Stopped: 06/08/1993 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| | 100.0 Milligram Daily |
| Batch: | Started: 01/01/1991 Stopped: 09/08/1993 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-------------------|-------|-------------|--------|---------|
| | Haemoglobin | | 02/08/1993 | 115 | |
| | Haemoglobin | | 06/08/1993 | 105 | |
| | Haemoglobin | | 09/08/1993 | 103 | |
| | Platelets | | 02/08/1993 | 124 | |
| | Platelets | | 06/08/1993 | 78 | |
| | Platelets | | 09/08/1993 | 67 | |
| | White blood cells | | 02/08/1993 | 4.5 | |

Additional Information:

Penicillin and sulphur allergies. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 89292 **Seq:** 1 **Gender:** M
Reported: 16/11/1993 **Weight:** 66.00
Hospitalisation: **Age:** 74Y
Onset Date: 06/08/1993 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

| | |
|---|---|
| CLAFORAN (Suspected) | Reason: Other cellulitis and abscess |
| Injection 4.0 Gram Daily Intravenous | |
| Batch: | Started: 02/08/1993 Stopped: 06/08/1993 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| 100.0 Milligram Daily | |
| Batch: | Started: 01/01/1991 Stopped: 09/08/1993 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-------------------|-------|-------------|--------|---------|
| | White blood cells | | 06/08/1993 | 3.2 | |
| | White blood cells | | 09/08/1993 | 2.3 | |

Additional Information:

Penicillin and sulphur allergies. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 89374 **Seq:** 1 **Gender:** M
Reported: 24/11/1993 **Weight:** 78.00
Hospitalisation: **Age:** 38Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

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

Medicine Details:

| | |
|--|---|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| Oral application | 25.0 Milligram Daily Oral |
| Batch: | Started: 01/04/1993 Stopped: 28/05/1993 |

Laboratory Investigations:

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

Additional Information:

Patient recommenced drug in July 1993 and reaction recurred the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 89438 **Seq:** 1 **Gender:** F
Reported: 29/11/1993 **Weight:** 0.00
Hospitalisation: **Age:** 27Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------|--------------------|-----------|
| Retroperitoneal fibrosis | | | |

Medicine Details:

| | |
|-----------------------------|--|
| DESERIL (Suspected) | Reason: Migraine |
| 3.0 Milligram Daily | |
| Batch: | Started: 30/11/1991 L TERM Stopped: 27/11/1993 |
| SINEQUAN (Suspected) | Reason: |
| 25.0 Milligram Daily | |
| Batch: | Started: 30/11/1991 Stopped: |

Laboratory Investigations:

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

Additional Information:

The dosage start dates for both drugs are not necessarily accurate but indicate that start occurred sometime during the month. The dosage stop date for Deseril is not necessarily accurate but indicates that stoppage occurred sometime during the month. Deseril was taken at 3 mg/day for 5 months, then a month off treatment, but still developed retroperitoneal fibrosis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 89584 | Seq: 1 | Gender: M |
| Reported: 01/12/1993 | | Weight: 60.00 |
| Hospitalisation: | | Age: 77Y |
| Onset Date: | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|----------------------|-----------|
| Rash | | Red blotches on leg. | |

Medicine Details:

| | | |
|---------------------|----------------------|----------------------|
| PANADOL (Suspected) | 0.0 | Reason: As necessary |
| Batch: | Started: | Stopped: |
| LASIX (Suspected) | 40.0 Milligram | Reason: Daily |
| Batch: | Started: | Stopped: |
| SLOW-K (Suspected) | 2.0 Dose Unspecified | Reason: Daily |
| Batch: | Started: | Stopped: |
| FELDENE (Suspected) | 20.0 Milligram | Reason: Daily |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 89584

Seq: 1

Gender: M

Reported: 01/12/1993

Weight: 60.00

Hospitalisation:

Age: 77Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|-----------------------------|---------------------------------|
| ZYLOPRIM (Suspected) | Reason: |
| 100.0 Milligram | Daily |
| Batch: | Started: Stopped: |
| SINEQUAN (Suspected) | Reason: |
| 25.0 Milligram | Daily |
| Batch: | Started: Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 89635 **Seq:** 1 **Gender:** F
Reported: 06/12/1993 **Weight:** 60.00
Hospitalisation: **Age:** 68Y
Onset Date: 29/11/1993 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------------------|----------|--------------------|-----------|
| Myalgia Oedema peripheral | | | |

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Depression |
| Oral application | 125.0 Milligram Daily Oral |
| Batch: | Started: 09/11/1993 Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 90357 **Seq:** 1 **Gender:** F
Reported: 05/01/1994 **Weight:** 70.00
Hospitalisation: **Age:** 72Y
Onset Date: 15/11/1993 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|---|--|
| PREPULSID (Suspected) | Reason: Abdominal pain |
| 30.0 Milligram Daily | |
| Batch: Started: 01/06/1993 Stopped: 28/11/1993 | |
| INDERAL (Suspected) | Reason: Abnormal involuntary movement |
| Tablet 80.0 Milligram Daily Oral | |
| Batch: Started: 01/01/1986 Stopped: | |
| SINEQUAN (Suspected) | Reason: Abnormal involuntary movement |
| 50.0 Milligram Daily | |
| Batch: Started: 01/01/1986 Stopped: | |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 90640 **Seq:** 1 **Gender:** M
Reported: 24/01/1994 **Weight:**
Hospitalisation: **Age:** 15Y
Onset Date: 31/08/1993 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|----------------------------|
| SINEQUAN (Suspected) | Reason: |
| Batch: | 125.0 Milligram Daily |
| Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 90693 | Seq: 1 | Gender: M |
| Reported: 27/01/1994 | | Weight: 63.00 |
| Hospitalisation: | | Age: 68Y |
| Onset Date: 31/01/1993 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | |
|-------------------------------|---|
| PRAMIN (Suspected) | Reason: Nausea and vomiting |
| Tablet | 30.0 Milligram Daily Oral |
| Batch: | Started: 01/01/1986 Stopped: 26/03/1993 |
| ISOPTIN SR (Suspected) | Reason: Essential benign hypertension |
| Tablet, modified release | 240.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: CONTIN |
| FRUSEMIDE (Suspected) | Reason: Essential benign hypertension |
| Oral application | 40.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: CONTIN |
| LOSEC (Suspected) | Reason: Ulcer of duodenum w/o ment perf |
| Capsule | 60.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 90693 **Seq:** 1

Gender: M

Reported: 27/01/1994

Weight: 63.00

Hospitalisation:

Age: 68Y

Onset Date: 31/01/1993

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|--|-----------------|--------------------------------------|------------------------|
| PREDNISOLONE (Suspected) | | Reason: Unspecified arthritis | |
| Oral application | 10.0 Milligram | Daily | Oral |
| Batch: | Started: | L TERM | Stopped: CONTIN |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | |
| Oral application | 50.0 Milligram | Daily | Oral |
| Batch: 3 | Started: | L TERM | Stopped: CONTIN |

Laboratory Investigations:

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 90952 | Seq: 1 | Gender: F |
| Reported: 09/02/1994 | | Weight: 52.00 |
| Hospitalisation: | | Age: 54Y |
| Onset Date: 21/01/1994 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------------------|----------|--------------------|-----------|
| Hepatic function abnormal Nausea | | | |

Medicine Details:

| | | |
|--|-----------------|---------------------------|
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: Depression |
| Oral application | 50.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: |
| PREDNISOLONE (Suspected) | | Reason: |
| Oral application | 37.5 Milligram | Daily Oral |
| Batch: | Started: | Stopped: |
| TIMENTIN (Suspected) | | Reason: |
| Injection | 12.4 Gram | Daily Intravenous |
| Batch: | Started: | Stopped: |
| RANITIDINE (Suspected) | | Reason: |
| Tablet | 300.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 90952

Seq: 1

Gender: F

Reported: 09/02/1994

Weight: 52.00

Hospitalisation:

Age: 54Y

Onset Date: 21/01/1994

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|---|----------------------------|-----------------|------|
| SPIRONOLACTONE (Suspected) | | Reason: | |
| Tablet | 200.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |
| AMIODARONE HYDROCHLORIDE (Suspected) | | Reason: | |
| | 600.0 Milligram | Daily | |
| Batch: | Started: 19/01/1994 | Stopped: | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 90980 | Seq: 1 | Gender: M |
| Reported: 09/02/1994 | | Weight: |
| Hospitalisation: | | Age: 74Y |
| Onset Date: 20/01/1994 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | |
|--|---|
| MIANSERIN HYDROCHLORIDE (Suspected) | Reason: |
| 20.0 Milligram Daily | |
| Batch: | Started: 14/01/1994 Stopped: 24/01/1994 |
| DEPTRAN (Suspected) | Reason: |
| 25.0 Milligram Daily | |
| Batch: | Started: 10/01/1994 Stopped: 28/01/1994 |
| COLOXYL (Suspected) | Reason: |
| 4.0 Dose Unspecified Daily | |
| Batch: | Started: Stopped: CONTIN |
| AMLODIPINE (Suspected) | Reason: |
| 10.0 Milligram Daily | |
| Batch: | Started: Stopped: CONTIN |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|---------|
| | ALT = SGPT | | 10/01/1994 | 15 | |
| | ALT = SGPT | | 20/01/1994 | 44 | |
| | ALT = SGPT | | 25/01/1994 | 16 | |
| | ALT = SGPT | | 24/01/1994 | 18 | |
| | ALT = SGPT | | 03/02/1994 | 14 | |
| | AST = SGOT | | 10/01/1994 | 15 | |
| | AST = SGOT | | 25/01/1994 | 16 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 90980 **Seq:** 1 **Gender:** M
Reported: 09/02/1994 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 20/01/1994 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

| | |
|------------------------------|--|
| ZANTAC (Suspected) | Reason: |
| 150.0 Milligram Daily | |
| Batch: | Started: Stopped: CONTIN |
| PREPULSID (Suspected) | Reason: |
| 15.0 Milligram Daily | |
| Batch: | Started: Stopped: CONTIN |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|---------|
| | AST = SGOT | | 03/02/1994 | 17 | |
| | AST = SGOT | | 24/01/1994 | 15 | |
| | AST = SGOT | | 20/01/1994 | 32 | |
| | Bilirubin | | 10/01/1994 | 7 | |
| | Bilirubin | | 20/01/1994 | 8 | |
| | Bilirubin | | 24/01/1994 | 7 | |
| | Bilirubin | | 25/01/1994 | 4 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|----------------------------|--------|-------------------------------|
| Case Number: 90980 | Seq: 1 | Gender: M |
| Reported: 09/02/1994 | | Weight: |
| Hospitalisation: | | Age: 74Y |
| Onset Date: 20/01/1994 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

Medicine Details:

| | | |
|-------------------------------------|---------------------|---------------------|
| MIANSERIN HYDROCHLORIDE (Suspected) | Reason: | |
| 20.0 Milligram | Daily | |
| Batch: | Started: 14/01/1994 | Stopped: 24/01/1994 |
| DEPTRAN (Suspected) | Reason: | |
| 25.0 Milligram | Daily | |
| Batch: | Started: 10/01/1994 | Stopped: 28/01/1994 |
| COLOXYL (Suspected) | Reason: | |
| 4.0 Dose Unspecified | Daily | |
| Batch: | Started: | Stopped: CONTIN |
| AMLODIPINE (Suspected) | Reason: | |
| 10.0 Milligram | Daily | |
| Batch: | Started: | Stopped: CONTIN |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|---------|
| | Bilirubin | | 03/02/1994 | 5 | |
| | GGT = SGGT = | | 10/01/1994 | 80 | |
| | GGT = SGGT = | | 25/01/1994 | 157 | |
| | GGT = SGGT = | | 24/01/1994 | 168 | |
| | GGT = SGGT = | | 20/01/1994 | 263 | |
| | GGT = SGGT = | | 03/02/1994 | 100 | |
| | SAP = ALP | | 10/01/1994 | 81 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 90980 Seq: 1

Gender: M

Reported: 09/02/1994

Weight:

Hospitalisation:

Age: 74Y

Onset Date: 20/01/1994

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|-----------------------|----------|----------|--------|
| ZANTAC (Suspected) | Reason: | | |
| 150.0 Milligram | Daily | | |
| Batch: | Started: | Stopped: | CONTIN |
| PREPULSID (Suspected) | Reason: | | |
| 15.0 Milligram | Daily | | |
| Batch: | Started: | Stopped: | CONTIN |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-----------|-------|-------------|--------|---------|
| | SAP = ALP | | 20/01/1994 | 137 | |
| | SAP = ALP | | 24/01/1994 | 100 | |
| | SAP = ALP | | 25/01/1994 | 98 | |
| | SAP = ALP | | 03/02/1994 | 86 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|--|---------------|--------------------------------------|
| Case Number: 91455 | Seq: 1 | Gender: F |
| Reported: 08/03/1994 | | Weight: |
| Hospitalisation: Admitted to hospital | | Age: 54Y |
| Onset Date: | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Dizziness | | | |
| Urticaria | Severe | | |

Medicine Details:

| | |
|------------------------------|-----------------|
| CARDIZEM (Other drug) | Reason: |
| 180.0 Milligram | Daily |
| Batch: | Started: |
| | Stopped: |
| SINEQUAN (Suspected) | Reason: |
| 50.0 Milligram | Daily |
| Batch: | Started: |
| | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 93019 | Seq: 1 | Gender: F |
| Reported: 16/05/1994 | | Weight: |
| Hospitalisation: | | Age: 81Y |
| Onset Date: 26/04/1994 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--------------------|-----------|
| Thrombocytopenia | Severe | | |

Medicine Details:

| | |
|-----------------------------|---|
| LOSEC (Other drug) | Reason: |
| 40.0 Milligram Daily | |
| Batch: | Started: L TERM Stopped: CONTIN |
| SEREPAX (Other drug) | Reason: |
| 30.0 Milligram Daily | |
| Batch: | Started: L TERM Stopped: CONTIN |
| PANADOL (Other drug) | Reason: |
| 8.0 Dose Unspecified Daily | |
| Batch: | Started: Stopped: CONTIN |
| TEGRETOL (Suspected) | Reason: Pain |
| 600.0 Milligram Daily | |
| Batch: | Started: 01/04/1994 Stopped: 30/04/1994 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-----------|-------|-------------|--------|---------|
| | Platelets | | 19/04/1994 | 207 | |
| | Platelets | | 26/04/1994 | 170 | |
| | Platelets | | 30/04/1994 | 33 | |
| | Platelets | | 02/05/1994 | 57 | |
| | Platelets | | 04/05/1994 | 157 | |
| | Platelets | | 10/05/1994 | 263 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 93019

Seq: 1

Gender: F

Reported: 16/05/1994

Weight:

Hospitalisation:

Age: 81Y

Onset Date: 26/04/1994

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

SINEQUAN (Suspected)

Reason: Pain

50.0 Milligram Daily

Batch:

Started: L TERM

Stopped: 03/05/1994

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 93033 | Seq: 1 | Gender: M |
| Reported: 19/05/1994 | | Weight: 64.00 |
| Hospitalisation: | | Age: 70Y |
| Onset Date: 14/05/1994 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|-------------------------------|-----------|
| Rash erythematous Pruritus Purpura | | Rash on trunk and upper legs. | Teldane |

Medicine Details:

| | |
|-------------------------------------|---|
| AUGMENTIN FORTE (Suspected) | Reason: Acute bronchitis&bronchiolitis |
| 3.0 Dose Unspecified Daily | |
| Batch: | Started: 13/05/1994 Stopped: 14/05/1994 |
| BRICANYL (Suspected) | Reason: Acute bronchitis&bronchiolitis |
| Solution 30.0 Millilitre Daily Oral | |
| Batch: | Started: 13/05/1994 Stopped: |
| DEPTRAN (Suspected) | Reason: Depression |
| Tablet 112.0 Milligram Daily Oral | |
| Batch: | Started: 01/01/1984 Stopped: CONTIN |
| ZOCOR (Suspected) | Reason: Othr&unspec metabolic diseases |
| 1.0 Dose Unspecified Alternate days | |
| Batch: | Started: 01/01/1991 Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:

Patient was also taking one white capsule daily since 1974 for hypertension. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 93056 | Seq: 1 | Gender: F |
| Reported: 18/05/1994 | | Weight: 70.00 |
| Hospitalisation: | | Age: 59Y |
| Onset Date: 08/04/1994 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|--------------------|-----------|
| Dermatitis bullous | | | |

Medicine Details:

| | |
|--|----------------------------|
| ALPRAZOLAM (Suspected) | Reason: |
| 500.0 Microgram | As necessary |
| Batch: | Started: |
| Batch: | Stopped: |
| TEGRETOL (Suspected) | Reason: |
| 200.0 Milligram | Daily |
| Batch: | Started: 22/02/1994 |
| | Stopped: 15/04/1994 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| 250.0 Milligram | Daily |
| Batch: | Started: 01/01/1992 |
| | Stopped: |
| PREMARIN (Suspected) | Reason: |
| 625.0 Microgram | Daily |
| Batch: | Started: |
| | Stopped: |

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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 93776 | Seq: 1 | Gender: M |
| Reported: 17/06/1994 | | Weight: 90.00 |
| Hospitalisation: | | Age: 74Y |
| Onset Date: 09/06/1994 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--------------------------------|-----------|
| Rash erythematous | | Bright red upper body. | |
| Face oedema | | Swelling face cheeks and eyes. | |

Medicine Details:

| | |
|-------------------------------|---|
| MONOPRIL (Other drug) | Reason: Essential benign hypertension |
| 20.0 Milligram | Daily |
| Batch: | Started: 01/01/1994 Stopped: |
| SULPHUR (Other drug) | Reason: Other prophylactic procedures |
| 50.0 Milligram | Daily |
| Batch: | Started: 01/01/1994 Stopped: |
| VOLTAREN (Other drug) | Reason: Unspecified arthritis |
| 100.0 Milligram | Daily |
| Batch: | Started: 01/01/1994 Stopped: |
| CLARATYNE (Other drug) | Reason: |
| 1.0 Dose Unspecified | Daily |
| Batch: | Started: 01/03/1994 Stopped: CONTIN |

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 93776

Seq: 1

Gender: M

Reported: 17/06/1994

Weight: 90.00

Hospitalisation:

Age: 74Y

Onset Date: 09/06/1994

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

| | | | |
|----------------------------|---------------------------------------|----------------------------|------|
| RULIDE (Suspected) | Reason: Bronchitis,unqualified | | |
| Tablet | 10.0 Milligram | Daily | Oral |
| Batch: | Started: 07/06/1994 | Stopped: 09/06/1994 | |
| DEPTRAN (Suspected) | Reason: Depression | | |
| | 125.0 Milligram | Daily | |
| Batch: | Started: 01/01/1994 | Stopped: | |

Laboratory Investigations:

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 94689 | Seq: 1 | Gender: F |
| Reported: 29/07/1994 | | Weight: |
| Hospitalisation: | | Age: 70Y |
| Onset Date: 20/04/1994 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | | | |
|--|----------------------------|---|-------------|
| FERRO-GRADUMET (Other drug) | | Reason: | |
| Tablet | 350.0 Milligram | Daily | Oral |
| Batch: | Started: 15/04/1994 | Stopped: | CONTIN |
| MEGAFOL (Other drug) | | Reason: | |
| Oral application | 500.0 Microgram | Daily | Oral |
| Batch: | Started: 18/04/1994 | Stopped: | CONTIN |
| FLUCLOXACILLIN SODIUM (Suspected) | | Reason: Otr&nos infec¶sit diseases | |
| Injection | 2.0 Gram | Daily | Intravenous |
| Batch: | Started: 08/04/1994 | Stopped: | 14/04/1994 |
| STAPHYLEX (Suspected) | | Reason: Unspecified septicemia | |
| Oral application | 1.0 Gram | Daily | Oral |
| Batch: | Started: 14/04/1994 | Stopped: | 03/05/1994 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------------|-------------|--------|---------|
| | ALT = SGPT | 5 - 45 U/L | 15/05/1994 | 13 | |
| | ALT = SGPT | 5 - 45 U/L | 16/05/1994 | 21 | |
| | ALT = SGPT | 5 - 45 U/L | 20/07/1994 | 68 | |
| | ALT = SGPT | 5 - 45 U/L | 25/07/1994 | 13 | |
| | ALT = SGPT | 5 - 45 U/L | 04/07/1994 | 18 | |
| | ALT = SGPT | 5 - 45 U/L | 27/06/1994 | 25 | |
| | AST = SGOT | 10 - 45 U/L | 15/05/1994 | 46 | |

Additional Information:

On the day of admission the patient received four units of packed cells.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 94689 Seq: 1

Gender: F

Reported: 29/07/1994

Weight:

Hospitalisation:

Age: 70Y

Onset Date: 20/04/1994

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|-----------------------------|---|----------------------------|-------------|
| AMOXIL (Suspected) | Reason: Otr&nos infec¶sit diseases | | |
| Injection | 1.5 Gram | Daily | Intravenous |
| Batch: | Started: 09/04/1994 | Stopped: 14/04/1994 | |
| ROCEPHIN (Suspected) | Reason: Otr&nos infec¶sit diseases | | |
| Injection | 1.0 Gram | Daily | Intravenous |
| Batch: | Started: 07/04/1994 | Stopped: 09/04/1994 | |
| DEPTRAN (Suspected) | Reason: Unspecified psychosis | | |
| Oral application | 25.0 Milligram | Daily | Oral |
| Batch: | Started: 27/04/1994 | Stopped: 27/04/1994 | |
| TOFRANIL (Suspected) | Reason: Unspecified psychosis | | |
| Tablet | 20.0 Milligram | Daily | Oral |
| Batch: | Started: 28/04/1994 | Stopped: 06/05/1994 | |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|---------------|-------------|--------|---------|
| | AST = SGOT | 10 - 45 U/L | 16/05/1994 | 41 | |
| | AST = SGOT | 10 - 45 U/L | 20/06/1994 | 90 | |
| | AST = SGOT | 10 - 45 U/L | 27/06/1994 | 43 | |
| | AST = SGOT | 10 - 45 U/L | 04/07/1994 | 52 | |
| | AST = SGOT | 10 - 45 U/L | 25/07/1994 | 53 | |
| | Bilirubin | 4 - 22 UMOL/L | 15/05/1994 | 6 | |
| | Bilirubin | 4 - 22 UMOL/L | 16/05/1994 | 4 | |

Additional Information:

On the day of admission the patient received four units of packed cells.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|----------------------------|--------|-------------------------------|
| Case Number: 94689 | Seq: 1 | Gender: F |
| Reported: 29/07/1994 | | Weight: |
| Hospitalisation: | | Age: 70Y |
| Onset Date: 20/04/1994 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

Medicine Details:

| | | | |
|--|----------------------------|---|-------------|
| FERRO-GRADUMET (Other drug) | | Reason: | |
| Tablet | 350.0 Milligram | Daily | Oral |
| Batch: | Started: 15/04/1994 | Stopped: | CONTIN |
| MEGAFOL (Other drug) | | Reason: | |
| Oral application | 500.0 Microgram | Daily | Oral |
| Batch: | Started: 18/04/1994 | Stopped: | CONTIN |
| FLUCLOXACILLIN SODIUM (Suspected) | | Reason: Otr&nos infec¶sit diseases | |
| Injection | 2.0 Gram | Daily | Intravenous |
| Batch: | Started: 08/04/1994 | Stopped: | 14/04/1994 |
| STAPHYLEX (Suspected) | | Reason: Unspecified septicemia | |
| Oral application | 1.0 Gram | Daily | Oral |
| Batch: | Started: 14/04/1994 | Stopped: | 03/05/1994 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-----------|---------------|-------------|--------|---------|
| | Bilirubin | 4 - 22 UMOL/L | 24/06/1994 | 3 | |
| | Bilirubin | 4 - 22 UMOL/L | 25/07/1994 | 4 | |
| | Bilirubin | 4 - 22 UMOL/L | 04/07/1994 | 5 | |
| | Bilirubin | 4 - 22 UMOL/L | 20/06/1994 | 2 | |
| | SAP = ALP | 40 - 150 U/L | 15/05/1994 | 174 | |
| | SAP = ALP | 40 - 150 U/L | 16/05/1994 | 158 | |
| | SAP = ALP | 40 - 150 U/L | 20/06/1994 | 277 | |

Additional Information:

On the day of admission the patient received four units of packed cells.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 94689 **Seq:** 1 **Gender:** F
Reported: 29/07/1994 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: 20/04/1994 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

| | |
|---|---|
| AMOXIL (Suspected) | Reason: Otr&nos infec¶sit diseases |
| Injection 1.5 Gram Daily Intravenous | |
| Batch: Started: 09/04/1994 Stopped: 14/04/1994 | |
| ROCEPHIN (Suspected) | Reason: Otr&nos infec¶sit diseases |
| Injection 1.0 Gram Daily Intravenous | |
| Batch: Started: 07/04/1994 Stopped: 09/04/1994 | |
| DEPTRAN (Suspected) | Reason: Unspecified psychosis |
| Oral application 25.0 Milligram Daily Oral | |
| Batch: Started: 27/04/1994 Stopped: 27/04/1994 | |
| TOFRANIL (Suspected) | Reason: Unspecified psychosis |
| Tablet 20.0 Milligram Daily Oral | |
| Batch: Started: 28/04/1994 Stopped: 06/05/1994 | |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-----------|--------------|-------------|--------|---------|
| | SAP = ALP | 40 - 150 U/L | 27/06/1994 | 242 | |
| | SAP = ALP | 40 - 150 U/L | 04/07/1994 | 285 | |
| | SAP = ALP | 40 - 150 U/L | 25/07/1994 | 202 | |

Additional Information:

On the day of admission the patient received four units of packed cells.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 94693 | Seq: 1 | Gender: M |
| Reported: 29/07/1994 | | Weight: 70.00 |
| Hospitalisation: | | Age: 47Y |
| Onset Date: 01/06/1994 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--|--------------------|
| Breast mass | | Development of lump in L breast, now 2 cm in diameter and mobile | Sinequan withdrawn |

Medicine Details:

| | | |
|------------------------------------|----------------------|--------------------|
| PANADEINE FORTE (Suspected) | Reason: | As necessary |
| Batch: | Started: | Stopped: |
| | 0.0 | |
| SINEQUAN (Suspected) | Reason: | Depression |
| Batch: | Started: | Stopped: |
| | 75.0 Milligram | Daily Oral |
| | 01/02/1988 | 28/07/1994 |
| DIPENTUM (Suspected) | Reason: | Regional enteritis |
| Batch: | Started: | Stopped: |
| | 3.0 Dose Unspecified | Daily Oral |
| | 01/04/1994 | |
| VOLTAREN (Suspected) | Reason: | Pain in joint |
| Batch: | Started: | Stopped: |
| | 2.0 Dose Unspecified | Daily Oral |
| | 01/12/1993 | 28/07/1994 |

Laboratory Investigations:

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

Additional Information:

The dosage start and stop dates are not necessarily accurate but indicate that start and stop occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 95265 | Seq: 1 | Gender: F |
| Reported: 25/08/1994 | | Weight: |
| Hospitalisation: | | Age: 57Y |
| Onset Date: 06/06/1994 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--------------------------------|
| Rash | | | Topical steroids, tar shampoo. |

Medicine Details:

| | |
|-----------------------------|---|
| LAMISIL (Suspected) | Reason: Dermatophytosis |
| Tablet | 250.0 Milligram Daily Oral |
| Batch: | Started: 25/04/1994 Stopped: 25/07/1994 |
| SINEQUAN (Suspected) | Reason: Depression |
| Oral application | 35.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: |
| DI-GESIC (Suspected) | Reason: Other disturbance of sensation |
| | 4.0 Dose Unspecified Daily |
| Batch: | Started: L TERM Stopped: |
| PREMARIN (Suspected) | Reason: Menopausal symptoms |
| Tablet | 625.0 Microgram 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 95575 | Seq: 1 | Gender: F |
| Reported: 01/09/1994 | | Weight: |
| Hospitalisation: | | Age: 39Y |
| Onset Date: 31/07/1994 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Detail

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

Medicine Details:

| | |
|---------------------------------------|---|
| NORIDAY (Other drug) | Reason: Contraception |
| 1.0 Dose Unspecified Daily | |
| Batch: | Started: L TERM Stopped: |
| BECOTIDE (Other drug) | Reason: Asthma |
| Inhalation 4.0 Dose Unspecified Daily | Inhalation |
| Batch: | Started: L TERM Stopped: |
| SINEQUAN (Suspected) | Reason: Migraine |
| Tablet 25.0 Milligram Daily | Oral |
| Batch: | Started: 19/07/1994 Stopped: 14/08/1994 |

Laboratory Investigations:

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

Additional Information:

Patient suffers from coeliac disease - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 95592 | Seq: 1 | Gender: F |
| Reported: 02/09/1994 | | Weight: 58.00 |
| Hospitalisation: | | Age: 14Y |
| Onset Date: 26/08/1994 | | DOB: |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------------------|-----------|
| Hallucination | | Hears a voice calling her name | |

Medicine Details:

| | | |
|-----------------------------|----------------------------|---------------------------|
| SINEQUAN (Suspected) | | Reason: Depression |
| Oral application | 50.0 Milligram | Daily Oral |
| Batch: | Started: 09/08/1994 | Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 96961 | Seq: 1 | Gender: F |
| Reported: 07/11/1994 | | Weight: 58.00 |
| Hospitalisation: | | Age: 46Y |
| Onset Date: 29/10/1994 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------|--------------------|-----------|
| Anticholinergic syndrome | | | |
| Confusional state | | | |
| Dystonia | | | |
| Extrapyramidal disorder | | | |
| Hyperhidrosis | | | |
| Hyperthermia malignant | | | |
| Hypertonia | | | |
| Pyrexia | | | |
| Tachycardia | | | |
| Tremor | | | |

Medicine Details:

| | | |
|----------------------------|------------------------------------|----------------------------|
| HEROIN (Other drug) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: |
| VALIUM (Other drug) | Reason: Anxiety neurosis | |
| 10.0 Milligram | Daily | |
| Batch: | Started: | Stopped: CONTIN |
| MAXOLON (Suspected) | Reason: Nausea and vomiting | |
| 20.0 Milligram | Total | |
| Batch: | Started: 29/10/1994 | Stopped: |
| AROPAX (Suspected) | Reason: Depression | |
| Tablet | 20.0 Milligram | Daily Oral |
| Batch: | Started: 20/10/1994 | Stopped: 31/10/1994 |

Laboratory Investigations:

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

Additional Information:

The patient had been on sinequan 100mg daily long term before being switched to paroxetine without washout period. "serotonergic syndrome" 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 96961

Seq: 1

Gender: F

Reported: 07/11/1994

Weight: 58.00

Hospitalisation:

Age: 46Y

Onset Date: 29/10/1994

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

DEPTRAN (Suspected)

Reason: Depression

Oral application

100.0 Milligram

Daily

Oral

Batch:

Started: 01/08/1994

Stopped: 29/10/1994

Laboratory Investigations:

Additional Information:

The patient had been on sinequan 100mg daily long term before being switched to paroxetine without washout period. "serotonergic syndrome" 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 96984 **Seq:** 1 **Gender:** F
Reported: 07/11/1994 **Weight:**
Hospitalisation: **Age:** 20Y
Onset Date: 31/08/1994 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------|----------|--|-----------|
| Hair texture abnormal | | Hair has become very greasy. | |
| Seborrhoea | | Increase in sebaceous secretion in scalp | |

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Depression |
| 50.0 Milligram | Daily |
| Batch: | Started: 01/07/1994 Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 97492 **Seq:** 1 **Gender:** F
Reported: 01/12/1994 **Weight:** 60.00
Hospitalisation: **Age:** 59Y
Onset Date: 30/11/1994 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------|----------|--------------------------|------------------|
| Coordination abnormal | | Developed uncoordination | |
| Oculogyration | | | |
| Tremor | | | Cogentin 2mg imi |

Medicine Details:

| | |
|----------------------------|--|
| DEPTRAN (Suspected) | Reason: Depression |
| Tablet | 25.0 Milligram 1 time Oral |
| Batch: | Started: 29/11/1994 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 97516 **Seq:** 1 **Gender:** F
Reported: 01/12/1994 **Weight:** 38.00
Hospitalisation: **Age:** 49Y
Onset Date: 20/07/1994 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|---|------------------------------|
| DAPSONE (Suspected) | Reason: |
| 200.0 Milligram Weekly | |
| Batch: Started: 29/03/1994 Stopped: CONTIN | |
| FLUCONAZOLE (Suspected) | Reason: Moniliasis |
| Capsule 200.0 Milligram Daily Oral | |
| Batch: Started: 20/07/1994 Stopped: CONTIN | |
| DIDANOSINE (Suspected) | Reason: Hiv infection |
| 400.0 Milligram Daily | |
| Batch: Started: 24/11/1993 Stopped: 24/08/1994 | |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| 200.0 Milligram Daily | |
| Batch: Started: 27/10/1993 Stopped: CONTIN | |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-----------|-------|-------------|--------|---------|
| | SAP = ALP | | 20/07/1994 | 289 | |
| | SAP = ALP | | 17/08/1994 | 1127 | |
| | SAP = ALP | | 24/08/1994 | 1349 | |

Additional Information:

Patient died on the 22/10/94.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 97516

Seq: 1

Gender: F

Reported: 01/12/1994

Weight: 38.00

Hospitalisation:

Age: 49Y

Onset Date: 20/07/1994

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|-------------------------------|--|
| CLONAZEPAM (Suspected) | Reason: Anxiety neurosis |
| 200.0 Microgram Daily | |
| Batch: | Started: 27/10/1993 |
| | Stopped: CONTIN |
| F.G.F. (Suspected) | Reason: Iron deficiency anemias |
| 270.0 Milligram Daily | |
| Batch: | Started: 27/10/1993 |
| | Stopped: CONTIN |

Laboratory Investigations:

Additional Information:

Patient died on the 22/10/94.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 97547 | Seq: 1 | Gender: M |
| Reported: 05/12/1994 | | Weight: 86.00 |
| Hospitalisation: | | Age: 61Y |
| Onset Date: | | DOB: |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | |
|------------------------------|---|
| PEPCIDINE (Suspected) | Reason: Otr disorders stomach function |
| 60.0 Milligram | Daily |
| Batch: | Started: 01/08/1994 Stopped: |
| SINEQUAN (Suspected) | Reason: Otr disorders stomach function |
| 50.0 Milligram | Daily |
| Batch: | Started: 01/09/1993 Stopped: 28/11/1994 |

Laboratory Investigations:

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

Additional Information:

Patient experienced same reaction with tagamet. 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 stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 98544 | Seq: 1 | Gender: M |
| Reported: 30/01/1995 | | Weight: 90.00 |
| Hospitalisation: | | Age: 35 |
| Onset Date: 25/01/1995 | | DOB: 05/07/1959 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------------|-----------|
| Convulsion Grand mal convulsion Syncope | | Complex partial seizures | Tegretol |

Medicine Details:

| | |
|-----------------------------|---|
| CLOZARIL (Suspected) | Reason: Unspecified schizophrenia |
| Oral application | 400.0 Milligram Daily Oral |
| Batch: | Started: 01/04/1994 Stopped: CONTIN |
| SINEQUAN (Suspected) | Reason: Depression |
| Tablet | 75.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: CONTIN |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-------------------|-------|-------------|--------|--|
| | Electroencephalog | | | | Eeg showed epileptic activity arising from the right anterior regions with some secondary spread to the other side with also |

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 98836 **Seq:** 1 **Gender:** M
Reported: 08/02/1995 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------------|-----------------------|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| Batch: | Started: 0.0 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|--|---------------|--------------------------------------|
| Case Number: 99086 | Seq: 1 | Gender: U |
| Reported: 22/02/1995 | | Weight: |
| Hospitalisation: Admitted to hospital | | Age: |
| Onset Date: 31/12/1994 | | DOB: |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--------------------|
| Anorexia | | | Parenteral feeding |
| Hepatitis | | | |
| Malabsorption | | | |
| Malaise | | | |

Medicine Details:

| | | |
|----------------------------|-----------------|-----------------|
| LIPEX (Suspected) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: |
| <hr/> | | |
| IMDUR (Suspected) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: |
| <hr/> | | |
| DEPTRAN (Suspected) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|---|
| | Liver biopsy | | | | A liver biopsy was performed which showed evidence of acute |

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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 99321 | Seq: 1 | Gender: F |
| Reported: 06/03/1995 | | Weight: |
| Hospitalisation: | | Age: 55Y |
| Onset Date: 17/02/1995 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------|-----------|
| Orthostatic hypotension | | | |
| Tachycardia | | | |

Medicine Details:

| | | |
|-----------------------------|----------------------------|---------------------------|
| SINEQUAN (Suspected) | | Reason: Depression |
| Tablet | 50.0 Milligram | Daily Oral |
| Batch: | Started: 23/01/1995 | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 100989 **Seq:** 1 **Gender:** M
Reported: 22/05/1995 **Weight:** 70.00
Hospitalisation: **Age:** 40Y
Onset Date: 22/02/1995 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------|--------------------|-----------|
| Retroperitoneal fibrosis | | | |

Medicine Details:

| | |
|---|---|
| PROZAC (Suspected) | Reason: Depression |
| 40.0 Milligram Daily | |
| Batch: | Started: 01/02/1994 Stopped: 28/04/1995 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| Oral application 75.0 Milligram Daily Oral | |
| Batch: | Started: 01/02/1994 Stopped: 28/03/1994 |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 103055 **Seq:** 1 **Gender:** M
Reported: 28/08/1995 **Weight:** 118.00
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|---------------------------------|-----------|
| Hallucination Drug withdrawal syndrome Hyperhidrosis Nightmare | | Hypnagogic hallucinations-as if | |

Medicine Details:

| | |
|---|--|
| PAROXETINE HYDROCHLORIDE (Suspected) | Reason: Depression |
| Tablet 30.0 Milligram Daily Oral | |
| Batch: | Started: Stopped: 28/02/1995 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| 25.0 Milligram Daily | |
| Batch: | Started: Stopped: 28/02/1995 |

Laboratory Investigations:

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

Additional Information:

Reaction occurred two days after ceasing paroxetine and resolved when restarted paroxetine again. two days later, less than 24 hours after ceasing doxepin, similar phenomena for 3 days, resolved when restarted doxepin. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 104537 **Seq:** 1 **Gender:** F
Reported: 09/11/1995 **Weight:** 60.00
Hospitalisation: **Age:** 64Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--------------------|-----------|
| Drug ineffective | | | |

Medicine Details:

| | | |
|-------------------------------|----------------------------|----------------------------|
| ESTRADERM (Other drug) | Reason: | |
| 25.0 Microgram | Daily | |
| Batch: | Started: | Stopped: |
| DEPTRAN (Suspected) | Reason: Depression | |
| 50.0 Milligram | Daily | |
| Batch: | Started: 24/10/1995 | Stopped: 05/11/1995 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 104653 | Seq: 1 | Gender: F |
| Reported: 15/11/1995 | | Weight: 70.00 |
| Hospitalisation: | | Age: 56Y |
| Onset Date: 02/09/1995 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------|-----------|
| Pruritus Hepatic function abnormal Jaundice Malaise | | Generalised | |

Medicine Details:

| | | |
|-------------------------------|----------------------------|---------------------|
| VOLTAREN (Suspected) | Reason: | |
| 0.0 | | |
| Batch: | Started: 18/07/1995 | Stopped: |
| SINEQUAN (Suspected) | Reason: | |
| 0.0 | | |
| Batch: | Started: 19/08/1995 | Stopped: |
| FORD PILLS (Suspected) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: |
| ZOCOR (Suspected) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: 02Y |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|---------|
| | ALT = SGPT | | 11/09/1995 | 1330 | |
| | ALT = SGPT | | 20/10/1995 | 574 | |
| | ALT = SGPT | | 09/11/1995 | 412 | |
| | AST = SGOT | | 11/09/1995 | 2270 | |
| | AST = SGOT | | 20/10/1995 | 1232 | |
| | AST = SGOT | | 09/11/1995 | 848 | |
| | Albumin | | 11/09/1995 | 40 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 104653 Seq: 1

Gender: F

Reported: 15/11/1995

Weight: 70.00

Hospitalisation:

Age: 56Y

Onset Date: 02/09/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|-----------------------------------|----------------|
| FLUCLOXACILLIN SODIUM (Suspected) | Reason: |
| Batch: | 2.0 Gram Daily |
| Started: 06/07/1995 | Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|---------|
| | Albumin | | 20/10/1995 | 31 | |
| | Albumin | | 09/11/1995 | 32 | |
| | Bilirubin | | 11/09/1995 | 227 | |
| | Bilirubin | | 20/10/1995 | 259 | |
| | Bilirubin | | 09/11/1995 | 179 | |
| | GGT = SGGT = | | 11/09/1995 | 153 | |
| | GGT = SGGT = | | 20/10/1995 | 218 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 104653 Seq: 1

Gender: F

Reported: 15/11/1995

Weight: 70.00

Hospitalisation:

Age: 56Y

Onset Date: 02/09/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|------------------------|------------------------------|
| VOLTAREN (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: 18/07/1995 Stopped: |
| SINEQUAN (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: 19/08/1995 Stopped: |
| FORD PILLS (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: Stopped: |
| ZOCOR (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: Stopped: 02Y |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|---------|
| | GGT = SGGT = | | 09/11/1995 | 241 | |
| | SAP = ALP | | 11/09/1995 | 402 | |
| | SAP = ALP | | 20/10/1995 | 356 | |
| | SAP = ALP | | 09/11/1995 | 428 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 104653 **Seq:** 1

Gender: F

Reported: 15/11/1995

Weight: 70.00

Hospitalisation:

Age: 56Y

Onset Date: 02/09/1995

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

FLUCLOXACILLIN SODIUM (Suspected)

Reason:

2.0 Gram

Daily

Batch:

Started: 06/07/1995

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 104852 **Seq:** 1 **Gender:** F
Reported: 24/11/1995 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: 14/11/1995 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|--------------------------|--------------------|
| Psychotic disorder | | Acute psychotic reaction | Diazepam, serenace |
| Delirium | | | |
| Delusion | | | |
| Paranoia | | | |

Medicine Details:

| | |
|---|----------------------------|
| SINEQUAN (Suspected) | Reason: Depression |
| 0.0 | |
| Batch: | Started: |
| | Stopped: 13/11/1995 |
| SERTRALINE HYDROCHLORIDE (Suspected) | Reason: Depression |
| 50.0 Milligram | Daily |
| Batch: | Started: 14/11/1995 |
| | Stopped: 15/11/1995 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 105483 | Seq: 1 | Gender: M |
| Reported: 21/12/1995 | | Weight: 74.00 |
| Hospitalisation: | | Age: 76Y |
| Onset Date: 15/11/1995 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | | |
|-----------------------------|-----------------|-------------------------------|
| SINEQUAN (Suspected) | Reason: | |
| 0.0 | | |
| Batch: | Started: | L TERM Stopped: |
| TIGASON (Suspected) | Reason: | |
| 0.0 | | |
| Batch: | Started: | L TERM Stopped: |
| GOLD NOS (Suspected) | Reason: | |
| 1.0 Dose Unspecified Weekly | | |
| Batch: | Started: | Stopped: |
| PREDNISOLONE (Suspected) | Reason: | |
| 25.0 Milligram Daily | | |
| Batch: | Started: | L TERM Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|-------|-------------|--------|---------|
| | ALT = SGPT | | 15/11/1995 | 80 | |
| | GGT = SGGT = | | 15/11/1995 | 463 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 105483

Seq: 1

Gender: M

Reported: 21/12/1995

Weight: 74.00

Hospitalisation:

Age: 76Y

Onset Date: 15/11/1995

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

BECLOFORTE (Suspected)

Reason:

8.0 Dose Unspecified Daily

Batch:

Started:

L TERM

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 106212 **Seq:** 1 **Gender:** F
Reported: 02/02/1996 **Weight:** 71.00
Hospitalisation: **Age:** 59
Onset Date: 25/10/1993 **DOB:** 08/12/1933
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------|
| Cardiomyopathy | | | Monopril, lasix. |

Medicine Details:

| | |
|----------------------------|---|
| DEPTRAN (Suspected) | Reason: Depression |
| 75.0 Milligram | Daily |
| Batch: | Started: 19/10/1990 Stopped: 29/04/1994 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 106299 **Seq:** 1 **Gender:** F
Reported: 07/02/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|---|
| AROPAX (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: 01/01/1995 Stopped: 21/08/1995 |
| SINEQUAN (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: 01/07/1995 Stopped: |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 106471 **Seq:** 1 **Gender:** F
Reported: 16/02/1996 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|-----------------------|-----------|
| Pruritus Drug withdrawal syndrome Insomnia | | Itching ears and eyes | |

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Depression |
| 75.0 Milligram | Daily |
| Batch: | Started: 01/01/1994 Stopped: 28/02/1996 |

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 109723 | Seq: 1 | Gender: M |
| Reported: 04/07/1996 | | Weight: |
| Hospitalisation: | | Age: 80 |
| Onset Date: 06/06/1996 | | DOB: 22/07/1915 |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--|-----------|
| Cerebellar syndrome Thinking abnormal Gait disturbance Coordination abnormal | | Cerebellar degeneration Cognitive impairment Gait ataxia | |

Medicine Details:

| | |
|-----------------------------|----------------------|
| SINEQUAN (Suspected) | Reason: |
| Batch: | 75.0 Milligram Daily |
| Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 109807 **Seq:** 1 **Gender:** F
Reported: 08/07/1996 **Weight:** 74.00
Hospitalisation: **Age:** 31Y
Onset Date: 31/03/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|--------------------|-----------|
| Increased appetite | | | |
| Weight increased | | | |

Medicine Details:

| | |
|---|---------------------------------|
| VALIUM (Other drug) | Reason: Anxiety neurosis |
| 30.0 Milligram Daily | |
| Batch: Started: 01/01/1995 Stopped: | |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| 50.0 Milligram Daily | |
| Batch: Started: 01/03/1996 Stopped: 28/06/1996 | |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 109951 **Seq:** 1 **Gender:** F
Reported: 15/07/1996 **Weight:** 60.00
Hospitalisation: **Age:** 46Y
Onset Date: 06/07/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|----------|------------------------|-----------|
| Dysgeusia Breath odour | | Bitter taste in mouth. | |

Medicine Details:

| | |
|---|--|
| PLENDIL (Other drug) Tablet Batch: Started: 01/01/1994 Stopped: CONTIN | Reason: Essential benign hypertension 10.0 Milligram Daily Oral |
| GRISOVIN (Suspected) Batch: Started: Stopped: | Reason: Dermatophytosis 500.0 Milligram Daily |
| FUCIDIN (Suspected) Ointment Batch: Started: Stopped: | Reason: 2.0 Dose Unspecified Daily Topical |
| ARISTOCORT (Suspected) Ointment Batch: Started: Stopped: | Reason: 2.0 Dose Unspecified Daily Topical |

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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 109951 **Seq:** 1

Gender: F

Reported: 15/07/1996

Weight: 60.00

Hospitalisation:

Age: 46Y

Onset Date: 06/07/1996

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|-----------------------------|--|
| SINEQUAN (Suspected) | Reason: Rash |
| Capsule | 10.0 Milligram Daily Oral |
| Batch: | Started: 07/05/1996 Stopped: |

Laboratory Investigations:

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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 111874 | Seq: 1 | Gender: F |
| Reported: 27/09/1996 | | Weight: |
| Hospitalisation: | | Age: 79Y |
| Onset Date: 24/08/1995 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|---|-----------|
| Hyponatraemia | | Tricyclic anti-depressant induced siadh | |

Medicine Details:

| | | |
|-------------------------------|-----------------|-----------------------------|
| PEPCIDINE (Other drug) | Reason: | Other diseases of esophagus |
| 0.0 | | |
| Batch: | Started: | Stopped: |
| OGEN (Other drug) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: |
| CALTRATE (Other drug) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: |
| PANAMAX (Other drug) | Reason: | Pain |
| Oral application | 500.0 Milligram | As necessary Oral |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-----------|---------|-------------|--------|---------|
| | Potassium | 3.4-4.8 | 21/01/1995 | 4.9 | |
| | Potassium | 3.4-4.8 | 01/11/1994 | 4.2 | |
| | Potassium | 3.4-4.8 | 24/08/1995 | 5.3 | |
| | Potassium | 3.4-4.8 | 22/08/1996 | 4.5 | |
| | Potassium | 3.4-4.8 | 23/05/1996 | 4.6 | |
| | Sodium | 134-144 | 21/01/1995 | 133 | |
| | Sodium | 134-144 | 01/11/1994 | 135 | |

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 111874

Seq: 1

Gender: F

Reported: 27/09/1996

Weight:

Hospitalisation:

Age: 79Y

Onset Date: 24/08/1995

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

| | | | |
|----------------------------|-----------------|-----------------------------|------|
| CARTIA (Other drug) | Reason: | | |
| Tablet | 100.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |
| DEPTRAN (Suspected) | Reason: | Specific disorders of sleep | |
| Capsule | 25.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |
| | 01/01/1993 | 13/06/1996 | |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------|---------|-------------|--------|---------|
| | Sodium | 134-144 | 24/08/1995 | 129 | |
| | Sodium | 134-144 | 23/05/1996 | 126 | |
| | Sodium | 134-144 | 22/08/1996 | 134 | |

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 112228 **Seq:** 1 **Gender:** F
Reported: 14/10/1996 **Weight:** 70.00
Hospitalisation: **Age:** 65Y
Onset Date: 30/09/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---------------------|----------|--|-----------|
| Rash maculo-papular | | Rash on left upper arm and thigh only. | |

Medicine Details:

| | |
|------------------------------|---|
| DEPTRAN (Suspected) | Reason: Pain |
| Oral application | 10.0 Milligram Daily Oral |
| Batch: | Started: 23/09/1996 Stopped: 30/09/1996 |
| PANADEINE (Suspected) | Reason: Pain |
| Oral application | 2.0 Dose Unspecified Daily Oral |
| Batch: | Started: L TERM Stopped: |
| FELDENE (Suspected) | Reason: Pain |
| | 1.0 Dose Unspecified Daily |
| Batch: | Started: L TERM Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 113109 **Seq:** 1 **Gender:** M
Reported: 13/11/1996 **Weight:** 90.00
Hospitalisation: **Age:** 54Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|----------|--------------------|-----------|
| Photosensitivity reaction | | | |

Medicine Details:

| | |
|--|---|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| 125.0 Milligram | Daily |
| Batch: | Started: 01/05/1995 Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 113408 **Seq:** 1 **Gender:** F
Reported: 25/11/1996 **Weight:**
Hospitalisation: **Age:** 37Y
Onset Date: 31/12/1996 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|-------------------------------------|
| SINEQUAN (Suspected) | Reason: |
| Batch: | Started: 0.0 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 113993 | Seq: 1 | Gender: M |
| Reported: 18/12/1996 | | Weight: |
| Hospitalisation: | | Age: 84 |
| Onset Date: 28/11/1996 | | DOB: 17/12/1911 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | | |
|--|----------------------------|----------------------------|
| SORBITOL (Other drug) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: |
| PARACETAMOL (Other drug) | Reason: | |
| 1.0 Gram | As necessary | |
| Batch: | Started: | Stopped: |
| COLOXYL WITH SENNA (Other drug) | Reason: | |
| 4.0 Dose Unspecified | Daily | |
| Batch: | Started: | Stopped: |
| PHENYTOIN SODIUM (Suspected) | Reason: | |
| 400.0 Milligram | Daily | |
| Batch: | Started: 03/11/1996 | Stopped: 28/11/1996 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-------------------|-------|-------------|--------|---------|
| | Lymphocytes | | 28/11/1996 | 0.5 | |
| | Neutrophils | | 28/11/1996 | 2.1 | |
| | Platelets | | 28/11/1996 | 61 | |
| | White blood cells | | 28/11/1996 | 2.7 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 113993 **Seq:** 1 **Gender:** M
Reported: 18/12/1996 **Weight:**
Hospitalisation: **Age:** 84
Onset Date: 28/11/1996 **DOB:** 17/12/1911
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

| | |
|--|---|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| 25.0 Milligram | Daily |
| Batch: | Started: L TERM Stopped: 28/11/1996 |
| NORFLOXACIN (Suspected) | Reason: |
| 800.0 Milligram | Daily |
| Batch: | Started: 20/11/1996 Stopped: 28/11/1996 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 115022 | Seq: 1 | Gender: F |
| Reported: 06/02/1997 | | Weight: |
| Hospitalisation: | | Age: 49Y |
| Onset Date: | | DOB: |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--------------------|-----------|
| Hallucination | | | |
| Insomnia | | | |
| Weight increased | | | |

Medicine Details:

| | | |
|-----------------------------|-----------------|---------------------------------|
| SINEQUAN (Suspected) | | Reason: Anxiety neurosis |
| Capsule | 10.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 115172 **Seq:** 1 **Gender:** F
Reported: 13/02/1997 **Weight:** 75.00
Hospitalisation: **Age:** 61
Onset Date: 31/12/1994 **DOB:** 14/10/1933
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--|-----------|
| Angioedema | | Face oedema including tongue and pharyngeal oedema | |

Medicine Details:

| | | | | |
|-----------------------------|--|----------|---------------------|----------|
| SINEQUAN (Suspected) | Reason: | | | |
| Batch: | 0.0 | Started: | Stopped: | |
| ESTIGYN (Suspected) | Reason: | | | |
| Batch: | 0.0 | Started: | Stopped: | |
| RENITEC (Suspected) | Reason: Essential benign hypertension | | | |
| Batch: | 20.0 Milligram | Daily | Started: 01/01/1992 | Stopped: |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 115182 **Seq:** 1 **Gender:** F
Reported: 12/02/1997 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Otr ecz&der due otr&unsp cause |
| Capsule | 25.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient discontinued sinequan for 4 weeks and condition resolved, took 1 cap again and had an immediate return of symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 115741 | Seq: 1 | Gender: F |
| Reported: 03/03/1997 | | Weight: |
| Hospitalisation: | | Age: 70Y |
| Onset Date: | | DOB: |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--|-----------|
| Asthenia | | Could not lift legs to get out of bed. | |

Medicine Details:

| | | |
|-----------------------------|-----------------|---------------------------------|
| SEREPAX (Other drug) | | Reason: Anxiety neurosis |
| Tablet | 0.0 | Oral |
| Batch: | Started: | Stopped: |
| SINEQUAN (Suspected) | | Reason: Depression |
| Capsule | 20.0 Milligram | Total Oral |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 115939 **Seq:** 1 **Gender:** M
Reported: 12/03/1997 **Weight:**
Hospitalisation: **Age:** 83Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|-------------------------------------|
| SINEQUAN (Suspected) | Reason: |
| Capsule | 10.0 Milligram Daily Oral |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 115940 **Seq:** 1 **Gender:** F
Reported: 12/03/1997 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------|-----------|
| Gingivitis Epistaxis | | Bleeding gums. | |

Medicine Details:

| | |
|-----------------------------|-------------------------------------|
| SINEQUAN (Suspected) | Reason: |
| Capsule | 75.0 Milligram Daily Oral |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 116741 **Seq:** 1 **Gender:** M
Reported: 14/04/1997 **Weight:**
Hospitalisation: **Age:** 48Y
Onset Date: 09/04/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Chest pain | | | |

Medicine Details:

| | | | |
|---|--|-------------------------------------|----------------------------------|
| SINEQUAN (Suspected) Capsule Batch: | 25.0 Milligram Started: 26/03/1997 | Daily Stopped: 07/04/1997 | Reason: Anxiety neurosis Oral |
| SINEQUAN (Suspected) Capsule Batch: | 20.0 Milligram Started: 08/04/1997 | Daily Stopped: | Reason: Anxiety neurosis Oral |
| SINEQUAN (Suspected) Capsule Batch: | 10.0 Milligram Started: 09/04/1997 | Daily Stopped: | Reason: Anxiety neurosis Oral |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|------------------------|--------|-------------------------------|
| Case Number: 117519 | Seq: 1 | Gender: F |
| Reported: 13/05/1997 | | Weight: 74.00 |
| Hospitalisation: | | Age: 73Y |
| Onset Date: 07/05/1997 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------|----------|--------------------|-----------|
| Hypertonia Myalgia | Severe | | |

Medicine Details:

| | | |
|---------------------------|---------------------------------------|----------------------------|
| ISORDIL (Other drug) | Reason: Chron isch heart dis no hyper | 2.0 Dose Unspecified Daily |
| Batch: | Started: | Stopped: CONTIN |
| BETALOC (Other drug) | Reason: Chron isch heart dis no hyper | 50.0 Milligram Daily |
| Batch: | Started: | Stopped: CONTIN |
| MURELAX (Other drug) | Reason: Anxiety neurosis | 30.0 Milligram Daily |
| Batch: | Started: | Stopped: CONTIN |
| KENACORT-A 10 (Suspected) | Reason: | 0.0 |
| Batch: | Started: 07/05/1997 | Stopped: |

Laboratory Investigations:

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

Additional Information:

History of allergy to stemetil and stelazine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 117519

Seq: 1

Gender: F

Reported: 13/05/1997

Weight: 74.00

Hospitalisation:

Age: 73Y

Onset Date: 07/05/1997

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|-------------------------------|--|
| LIGNOCAINE (Suspected) | Reason: |
| Injection | 1.0 Dose Unspecified 1 time Intraarticular |
| Batch: | Started: 07/05/1997 Stopped: |
| SINEQUAN (Suspected) | Reason: Anxiety neurosis |
| | 50.0 Milligram Daily |
| Batch: | Started: Stopped: CONTIN |

Laboratory Investigations:

Additional Information:

History of allergy to stemetil and stelazine.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 117698 | Seq: 1 | Gender: M |
| Reported: 19/05/1997 | | Weight: |
| Hospitalisation: | | Age: |
| Onset Date: | | DOB: |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | | |
|-----------------------------|-----------------|---------------------------------|
| SINEQUAN (Suspected) | | Reason: Anxiety neurosis |
| Capsule | 25.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: |
| INDERAL (Suspected) | | Reason: |
| Tablet | 20.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 117774 **Seq:** 1 **Gender:** F
Reported: 23/05/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 24/04/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | | |
|------------------------------|----------------------------|---|
| FOSAMAX (Suspected) | | Reason: Osteoporosis |
| Tablet | 10.0 Milligram | Daily Oral |
| Batch: | Started: 15/03/1997 | Stopped: 01/05/1997 |
| SINEQUAN (Suspected) | | Reason: Anxiety neurosis |
| Capsule | 20.0 Milligram | Daily Oral |
| Batch: | Started: 19/04/1996 | Stopped: |
| TEMAZEPAM (Suspected) | | Reason: |
| Oral application | 10.0 Milligram | Daily Oral |
| Batch: | Started: 01/01/1992 | Stopped: |
| CAPOTEN (Suspected) | | Reason: Congestive heart failure |
| Tablet | 25.0 Milligram | Daily Oral |
| Batch: | Started: 12/12/1995 | Stopped: |

Laboratory Investigations:

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

Additional Information:

Trimethoprim x 7 days 31jan-> 6 feb 1997. cephalixin 25m tds 6 mar->13 mar 97 exposure to quinine bisclulate uncertain. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 117774 Seq: 1

Gender: F

Reported: 23/05/1997

Weight:

Hospitalisation:

Age:

Onset Date: 24/04/1997

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | | |
|------------------------------|----------------------------|-----------------|--------------------------|--|
| ROCALTROL (Suspected) | | Reason: | Osteoporosis | |
| Capsule | 500.0 Microgram | Daily | Oral | |
| Batch: | Started: 01/01/1995 | Stopped: | CONTIN | |
| LASIX (Suspected) | | Reason: | Congestive heart failure | |
| Tablet | 40.0 Milligram | Daily | Oral | |
| Batch: | Started: 01/01/1995 | Stopped: | | |

Laboratory Investigations:

Additional Information:

Trimethoprim x 7 days 31jan-> 6 feb 1997. cephalixin 25m tds 6 mar->13 mar 97 exposure to quinine bisclulate uncertain. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 118323 **Seq:** 1 **Gender:** M
Reported: 16/06/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|--------------------|---|
| Dizziness Fatigue | | | Dose of drug reduced to lessen side effects |

Medicine Details:

| | |
|-----------------------------|-------------------------------------|
| SINEQUAN (Suspected) | Reason: Disturbance of sleep |
| 30.0 Milligram | Daily |
| 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: 1 Jan 1989 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 118372 **Seq:** 1 **Gender:** F
Reported: 18/06/1997 **Weight:** 66.00
Hospitalisation: **Age:** 49Y
Onset Date: 04/02/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Agitation | | | |
| Anxiety | | | |

Medicine Details:

| | |
|-----------------------------|-------------------------------------|
| MELLERIL (Suspected) | Reason: |
| Tablet | 75.0 Milligram Daily Oral |
| Batch: | Started: Stopped: |
| SINEQUAN (Suspected) | Reason: |
| | 60.0 Milligram Daily |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient stabilised on 75mg melleril since 1982. change of formulation of 50mg and 25mg tablets has caused major upset.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 118732 **Seq:** 1 **Gender:** F
Reported: 02/07/1997 **Weight:** 55.00
Hospitalisation: **Age:** 53Y
Onset Date: 12/05/1997 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

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

Medicine Details:

| | |
|----------------------------|---|
| EFEXOR (Suspected) | Reason: |
| 75.0 Milligram | Daily |
| Batch: | Started: 12/05/1997 Stopped: 21/06/1997 |
| DEPTRAN (Suspected) | Reason: Depression |
| 50.0 Milligram | Daily |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 118807 | Seq: 1 | Gender: F |
| Reported: 03/07/1997 | | Weight: 93.00 |
| Hospitalisation: | | Age: 52Y |
| Onset Date: 09/05/1997 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------------|-----------|
| Hyperglycaemia | | Fluctuating blood sugar. | |

Medicine Details:

| | |
|---------------------------------|--|
| OESTRADIOL (Suspected) | Reason: Menopausal symptoms |
| Implant | 0.0 Subcutaneous |
| Batch: | Started: 01/01/1994 Stopped: |
| FLIXOTIDE (Suspected) | Reason: Asthma |
| Inhalation | 4.0 Dose Unspecified Daily Inhalation |
| Batch: | Started: 01/04/1995 Stopped: |
| SANDOMIGRAN (Suspected) | Reason: Headache |
| Tablet | 2.0 Dose Unspecified Daily Oral |
| Batch: | Started: 01/05/1996 Stopped: |
| PREDNISOLONE (Suspected) | Reason: |
| Tablet | 7.5 Milligram Daily Oral |
| Batch: | Started: 01/05/1996 Stopped: |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 118846 **Seq:** 1 **Gender:** F
Reported: 04/07/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|--|
| SINEQUAN (Suspected) | Reason: Otr&unsp forms neuralg&neurit |
| Capsule | 10.0 Milligram Daily Oral |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 118998 **Seq:** 1 **Gender:** F
Reported: 10/07/1997 **Weight:**
Hospitalisation: **Age:** 75Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--|
| Dyspepsia | | | Cimetidine, disapride given with little success. |
| Oesophagitis | | | |

Medicine Details:

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| SINEQUAN (Suspected) | | Reason: | |
| Capsule | 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 119962 **Seq:** 1 **Gender:** F
Reported: 15/08/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|---------------------|-----------|
| Oedema | | Fluid retention | |
| Weight increased | | Weight gain of 3kg. | |

Medicine Details:

| | |
|-----------------------------|--|
| SINEQUAN (Suspected) | Reason: |
| Capsule | 50.0 Milligram Daily Oral |
| Batch: | Started: 01/04/1997 Stopped: |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 120683 | Seq: 1 | Gender: M |
| Reported: 10/09/1997 | | Weight: |
| Hospitalisation: | | Age: 71 |
| Onset Date: | | DOB: 04/03/1926 |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--------------------|-----------|
| Urinary retention | | | |

Medicine Details:

| | |
|---|--|
| PETHIDINE HYDROCHLORIDE (Other drug) | Reason: Abdominal pain |
| 100.0 Milligram | As necessary |
| Batch: | Started: 18/06/1997 Stopped: |
| AMLODIPINE (Other drug) | Reason: |
| 5.0 Milligram | Daily |
| Batch: | Started: L TERM Stopped: |
| EPILIM (Other drug) | Reason: Other&unspecified epilepsy |
| 1.0 Gram | Daily |
| Batch: | Started: Stopped: |
| DUCENE (Other drug) | Reason: Abdominal pain |
| 2.0 Milligram | Daily |
| Batch: | Started: L TERM Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 120683 **Seq:** 1 **Gender:** M
Reported: 10/09/1997 **Weight:**
Hospitalisation: **Age:** 71
Onset Date: **DOB:** 04/03/1926
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

| | |
|---|--|
| OMEPRAZOLE (Other drug) | Reason: Other diseases of esophagus |
| 40.0 Milligram Daily | |
| Batch: Started: Stopped: | |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| 50.0 Milligram Daily | |
| Batch: Started: L TERM Stopped: 17/06/1997 | |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| 75.0 Milligram Daily | |
| Batch: Started: 18/06/1997 Stopped: 24/06/1997 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 121196 **Seq:** 1 **Gender:** M
Reported: 29/09/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|--------------------|-----------|
| Erectile dysfunction | | | |

Medicine Details:

| | |
|---|---------------------------------|
| SINEQUAN (Suspected) | Reason: |
| Capsule 50.0 Milligram Daily Oral | |
| Batch: | Started: Stopped: |
| SINEQUAN (Suspected) | Reason: |
| Capsule 100.0 Milligram Daily Oral | |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient experienced reaction when dose of sinequan was increased from 50mg to 100mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 121544 | Seq: 1 | Gender: M |
| Reported: 15/10/1997 | | Weight: |
| Hospitalisation: | | Age: A7 |
| Onset Date: 31/12/1997 | | DOB: |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

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

Medicine Details:

| | |
|--|---|
| ZOCOR (Suspected) | Reason: Othr&unspec metabolic diseases |
| 0.0 | |
| Batch: | Started: |
| Batch: | Stopped: |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Specific disorders of sleep |
| Capsule | 10.0 Milligram Daily Oral |
| Batch: | Started: L TERM |
| Batch: | Stopped: |

Laboratory Investigations:

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

Additional Information:

Uncertain if caused by sinequan. considering changing statin. - the date of onset is not accurate but indicates that onset occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 122004 | Seq: 1 | Gender: F |
| Reported: 30/10/1997 | | Weight: |
| Hospitalisation: | | Age: 86Y |
| Onset Date: | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|---------------------|--|
| Rash Pruritus | | Eczematous eruption | Ceased amlodipine & frusemide. given topical steroids, dexepin at night, claritine and celestone v |

Medicine Details:

| | |
|--|---|
| AMLODIPINE (Suspected) | Reason: Essential benign hypertension |
| 5.0 Milligram | Daily |
| Batch: | Started: 11/05/1997 Stopped: 11/06/1997 |
| FRUSEMIDE (Suspected) | Reason: Essential benign hypertension |
| 40.0 Milligram | Daily Oral |
| Batch: | Started: 01/03/1996 Stopped: 16/09/1997 |
| POTASSIUM CHLORIDE (Suspected) | Reason: |
| 1.2 Gram | Daily Oral |
| Batch: | Started: 01/03/1996 Stopped: 16/09/1997 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| 10.0 Milligram | Daily |
| Batch: | Started: 11/09/1997 Stopped: CONTIN |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-------------|-------|-------------|--------|---|
| | Skin biopsy | | | | 11/9/97 skin biopsy - spongiotic dermatitis with eosinophils consistent with drug eruption. |

Additional Information:

Patient was on 5 mg amlodipine without ill effects but within 48 hours of doubling dose patient developed symptoms. not resolved after 3 months. 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 123370 **Seq:** 1 **Gender:** F
Reported: 15/12/1997 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|-------------------------------------|
| SINEQUAN (Suspected) | Reason: Depression |
| Capsule | 50.0 Milligram Daily Oral |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 123742 **Seq:** 1 **Gender:** M
Reported: 30/12/1997 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|-------------------------------------|--|
| ENDONE (Interaction) | Reason: |
| 5.0 Milligram Daily | |
| Batch: | Started: 01/01/1990 Stopped: |
| DEPTRAN (Interaction) | Reason: |
| 25.0 Milligram Daily | |
| Batch: | Started: 01/01/1997 Stopped: |
| DIAZEPAM (Other drug) | Reason: |
| 1.0 Dose Unspecified Daily | |
| Batch: | Started: 01/01/1990 Stopped: |
| PANADEINE FORTE (Other drug) | Reason: |
| 2.0 Dose Unspecified Daily | |
| Batch: | Started: 01/01/1993 Stopped: |

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 123742

Seq: 1

Gender: M

Reported: 30/12/1997

Weight:

Hospitalisation:

Age: 50Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|------------------------------|----------------------------|
| PREPULSID FORTE (Other drug) | Reason: |
| Batch: | 2.0 Dose Unspecified Daily |
| Started: 01/01/1993 | Stopped: |
| AROPAX (Other drug) | Reason: |
| Batch: | 1.0 Dose Unspecified Daily |
| Started: 01/01/1996 | Stopped: |

Laboratory Investigations:

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 123743 | Seq: 1 | Gender: M |
| Reported: 31/12/1997 | | Weight: |
| Hospitalisation: | | Age: 43Y |
| Onset Date: | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|----------------------|----------------------|
| Cough | | Continuing dry cough | Deptran discontinued |
| Gingival atrophy | | Shrinking gums | |
| Toothache | | Tooth pain | |
| Dysgeusia | | | |

Medicine Details:

| | |
|-----------------------------|---|
| BETALOC (Other drug) | Reason: Essential benign hypertension |
| Tablet | 100.0 Milligram Daily Oral |
| Batch: | Started: 01/01/1997 Stopped: |
| DEPTRAN (Suspected) | Reason: Depression |
| | 0.0 |
| Batch: | Started: 01/12/1996 Stopped: 28/12/1997 |
| DILANTIN (Suspected) | Reason: Other&unspecified epilepsy |
| Oral application | 500.0 Milligram Daily Oral |
| Batch: | Started: 01/01/1992 Stopped: |

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 125230 **Seq:** 1 **Gender:** F
Reported: 23/02/1998 **Weight:**
Hospitalisation: **Age:** 46Y
Onset Date: 15/02/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|----------------------------------|-----------|
| Pollakiuria | | Increased frequency of urination | |

Medicine Details:

| | | | |
|-----------------------------|----------------------------|-----------------|--------|
| SINEQUAN (Suspected) | Reason: Depression | | |
| Capsule | 20.0 Milligram | Daily | Oral |
| Batch: | Started: 12/02/1998 | Stopped: | CONTIN |

Laboratory Investigations:

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

Additional Information:

Patient has had unsatisfactory experiences with 10 other anti-depressants commenced sinequan 4 days ago. she commenced on 10mg/day for two days and then increased the dose to 10mg morning and evening. since increasing the dose the reaction has occurred.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 126092 **Seq:** 1 **Gender:** M
Reported: 23/03/1998 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|---------------------------------|
| SINEQUAN (Suspected) | Reason: Anxiety neurosis |
| Tablet | 0.0 Daily Oral |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:

The patient also has hepatitis c



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 127344 **Seq:** 1 **Gender:** F
Reported: 13/05/1998 **Weight:**
Hospitalisation: **Age:** 58Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--|-----------|
| Weight increased | | Gained 1 stone during first 2 years of | |

Medicine Details:

| | |
|-----------------------------|--|
| SINEQUAN (Suspected) | Reason: Anxiety neurosis |
| Capsule | 0.0 Oral |
| Batch: | Started: 01/01/1995 Stopped: |

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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 127727 **Seq:** 1 **Gender:** F
Reported: 25/05/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|-------------------------|-----------|
| Dysgeusia | | Bitter persistant taste | |

Medicine Details:

| | |
|---|--|
| DEPTRAN (Interaction) | Reason: Depression |
| Tablet 50.0 Milligram Daily Oral | |
| Batch: | Started: L TERM Stopped: |
| RENITEC (Interaction) | Reason: Essential benign hypertension |
| Tablet 2.5 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 129440 **Seq:** 1 **Gender:** F
Reported: 21/07/1998 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: 31/07/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Detail

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

Medicine Details:

| | | | | | |
|---|------------------------------------|----------|-------------|----------|----------|
| DIAZEPAM (Other drug) | Reason: | | | | |
| Batch: | 0.0 | Started: | Stopped: | | |
| ENALAPRIL MALEATE (Other drug) | Reason: | | | | |
| Batch: | 0.0 | Started: | Stopped: | | |
| VERAPAMIL HYDROCHLORIDE (Other drug) | Reason: | | | | |
| Batch: | 240.0 Milligram | Daily | Started: | Stopped: | |
| OESTRADIOL (Other drug) | Reason: Menopausal symptoms | | | | |
| Cream | 22.0 Milligram | Daily | Transdermal | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient had same reaction when withdrawing from sinequan once before. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 129440

Seq: 1

Gender: F

Reported: 21/07/1998

Weight:

Hospitalisation:

Age: 55Y

Onset Date: 31/07/1998

DOB:

Outcome: Not yet recovered

Causality: Causality certain

Reaction Detail

Medicine Details:

| | | | |
|-----------------------------|-----------------|-----------------|------|
| SINEQUAN (Suspected) | | Reason: | |
| Capsule | 10.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |

Laboratory Investigations:

Additional Information:

Patient had same reaction when withdrawing from sinequan once before. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 130187 **Seq:** 1 **Gender:** F
Reported: 14/08/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|-------------------------------------|
| SINEQUAN (Suspected) | Reason: Depression |
| Capsule | 25.0 Milligram Daily Oral |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 130188 **Seq:** 1 **Gender:** F
Reported: 14/08/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|-------------------------------------|
| SINEQUAN (Suspected) | Reason: Depression |
| Capsule | 50.0 Milligram Daily Oral |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 130413 | Seq: 1 | Gender: M |
| Reported: 24/08/1998 | | Weight: 70.00 |
| Hospitalisation: | | Age: 35Y |
| Onset Date: 16/06/1998 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--|--|
| Hypertonia Drug withdrawal syndrome Insomnia Myalgia | | Muscle spasms and cramps especially to | Changed therapy to tofranil after sudden depran cessation with decreased symptoms. |

Medicine Details:

| | | |
|----------------------------|----------------------------|----------------------------|
| DEPTRAN (Suspected) | | Reason: Depression |
| Oral application | 25.0 Milligram | Daily Oral |
| Batch: | Started: 01/01/1998 | Stopped: 10/06/1998 |

Laboratory Investigations:

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

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 130546 | Seq: 1 | Gender: F |
| Reported: 25/08/1998 | | Weight: |
| Hospitalisation: | | Age: AD |
| Onset Date: 26/06/1998 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------------------|----------|--------------------|-----------|
| Convulsion | | | |
| Drug withdrawal syndrome neonatal | | | |
| Fatigue | | | |
| Feeding disorder neonatal | | | |
| Respiratory disorder | | | |

Medicine Details:

| | |
|--|-----------------|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: |
| | Stopped: |
| PROTHIADEN (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: |
| | Stopped: |

Laboratory Investigations:

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

Additional Information:

Doxepin and prothiaden administered to the mother in pregnancy and puerperium. symptoms suggestive of drug withdrawal. tachypnoea and abnormal jerky jittery movements starting soon after birth, followed after some days by lethargy, poor feeding, failure to gain weight on breast feeds. baby improved markedly when formula fed. long term outcome unknown.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 130872 | Seq: 1 | Gender: M |
| Reported: 07/09/1998 | | Weight: |
| Hospitalisation: | | Age: |
| Onset Date: 12/08/1998 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|--------------------|-----------|
| Personality disorder | | Personality change | |
| Flushing | | | |
| Headache | | | |
| Hyperhidrosis | | | |
| Insomnia | | | |
| Muscle twitching | | | |

Medicine Details:

| | | | |
|-----------------------------|----------------------------|---|--------|
| SINEQUAN (Suspected) | | Reason: Othr and unspecified urticaria | |
| Capsule | 30.0 Milligram | Daily | Oral |
| Batch: | Started: 10/08/1998 | Stopped: | CONTIN |

Laboratory Investigations:

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

Additional Information:

Pt titrated dose of sinequan from 10mg to 30mg daily and experienced symptoms so has dropped back to 10mg at which the adverse events diminished.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 130880 **Seq:** 1 **Gender:** F
Reported: 07/09/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | | | |
|-----------------------------|-----------------|--------|-----------------|
| SINEQUAN (Suspected) | Reason: | | |
| Capsule | 0.0 | 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 130904 | Seq: 1 | Gender: F |
| Reported: 08/09/1998 | | Weight: 49.00 |
| Hospitalisation: | | Age: 67Y |
| Onset Date: 06/08/1998 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|----------------|
| Hyponatraemia | | | Ceased doxepin |

Medicine Details:

| | | |
|--|----------------------------|----------------------------|
| CAPADEX (Other drug) | Reason: | |
| 0.0 | As necessary | |
| Batch: | Started: | Stopped: |
| OXAZEPAM (Other drug) | Reason: | |
| 15.0 Milligram | Daily | |
| Batch: | Started: | Stopped: CONTIN |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression | |
| 100.0 Milligram | Daily | |
| Batch: | Started: 01/07/1998 | Stopped: 06/08/1998 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------|-------|-------------|--------|---------|
| | Sodium | | 13/07/1998 | 139 | |
| | Sodium | | 06/08/1998 | 120 | |

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 131131 **Seq:** 1 **Gender:** F
Reported: 11/09/1998 **Weight:** 70.00
Hospitalisation: **Age:** 84Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---------------------------------------|
| Constipation | | | Ceased doxepin and started citalopram |

Medicine Details:

| | |
|--|----------------------------|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| 50.0 Milligram | Daily |
| Batch: | Started: |
| | Stopped: 16/06/1998 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 132554 | Seq: 1 | Gender: F |
| Reported: 30/10/1998 | | Weight: 74.00 |
| Hospitalisation: | | Age: 77Y |
| Onset Date: 19/10/1998 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|--------------------|--|
| Myalgia | | Body ache | Pt recovered upon stopping sinequan and tenormin |
| Periorbital oedema | | Puffy eyes | |
| Amnesia | | | |
| Fatigue | | | |
| Nausea | | | |
| Visual disturbance | | | |

Medicine Details:

| | |
|-----------------------------|--|
| SINEQUAN (Suspected) | Reason: |
| 10.0 Milligram | Daily |
| Batch: | Started: 01/01/1988 Stopped: |
| TENORMIN (Suspected) | Reason: |
| 50.0 Milligram | Daily |
| Batch: | Started: 01/01/1988 Stopped: |

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 133235 **Seq:** 1 **Gender:** M
Reported: 18/11/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 83Y
Onset Date: 25/10/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------|--------------------------|
| Orthostatic hypotension | | | Ceased depran and endep. |

Medicine Details:

| | |
|-----------------------------|--|
| COLOXYL (Other drug) | Reason: Constipation |
| 50.0 Milligram | As necessary |
| Batch: | Started: L TERM Stopped: |
| CAPADEX (Other drug) | Reason: Pain |
| 0.0 | As necessary |
| Batch: | Started: Stopped: |
| QUINSUL (Other drug) | Reason: Pain in limb |
| 300.0 Milligram | Daily |
| Batch: | Started: L TERM Stopped: |
| ASPIRIN (Other drug) | Reason: Chron isch heart dis no hyper |
| 100.0 Milligram | Daily |
| Batch: | Started: L TERM Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 133235 **Seq:** 1 **Gender:** M
Reported: 18/11/1998 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 83Y
Onset Date: 25/10/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

| | |
|-----------------------------|---------------------------------|
| AMFAMOX (Other drug) | Reason: |
| 80.0 Milligram Daily | |
| Batch: | Started: Stopped: |
| ENDEP (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: Stopped: |
| DEPTRAN (Suspected) | Reason: |
| 50.0 Milligram Daily | |
| Batch: | Started: Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 134457 | Seq: 1 | Gender: F |
| Reported: 21/12/1998 | | Weight: |
| Hospitalisation: | | Age: 85Y |
| Onset Date: 12/12/1998 | | DOB: |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|---|-----------------------|
| Somnolence | | Drowsy but communicating. | Doxepin discontinued. |
| Hemiparesis | | Left sided weakness, difficulty in walking. | |

Medicine Details:

| | | |
|--|----------------------------|----------------------------|
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: Depression |
| Capsule | 50.0 Milligram | Total Oral |
| Batch: | Started: 11/12/1998 | Stopped: 13/12/1998 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 135756 **Seq:** 1 **Gender:** F
Reported: 02/02/1999 **Weight:**
Hospitalisation: **Age:** 77
Onset Date: **DOB:** 02/03/1921
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------------|
| Hyponatraemia | | | Deptran ceased. |

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 136984 **Seq:** 1 **Gender:** M
Reported: 08/03/1999 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|----------------------|-----------------------|
| Erectile dysfunction | | Erectile dysfunction | Sinequan discontinued |

Medicine Details:

| | |
|-----------------------------|-------------------------------------|
| SINEQUAN (Suspected) | Reason: Depression |
| Capsule | 50.0 Milligram Daily Oral |
| 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 137056 | Seq: 1 | Gender: M |
| Reported: 08/03/1999 | | Weight: |
| Hospitalisation: | | Age: 74Y |
| Onset Date: 31/12/1996 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|---|------------------------|
| Libido decreased | | Loss of libido about 3 years ago. | Sinequan discontinued. |
| Gynaecomastia | | Pat. developed enlarged breasts about 3 | |

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Depression |
| 200.0 Milligram | Daily |
| Batch: | Started: 01/01/1980 Stopped: 31/01/1996 |

Laboratory Investigations:

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

Additional Information:

The patient still has these problems since stopping sinequan 3 years ago. - the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 137286 | Seq: 1 | Gender: F |
| Reported: 12/03/1999 | | Weight: |
| Hospitalisation: | | Age: |
| Onset Date: 08/03/1999 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-------------------|
| Depression | | Depressed | Deptran (doxepin) |

Medicine Details:

| | | |
|------------------------------------|----------------------------|---------------------------|
| NICORETTE PATCH (Suspected) | | Reason: Smoker |
| Cream | 15.0 Milligram | Daily Transdermal |
| Batch: | Started: 08/03/1999 | Stopped: CONTIN |
| DEPTRAN (Suspected) | | Reason: Depression |
| Tablet | 0.0 | Daily Oral |
| Batch: | Started: | Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:

History of chronic depression



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 138414 | Seq: 1 | Gender: F |
| Reported: 14/04/1999 | | Weight: 70.00 |
| Hospitalisation: | | Age: 76Y |
| Onset Date: 31/03/1999 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|----------------------|---------------------------|
| Pruritus Rash | | Itchy skin eruption. | Ceased lipex,sinequan and |

Medicine Details:

| | |
|--|---|
| LASIX (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: Stopped: |
| LIPEX (Suspected) | Reason: Othr&unspec metabolic diseases |
| Tablet 20.0 Milligram Daily Oral | |
| Batch: | Started: 01/01/1993 Stopped: 28/03/1999 |
| SINEQUAN (Suspected) | Reason: |
| Capsule 25.0 Milligram Daily Oral | |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:

Recommended sinequan and lasix. see original report for details of other drugs. - warfarin, isoptin sr, zantac and prinivil. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 140446 **Seq:** 1 **Gender:** F
Reported: 15/06/1999 **Weight:** 79.00
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|----------------|
| Cough | | Dry cough | Deptran ceased |

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Dry cough with deptran but stops when drug ceased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 140717 **Seq:** 1 **Gender:** M
Reported: 21/06/1999 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: 20/02/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|----------|-------------------------------|-----------------|
| Photosensitivity reaction | | Reddened area on exposed arm. | Deptran ceased. |

Medicine Details:

| | |
|----------------------------|---|
| DEPTRAN (Suspected) | Reason: Depression |
| 50.0 Milligram | Daily |
| Batch: | Started: 17/12/1998 Stopped: 24/02/1999 |

Laboratory Investigations:

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

Additional Information:

See original report for other drug details - ms contin, antenex, pulmicort nebules, ventolin nebules & ceclor susp.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 141892 **Seq:** 1 **Gender:** F
Reported: 23/07/1999 **Weight:** 94.00
Hospitalisation: **Age:** 51Y
Onset Date: 11/06/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|------------------------------|----------------------|
| SINGULAIR (Suspected) | Reason: |
| Batch: | 0.0 |
| Started: | Stopped: |
| SINEQUAN (Suspected) | Reason: |
| Batch: | 10.0 Milligram Daily |
| Started: 11/06/1999 | Stopped: |

Laboratory Investigations:

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

Additional Information:

See original report for other drugs: atrovent, ventolin, flixotide, largactil, lasix, oxis prednisone, prepulsid and other drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|--|---------------|--------------------------------------|
| Case Number: 142040 | Seq: 1 | Gender: F |
| Reported: 29/07/1999 | | Weight: |
| Hospitalisation: Admitted to hospital | | Age: 89Y |
| Onset Date: 07/12/1998 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|---------------------------------------|--|
| Confusional state | | Deterioration for 2 weeks - increased | High salt diet and fluids, iv normal saline and kcl. paroxetine ceased and other medications |
| Vomiting | | Poor oral intake / vomiting | |
| Hypokalaemia | | | |
| Hyponatraemia | | | |

Medicine Details:

| | |
|---|----------------------------|
| MODURETIC (Suspected) | Reason: |
| 1.0 Dose Unspecified Daily | |
| Batch: | Started: |
| | Stopped: 23/12/1998 |
| PAROXETINE HYDROCHLORIDE (Suspected) | Reason: Depression |
| 20.0 Milligram Daily | |
| Batch: | Started: |
| | Stopped: 23/12/1998 |
| SINEQUAN (Suspected) | Reason: |
| Capsule 10.0 Milligram Daily Oral | |
| Batch: | Started: |
| | Stopped: 23/12/1998 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|-----------|-------|-------------|--------|---------|
| | Potassium | | 23/12/1998 | 2.5 | |
| | Sodium | | 23/12/1998 | 108 | |

Additional Information:

See original report for details of other drugs - prednisone, senokot.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 143867 | Seq: 1 | Gender: M |
| Reported: 20/09/1999 | | Weight: |
| Hospitalisation: | | Age: 70Y |
| Onset Date: 31/12/1999 | | DOB: |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-------------------------|
| Tinnitus | | | No action taken as yet. |

Medicine Details:

| | | | |
|-----------------------------|----------------------------|-----------------|------|
| SINEQUAN (Suspected) | | Reason: | |
| Capsule | 25.0 Milligram | Daily | Oral |
| Batch: | Started: 01/01/1989 | Stopped: | |

Laboratory Investigations:

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

Additional Information:

The patient reported that he suffers from ringing in his ears which seems to improve slightly if he stops taking sinequan for a few days. the reporting pharmacist commented that the patient has a general background of hearing problems but could not be more specific. the patient is not taking any other medication. - the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 145985 **Seq:** 1 **Gender:** M
Reported: 16/11/1999 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: 17/09/1999 **DOB:** 09/06/1963
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------------------------|----------|--------------------|-----------|
| Fatigue Hyperhidrosis Tremor | | | |

Medicine Details:

| | |
|----------------------------|---|
| DEPTRAN (Suspected) | Reason: Pain |
| 10.0 Milligram | Daily |
| Batch: | Started: 17/09/1999 Stopped: 18/09/1999 |

Laboratory Investigations:

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

Additional Information:

See original report for details of other drug - paracetamol/codeine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 146080 **Seq:** 1 **Gender:** M
Reported: 03/11/1999 **Weight:**
Hospitalisation: **Age:** 71Y
Onset Date: **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------------------|
| Flushing | | Flushing feeling | Cessation of deptran. |
| Dizziness | | Lightheadedness | |
| Tremor | | | |

Medicine Details:

| | | |
|---|----------------------------|----------------------------|
| DEPTRAN (Interaction) | | Reason: Vertigo |
| Oral application | 50.0 Milligram | As necessary Oral |
| Batch: | Started: 01/08/1999 | Stopped: 28/09/1999 |
| HYPERICUM-ST JOHN'S WORT (Interaction) | | Reason: Nervousness |
| Oral application | 2.0 Gram | Daily Oral |
| Batch: | Started: 01/09/1999 | Stopped: 28/09/1999 |

Laboratory Investigations:

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

Additional Information:

Sequelae: underlying depression remains untreated. see original report for details of other drugs - digoxin, celery tonic, glutamine, ginkgo biloba. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 147088 | Seq: 1 | Gender: F |
| Reported: 15/12/1999 | | Weight: 66.00 |
| Hospitalisation: | | Age: 74 |
| Onset Date: 01/10/1999 | | DOB: 29/01/1925 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--|------------------------------|
| Gait disturbance | | Legs felt stiff, very short steps on walking | |
| Hypertonia | | | Sinequan reduced to 1 nocte. |

Medicine Details:

| | |
|-------------------------------|---|
| VALPRO (Interaction) | Reason: Other&unspecified epilepsy |
| 800.0 Milligram | Daily |
| Batch: | Started: 01/07/1999 Stopped: |
| SINEQUAN (Interaction) | Reason: |
| 50.0 Milligram | Daily |
| Batch: | Started: 01/01/1995 Stopped: 01/11/1999 |

Laboratory Investigations:

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

Additional Information:

Pt also taking aurorix, naproxen, minidiab, jazil, premarin, serepax. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 148364 **Seq:** 1 **Gender:** F
Reported: 27/01/2000 **Weight:**
Hospitalisation: **Age:** 33Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--------------------|------------------------------|
| Drug ineffective | | | Plans to discontinue doxepin |

Medicine Details:

| | |
|--|---|
| ZOLOFT (Interaction) | Reason: Depression |
| 50.0 Milligram Daily | |
| Batch: | Started: Stopped: |
| DOXEPIN HYDROCHLORIDE (Interaction) | Reason: Otr&unsp vertebrogen pain synd |
| 10.0 Milligram Daily | |
| 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: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 152426 **Seq:** 1 **Gender:** F
Reported: 05/05/2000 **Weight:**
Hospitalisation: **Age:** 87Y
Onset Date: 24/02/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|--|
| Agitation Confusional state Nightmare | | | Therapy with sinequan and inderal ceased, add risperdal. |

Medicine Details:

| | |
|-----------------------------|--|
| INDERAL (Other drug) | Reason: Essential benign hypertension |
| 80.0 Milligram Daily | |
| Batch: | Started: Stopped: |
| SINEQUAN (Suspected) | Reason: |
| 25.0 Milligram Daily | |
| Batch: | Started: 24/02/2000 Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient also taking monopril, iscover, triprim.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 152621 **Seq:** 1 **Gender:** F
Reported: 15/05/2000 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------|
| Hyponatraemia | | | Sinequan ceased. |

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:

Patient actually felt better while on sinequan.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 152692 **Seq:** 1 **Gender:** F
Reported: 16/05/2000 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|------------------|
| Hepatic function abnormal Hyperuricaemia Hyponatraemia Malaise | | | Sinequan ceased. |

Medicine Details:

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

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPI
HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 157333 | Seq: 1 | Gender: F |
| Reported: 04/09/2000 | | Weight: |
| Hospitalisation: | | Age: 73 |
| Onset Date: 25/08/2000 | | DOB: 03/01/1927 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|---|
| Anaemia Confusional state Hepatic function abnormal Pyrexia Red blood cell sedimentation rate | | | Patient admitted to hospital, all therapy ceased. |

Medicine Details:

| | | |
|---|-----------------|----------------------------|
| SINEMET (Other drug) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: CONTIN |
| RIVOTRIL (Other drug) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: |
| ARICEPT (Suspected) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: 25/08/2000 |
| SELEGILINE HYDROCHLORIDE (Suspected) | Reason: | |
| 0.0 | | |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|---------|-------------|--------|---------|
| | ALT = SGPT | 5 - 55 | 28/08/2000 | 38 | |
| | ALT = SGPT | 5 - 55 | 30/08/2000 | 56 | |
| | Albumin | 33 - 50 | 28/08/2000 | 30 | |
| | Albumin | 33 - 50 | 30/08/2000 | 34 | |
| | Bilirubin | 2 - 20 | 28/08/2000 | 11 | |
| | Bilirubin | 2 - 20 | 30/08/2000 | 9 | |
| | GGT = SGGT = | 12 - 43 | 28/08/2000 | 378 | |

Additional Information:

Patient also taking doxepin, levodopa, benzodiazepine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 157333 **Seq:** 1 **Gender:** F
Reported: 04/09/2000 **Weight:**
Hospitalisation: **Age:** 73
Onset Date: 25/08/2000 **DOB:** 03/01/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

| | |
|--|---------------------------------|
| CABASER (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: Stopped: |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: Stopped: |
| LEVODOPA (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: Stopped: |
| PROTHIADEN (Suspected) | Reason: |
| 0.0 | |
| Batch: | Started: Stopped: |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------------|----------|-------------|--------|---------|
| | GGT = SGGT = | 12 - 43 | 30/08/2000 | 359 | |
| | SAP = ALP | 20 - 110 | 28/08/2000 | 285 | |
| | SAP = ALP | 20 - 110 | 30/08/2000 | 265 | |

Additional Information:

Patient also taking doxepin, levodopa, benzodiazepine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 157333

Seq: 1

Gender: F

Reported: 04/09/2000

Weight:

Hospitalisation:

Age: 73

Onset Date: 25/08/2000

DOB: 03/01/1927

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|---------------------------|----------------------------------|----------------------------|------|
| COMTAN (Suspected) | Reason: Paralysis agitans | | |
| Tablet | 200.0 Milligram | Daily | Oral |
| Batch: | Started: 17/07/2000 | Stopped: 25/08/2000 | |

Laboratory Investigations:

Additional Information:

Patient also taking doxepin, levodopa, benzodiazepine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 160686 **Seq:** 1 **Gender:** F
Reported: 09/01/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: 30/07/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|-----------------------------|-------------------------------------|
| SINEQUAN (Suspected) | Reason: |
| Capsule | 25.0 Milligram Daily Oral |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient increased dose of sinequin from 25mg to 50mg daily, then experienced symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 160811 **Seq:** 1 **Gender:** M
Reported: 19/01/2001 **Weight:** 60.00
Hospitalisation: Admitted to hospital **Age:** 66Y
Onset Date: 17/01/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------------------|----------|--------------------|-------------------------------|
| Hypotension Face oedema | | Bp 90/50 | Patient hospitalised. deptran |

Medicine Details:

| | |
|--|---------------------------------|
| ZYBAN SR (Interaction) Tablet 300.0 Milligram Daily Oral Batch: Started: Stopped: | Reason: |
| DEPTRAN (Interaction) 30.0 Milligram Daily Batch: Started: Stopped: 17/01/2001 | Reason: Anxiety neurosis |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 160960 **Seq:** 1 **Gender:** F
Reported: 29/01/2001 **Weight:** 76.00
Hospitalisation: **Age:** 46Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | |
|----------------------------|--|
| DEPTRAN (Suspected) | Reason: Depression |
| 20.0 Milligram Daily | |
| Batch: | Started: 06/12/2000 Stopped: |
| TOPAMAX (Suspected) | Reason: |
| 50.0 Milligram Daily | |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient also taking mersyndol and iv vitamin c. patient has cfs with low levels of t4 helper cells, t8 suppressor cells and mature t3 lymphocytes.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 163781 | Seq: 1 | Gender: F |
| Reported: 18/04/2001 | | Weight: |
| Hospitalisation: | | Age: 49 |
| Onset Date: 04/03/2001 | | DOB: 02/07/1951 |
| Outcome: Recovered | | Causality: Causality probable |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|-------------------|
| Confusional state Convulsion Delirium | | | Bupropion ceased. |

Medicine Details:

| | |
|---|---|
| ZYBAN SR (Interaction) | Reason: Smoker |
| Tablet | 150.0 Milligram Daily Oral |
| Batch: | Started: 28/02/2001 Stopped: 23/03/2001 |
| FLUOXETINE HYDROCHLORIDE (Interaction) | Reason: Depression |
| | 20.0 Milligram Daily |
| Batch: | Started: L TERM Stopped: |
| DOXEPIN HYDROCHLORIDE (Interaction) | Reason: Anxiety neurosis |
| Oral application | 100.0 Milligram Daily Oral |
| Batch: | Started: Stopped: |
| ORUDIS SR (Other drug) | Reason: Unspecified arthritis |
| Oral application | 1.0 Dose Unspecified Daily Oral |
| Batch: | Started: Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 163781 **Seq:** 1 **Gender:** F
Reported: 18/04/2001 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: 04/03/2001 **DOB:** 02/07/1951
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

| | |
|-----------------------------------|--|
| SULFASALAZINE (Other drug) | Reason: Regional enteritis |
| 1.5 Gram | Daily |
| Batch: | Started: L TERM Stopped: |
| PANTOPRAZOLE (Other drug) | Reason: Other diseases of esophagus |
| Oral application | 80.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 165066 | Seq: 1 | Gender: F |
| Reported: 01/06/2001 | | Weight: |
| Hospitalisation: | | Age: 25Y |
| Onset Date: 30/03/2001 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-----------------|----------|--------------------|---|
| Cervix disorder | | Cervical erosion | Pt booked in for day surgery to have cervical lesion excised. |

Medicine Details:

| | | | |
|------------------------------|----------------------------|------------------------------|--------|
| NORIMIN-1 (Suspected) | | Reason: Contraception | |
| Tablet | 1.0 Dose Unspecified | Daily | Oral |
| Batch: | Started: 01/09/2000 | Stopped: | CONTIN |
| DEPTRAN (Suspected) | | Reason: | |
| Tablet | 25.0 Milligram | Daily | Oral |
| Batch: | Started: 30/03/2001 | Stopped: | CONTIN |

Laboratory Investigations:

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

Additional Information:

The dose start date is not necessarily accurate but indicates normin-1 was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 166631 **Seq:** 1 **Gender:** F
Reported: 19/07/2001 **Weight:** 50.00
Hospitalisation: **Age:** 88Y
Onset Date: 03/04/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------------------|-----------|
| Alopecia | | Scalp, eyelashes and eyebrows. | |

Medicine Details:

| | |
|-----------------------------|--|
| SINEQUAN (Suspected) | Reason: |
| Capsule | 25.0 Milligram Daily Oral |
| Batch: | Started: 01/03/2001 Stopped: |

Laboratory Investigations:

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

Additional Information:

Patient is allergic to - aldomet, bactrim and tetoxoid.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 167394 **Seq:** 1 **Gender:** M
Reported: 10/08/2001 **Weight:**
Hospitalisation: **Age:** 44
Onset Date: 15/05/2001 **DOB:** 31/12/1956
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|---|---------------|
| Tinnitus | | Felt noises in head as if electric discharge. | Zyban ceased. |
| Muscle twitching | | | |

Medicine Details:

| | |
|-------------------------------------|---|
| ZYBAN SR (Interaction) | Reason: Smoker |
| 0.0 | |
| Batch: | Started: 09/05/2001 Stopped: 18/05/2001 |
| DEPTRAN (Interaction) | Reason: Depression |
| 150.0 Milligram Daily | |
| Batch: | Started: L TERM Stopped: CONTIN |
| PANADEINE FORTE (Other drug) | Reason: Pain |
| 8.0 Dose Unspecified Daily | |
| Batch: | Started: L TERM Stopped: CONTIN |
| DIAZEPAM (Other drug) | Reason: Anxiety neurosis |
| 10.0 Milligram Daily | |
| Batch: | Started: L TERM Stopped: CONTIN |

Laboratory Investigations:

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

Additional Information:

Deptran reduced to 1x50mg prior to zyban sr commencement. the date of onset is not necessarily accurate but indicates onset sometime in the middle of the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 167818 **Seq:** 1 **Gender:** M
Reported: 23/08/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Agitation | | | |
| Somnolence | | | |

Medicine Details:

| | | | |
|-----------------------------|----------------------------|-----------------|--------|
| SINEQUAN (Suspected) | Reason: Depression | | |
| Tablet | 25.0 Milligram | Daily | Oral |
| Batch: | Started: 18/08/2001 | Stopped: | CONTIN |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 175229 | Seq: 1 | Gender: M |
| Reported: 07/05/2002 | | Weight: |
| Hospitalisation: | | Age: 87Y |
| Onset Date: 20/03/2002 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------------|---|
| Gait disturbance Hyponatraemia Vertigo | | Gait disorder and falls. | Doxepin, diclofenac and tramadol ceased. changed pain relief to ms contin 5mg bd. reduced diamicon dose to 40ma hd. |

Medicine Details:

| | | | |
|--|-----------------|-----------------|--------|
| SENEGA AND AMMONIA (Other drug) | | Reason: | |
| Oral Liquid | 30.0 Millilitre | Daily | Oral |
| Batch: | Started: | Stopped: | |
| PARACETAMOL (Other drug) | | Reason: | |
| Tablet | 6.0 Gram | Daily | Oral |
| Batch: | Started: | Stopped: | CONTIN |
| ASPIRIN (Other drug) | | Reason: | |
| Tablet | 150.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | CONTIN |
| PERINDOPRIL (Other drug) | | Reason: | |
| Tablet | 4.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | CONTIN |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------|--------|-------|-------------|--------|------------------------|
| | Sodium | | 20/03/2002 | 124 | On admission na - 124. |
| | Sodium | | 31/03/2002 | 135 | On admission na - 124. |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 175229 Seq: 1

Gender: M

Reported: 07/05/2002

Weight:

Hospitalisation:

Age: 87Y

Onset Date: 20/03/2002

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|---|----------------|
| GLICLAZIDE (Other drug) | Reason: |
| Tablet 160.0 Milligram Daily Oral | |
| Batch: Started: Stopped: CONTIN | |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| Capsule 10.0 Milligram Daily Oral | |
| Batch: Started: Stopped: | |
| DICLOFENAC SODIUM (Suspected) | Reason: |
| Tablet 50.0 Milligram Daily Oral | |
| Batch: Started: 16/03/2002 Stopped: | |
| TRAMADOL HYDROCHLORIDE (Suspected) | Reason: |
| Tablet 200.0 Milligram Daily Oral | |
| Batch: Started: 22/02/2002 Stopped: | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 176296 **Seq:** 1 **Gender:** F
Reported: 14/06/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|---------------------------|
| Hyponatraemia | | | Patient was hospitalised. |

Medicine Details:

| | |
|-----------------------------|-------------------------------------|
| SINEQUAN (Suspected) | Reason: Depression |
| Batch: | Started: 0.0 Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 177744 | Seq: 1 | Gender: M |
| Reported: 01/08/2002 | | Weight: 80.00 |
| Hospitalisation: | | Age: 66 |
| Onset Date: 28/07/2002 | | DOB: 12/08/1935 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--|
| Headache | | Headache at night. | Reduced doxepin to 125mg at night. date of recovery: 29/7/02 |
| Dizziness | | | |

Medicine Details:

| | |
|--|----------------|
| BACLOFEN (Other drug) 50.0 Milligram Daily Batch: Started: Stopped: | Reason: |
| ASPIRIN (Other drug) 150.0 Milligram Daily Batch: Started: Stopped: | Reason: |
| LIPITOR (Other drug) 40.0 Milligram Daily Batch: Started: Stopped: | Reason: |
| NICORANDIL (Other drug) 10.0 Milligram Daily Batch: Started: 24/07/2002 Stopped: | Reason: |

Laboratory Investigations:

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

Additional Information:

Headaches at night after doxepin increased to 150mg from 125mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 177744

Seq: 1

Gender: M

Reported: 01/08/2002

Weight: 80.00

Hospitalisation:

Age: 66

Onset Date: 28/07/2002

DOB: 12/08/1935

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

DEPTRAN (Suspected)

Reason: Depression

25.0 Milligram

Daily

Batch:

Started: 23/07/2002

Stopped:

Laboratory Investigations:

Additional Information:

Headaches at night after doxepin increased to 150mg from 125mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 178560 | Seq: 1 | Gender: F |
| Reported: 30/08/2002 | | Weight: 62.00 |
| Hospitalisation: | | Age: 44 |
| Onset Date: 14/03/2002 | | DOB: 30/01/1958 |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|------------------------|-----------------|
| Gravitational oedema | | Fluid retention ankle. | |
| Weight increased | | Weight gain 8kg. | Ceased deptran. |
| Dysphagia | | | |

Medicine Details:

| | |
|-----------------------------|---|
| EPILIM (Other drug) | Reason: Depression |
| Oral application | 400.0 Milligram Daily Oral |
| Batch: | Started: L TERM Stopped: |
| OROXINE (Other drug) | Reason: Myxedema |
| Oral application | 100.0 Microgram Daily Oral |
| Batch: | Started: L TERM Stopped: |
| DEPTRAN (Suspected) | Reason: Depression |
| Capsule | 25.0 Milligram Daily Oral |
| Batch: | Started: 01/03/2002 Stopped: 01/08/2002 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 178854 | Seq: 1 | Gender: F |
| Reported: 11/09/2002 | | Weight: |
| Hospitalisation: | | Age: 84Y |
| Onset Date: 29/07/2002 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------|--|
| Orthostatic hypotension | | | Ceased doxepin, methyldopa, and verapamil. |

Medicine Details:

| | | | |
|-------------------------------------|-----------------|-----------------|--------|
| WARFARIN SODIUM (Other drug) | | Reason: | |
| Tablet | 0.0 | | Oral |
| Batch: | Started: | Stopped: | CONTIN |
| PREDNISONE (Other drug) | | Reason: | |
| Tablet | 15.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | CONTIN |
| POTASSIUM NOS (Other drug) | | Reason: | |
| Tablet | 1.2 Gram | Daily | Oral |
| Batch: | Started: | Stopped: | CONTIN |
| FRUSEMIDE (Other drug) | | Reason: | |
| Tablet | 40.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | CONTIN |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 178854 **Seq:** 1 **Gender:** F
Reported: 11/09/2002 **Weight:**
Hospitalisation: **Age:** 84Y
Onset Date: 29/07/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

| | |
|--|---|
| VERAPAMIL HYDROCHLORIDE (Suspected) | Reason: Otr&nos disord of heart rhythm |
| Tablet 120.0 Milligram Daily Oral | |
| Batch: Started: Stopped: 29/07/2002 | |
| METHYLDOPA (Suspected) | Reason: Essential benign hypertension |
| Tablet 375.0 Milligram Daily Oral | |
| Batch: Started: Stopped: 29/07/2002 | |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| Tablet 50.0 Milligram Daily Oral | |
| Batch: Started: Stopped: 29/07/2002 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|---------------------------------------|--------|-------------------------------|
| Case Number: 178902 | Seq: 1 | Gender: M |
| Reported: 07/08/2002 | | Weight: 0.00 |
| Hospitalisation: Admitted to hospital | | Age: 24 |
| Onset Date: | | DOB: 23/09/1977 |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------------|----------|--|---|
| Therapeutic response decreased | Life | Lack of efficacy, heart palpitations, hearing voices, collapsed, serotonin syndrome, paranoia, psychosis and schizophrenia | All medications were stopped after the "arrest" and he was started on pethidine, oxycontin, baclofen and valium. He was in the regular part of the hospital for approximately 12 days and then was committed to the mental health unit. |
| Hallucination | Life | | |
| Palpitations | Life | | |
| Paranoia | Life | | |

Medicine Details:

| | | | |
|---------------------|----------|--------------------|--|
| ZOLOFT (Suspected) | | Reason: Depression | |
| 25.0 Milligram | Daily | Oral | |
| Batch: | Started: | Stopped: | |
| <hr/> | | | |
| DEPTRAN (Suspected) | | Reason: | |
| 75.0 Milligram | Daily | Oral | |
| Batch: | Started: | Stopped: | |
| <hr/> | | | |
| ZOLOFT (Suspected) | | Reason: | |
| 400.0 Milligram | Daily | | |
| Batch: | Started: | Stopped: | |

Laboratory Investigations:

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

Additional Information:

The patient was on Zoloft 400mg daily dose for approximately three to four weeks when he began to hear voices. Once admitted, the hospital continued Zoloft but decreased the dose to 200mg daily for approximately the next three to four days.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 178902 **Seq:** 1 **Gender:** M
Reported: 07/08/2002 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 24
Onset Date: **DOB:** 23/09/1977
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|----------|--------------------|-----------|
| Psychotic disorder | Life | | |
| Schizophreniform disorder | Life | | |
| Serotonin syndrome | Life | | |
| Syncope | Life | | |

Medicine Details:

| | | |
|----------------------------|---------------------------|-----------------|
| ZOLOFT (Suspected) | Reason: Depression | |
| 25.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: |
| DEPTRAN (Suspected) | Reason: | |
| 75.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: |
| ZOLOFT (Suspected) | Reason: | |
| 400.0 Milligram | Daily | |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

Additional Information:

The patient was on Zoloft 400mg daily dose for approximately three to four weeks when he began to hear voices. Once admitted, the hospital continued Zoloft but decreased the dose to 200mg daily for approximately the next three to four days.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 179177 | Seq: 1 | Gender: F |
| Reported: 20/09/2002 | | Weight: |
| Hospitalisation: | | Age: 77Y |
| Onset Date: 02/08/2002 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------|-----------|
| Orthostatic hypotension | | | |

Medicine Details:

| | | |
|---|----------------------|--|
| ASPIRIN (Other drug) | | Reason: Other coagulation defects |
| Tablet | 150.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: 09/08/2002 |
| MEDROXYPROGESTERONE ACETATE (Other drug) | | Reason: Menopausal symptoms |
| Tablet | 10.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: 06/08/2002 |
| OESTROGENS CONJUGATED (Other drug) | | Reason: Menopausal symptoms |
| Tablet | 0.3 Milligram | Daily Oral |
| Batch: | Started: | Stopped: 06/08/2002 |
| AMIZIDE (Suspected) | | Reason: Essential benign hypertension |
| Tablet | 3.0 Dose Unspecified | Weekly Oral |
| Batch: | Started: | Stopped: 02/08/2002 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 179177 **Seq:** 1

Gender: F

Reported: 20/09/2002

Weight:

Hospitalisation:

Age: 77Y

Onset Date: 02/08/2002

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | | |
|--|----------------------|-----------------|-------------------------------|--|
| PROPRANOLOL HYDROCHLORIDE (Suspected) | | Reason: | Essential benign hypertension | |
| Tablet | 10.0 Milligram | Daily | Oral | |
| Batch: | Started: | Stopped: | 08/08/2002 | |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | Depression | |
| Oral application | 2.0 Dose Unspecified | Daily | Oral | |
| Batch: | Started: | Stopped: | 02/08/2002 | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 180648 | Seq: 1 | Gender: M |
| Reported: 15/11/2002 | | Weight: |
| Hospitalisation: | | Age: A5 |
| Onset Date: 28/08/2002 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------|--------------------|--|
| Coma | | | Patient was given iv valium. sinequin and valium were ceased, valium was recommenced |
| Drug withdrawal syndrome | | | |
| Grand mal convulsion | | | |

Medicine Details:

| | |
|-----------------------------|-----------------------------|
| SINEQUAN (Suspected) | Reason: Depression |
| 0.0 | |
| Batch: | Started: |
| | Stopped: |
| VALIUM (Suspected) | Reason: Pain in limb |
| 0.0 | |
| Batch: | Started: |
| | Stopped: |

Laboratory Investigations:

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

Additional Information:

The onset date is not necessarily accurate but indicates onset sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|--|---------------|--------------------------------------|
| Case Number: 181203 | Seq: 1 | Gender: F |
| Reported: 08/01/2003 | | Weight: 0.00 |
| Hospitalisation: Admitted to hospital | | Age: 78 |
| Onset Date: 20/11/2002 | | DOB: 21/10/1924 |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|--|------------------------------|
| Mucosal inflammation | Life | Mucositis causing respiratory failure. | Treated with iv Folinic Acid |
| Melaena | Life | | |
| Pancytopenia | Life | | |
| Pleural effusion | Life | | |
| Respiratory failure | Life | | |

Medicine Details:

| | | | |
|---------------------------------|-----------------|---|----------------------------|
| METHOTREXATE (Suspected) | | Reason: Other rheumatoid arthritis | |
| Tablet | 25.0 Milligram | Weekly | Oral |
| Batch: | Started: | L TERM | Stopped: 18/11/2002 |
| LASIX (Suspected) | | Reason: Edema and dropsy | |
| | 80.0 Milligram | Daily | |
| Batch: | Started: | | Stopped: 20/11/2002 |
| SLOW-K (Suspected) | | Reason: | |
| Tablet | 600.0 Milligram | Daily | Oral |
| Batch: | Started: | | Stopped: 20/11/2002 |
| ZANTAC (Suspected) | | Reason: | |
| Tablet | 300.0 Milligram | Daily | Oral |
| Batch: | Started: | | Stopped: 20/11/2002 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 181203 **Seq:** 1 **Gender:** F
Reported: 08/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 78
Onset Date: 20/11/2002 **DOB:** 21/10/1924
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

| | |
|--|--|
| ASPIRIN (Suspected) | Reason: |
| Oral application 100.0 Milligram Daily Oral | |
| Batch: | Started: Stopped: 21/11/2002 |
| DEPTRAN (Suspected) | Reason: Depression |
| Oral application 25.0 Milligram Daily Oral | |
| Batch: | Started: Stopped: 21/11/2002 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|--|---------------|--------------------------------------|
| Case Number: 187618 | Seq: 1 | Gender: M |
| Reported: 23/06/2003 | | Weight: 0.00 |
| Hospitalisation: Admitted to hospital | | Age: 77Y |
| Onset Date: 24/02/2003 | | DOB: |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|---|--|--|
| Hypokalaemia | Caused or prolonged inpatient hospitalisation | Hypokalaemia, renal function abnormal, hypotension postural. | ceased natrilix 1.5mg SR and decreased dose of Doxepin from 150mg to 75mg nocte. |
| Orthostatic hypotension | Caused or prolonged inpatient hospitalisation | | |
| Renal impairment | Caused or prolonged inpatient hospitalisation | | |

Medicine Details:

| | | |
|--|----------------------|--|
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: Depression |
| Capsule | 150.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: |
| FELODIPINE (Suspected) | | Reason: Depression |
| Tablet | 10.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: Contin |
| KARVEZIDE 300/12.5 (Suspected) | | Reason: Essential benign hypertension |
| Tablet | 1.0 Dose Unspecified | Daily Oral |
| Batch: | Started: | Stopped: contin |
| NATRILIX SR (Suspected) | | Reason: Essential benign hypertension |
| Tablet | 1.5 Milligram | Daily Oral |
| Batch: | Started: | Stopped: 28/02/2003 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------------|------------|-------|-------------|--------|---------|
| 23/06/2003 | Creatinine | | 24/02/2003 | 0.25 | |
| 23/06/2003 | Potassium | | 24/02/2003 | 3.2 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 188416 | Seq: 1 | Gender: F |
| Reported: 11/07/2003 | | Weight: 0.00 |
| Hospitalisation: | | Age: 75Y |
| Onset Date: 13/05/2003 | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|---------------------------------|--|
| Hyponatraemia | | Hyponatremia and hyperurecaemia | Ceased Amizide, doxepin, ibuprofen, aspirin. Commenced multivitamin and triple therapy for H.pylori/ |
| Gastric ulcer | | | |
| Hyperuricaemia | | | |

Medicine Details:

| | | | | | |
|--|-----------------|------------------|-----------------|----------------|--|
| IBUPROFEN (Interaction) | | | | Reason: | |
| Tablet | 400.0 | Milligram | As necessary | Oral | |
| Batch: | Started: | 26/05/2002 | Stopped: | 13/05/2003 | |
| DOXEPIN HYDROCHLORIDE (Interaction) | | | | Reason: | |
| Capsule | 25.0 | Milligram | Daily | Oral | |
| Batch: | Started: | 16/11/2002 | Stopped: | 13/05/2003 | |
| AMIZIDE (Interaction) | | | | Reason: | |
| Tablet | 1.0 | Dose Unspecified | Daily | Oral | |
| Batch: | Started: | 16/10/2001 | Stopped: | 13/05/2003 | |
| ASPIRIN (Interaction) | | | | Reason: | |
| Tablet | 150.0 | Milligram | Daily | Oral | |
| Batch: | Started: | 16/10/2001 | Stopped: | 15/05/2003 | |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------------|------------|-------|-------------|--------|---------|
| 11/07/2003 | Other data | | | | |

Additional Information:

Patient was also taking paracetamol, Timolol, Metoclopramide, Diazepam, Thiamine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 194681 | Seq: 1 | Gender: F |
| Reported: 16/02/2004 | | Weight: 62.00 |
| Hospitalisation: | | Age: 66Y |
| Onset Date: | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------|--------------------------|---|-----------|
| Convulsion | Required Visit to Doctor | Seizures, agitation, flushing, confusion, sensory disturbances of feet, ataxia. | |
| Agitation | Required Visit to Doctor | | |
| Confusional state | Required Visit to Doctor | | |
| Coordination abnormal | Required Visit to Doctor | | |
| Flushing | Required Visit to Doctor | | |
| Sensory disturbance | Required Visit to Doctor | | |

Medicine Details:

| | | |
|-----------------------------|-----------------|---------------------------------|
| AVANZA (Suspected) | | Reason: Anxiety neurosis |
| Tablet | 60.0 Milligram | Daily |
| Batch: | Started: | Stopped: |
| TRAMAL (Suspected) | | Reason: |
| Tablet | 600.0 Milligram | Daily |
| Batch: | Started: | Stopped: |
| SINEQUAN (Suspected) | | Reason: |
| | 75.0 Milligram | Daily |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPI
HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 201905 | Seq: 1 | Gender: F |
| Reported: 21/10/2004 | | Weight: 68.00 |
| Hospitalisation: | | Age: 38 |
| Onset Date: | | DOB: 07/04/1966 |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|---|-----------|
| Headache Constipation Feeling hot Muscle spasms Nasopharyngitis Nausea Paraesthesia Tinnitus | | As dosage increased the patient complained of strange sensation in the left arm and wrist, headaches, nausea, shakes tinnitus, tingling in feet, spasms, 'hot and cold', anxiety, bags under the eyes and constipation. | |

Medicine Details:

| | | |
|---|----------------------------|---------------------------|
| DOXEPI HYDROCHLORIDE (Suspected) | | Reason: Depression |
| Capsule | 25.0 Milligram | Daily Oral |
| Batch: | Started: 24/09/2004 | Stopped: |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 201905 **Seq:** 1 **Gender:** F
Reported: 21/10/2004 **Weight:** 68.00
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 07/04/1966
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

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

Medicine Details:

| | | | |
|--|----------------------------|-----------------|------|
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression | | |
| Capsule | 25.0 Milligram | Daily | Oral |
| Batch: | Started: 24/09/2004 | Stopped: | |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|--|---------------|--------------------------------------|
| Case Number: 203503 | Seq: 1 | Gender: F |
| Reported: 13/12/2004 | | Weight: 0.00 |
| Hospitalisation: Admitted to hospital | | Age: 51 |
| Onset Date: 21/11/2004 | | DOB: 16/01/1953 |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|---|---|-----------------------------|
| Circulatory collapse | Caused or prolonged inpatient hospitalisation | Collapse at home, syncope. Complaints of feeling dizzy, anxious and jerking movements. Mild intention tremor. | Prozac and Sinequan ceased. |
| Anxiety | Caused or prolonged inpatient hospitalisation | | |
| Dizziness | Caused or prolonged inpatient hospitalisation | | |

Medicine Details:

| | |
|-------------------------------|---|
| PROZAC (Interaction) | Reason: |
| 240.0 Milligram | Daily |
| Oral | |
| Batch: | Started: 20/10/2004 Stopped: 22/11/2004 |
| SINEQUAN (Interaction) | Reason: |
| 250.0 Milligram | Daily |
| Oral | |
| Batch: | Started: 20/10/2004 Stopped: 22/11/2004 |
| MOGADON (Other drug) | Reason: Specific disorders of sleep |
| 20.0 Milligram | Oral |
| Batch: | Started: 15/03/2004 Stopped: 22/11/2004 |
| TEMAZE (Other drug) | Reason: Specific disorders of sleep |
| 20.0 Milligram | Oral |
| Batch: | Started: 15/11/2004 Stopped: 22/11/2004 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 203503 **Seq:** 1 **Gender:** F
Reported: 13/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 51
Onset Date: 21/11/2004 **DOB:** 16/01/1953
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|---|--------------------|-----------|
| Dyskinesia | Caused or prolonged inpatient hospitalisation | | |
| Syncope | Caused or prolonged inpatient hospitalisation | | |
| Tremor | Caused or prolonged inpatient hospitalisation | | |

Medicine Details:

| | |
|----------------------------|----------------------------|
| ORDINE (Other drug) | Reason: Headache |
| 200.0 Milligram | Daily |
| Oral | |
| Batch: | Started: 20/10/2004 |
| | Stopped: 22/11/2004 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 208138 **Seq:** 1 **Gender:** M
Reported: 24/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 60
Onset Date: 18/05/2005 **DOB:** 11/06/1944
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------------------------|-----------------------|--|-------------------------|
| Headache | Incapacity/disability | Severe headaches,nausea, prostration, mental obtundation | Cessation of medication |
| Depressed level of consciousness | Incapacity/disability | | |
| Nausea | Incapacity/disability | | |
| Prostration | Incapacity/disability | | |

Medicine Details:

| | | | |
|--|----------------------------|----------------------------|------|
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | |
| Tablet | 10.0 Milligram | Daily | Oral |
| Batch: | Started: 17/05/2005 | Stopped: 20/05/2005 | 0 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 208324 **Seq:** 1

Gender: M

Reported: 31/05/2005

Weight: 0.00

Hospitalisation:

Age: 58Y

Onset Date: 10/05/2005

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Depression |
| Capsule | 10.0 Milligram Daily Oral |
| Batch: | Started: Stopped: 10/05/2005 0 |
| LASIX (Suspected) | Reason: |
| | 20.0 Milligram Daily |
| Batch: | Started: 10/05/2005 Stopped: |

Laboratory Investigations:

Additional Information:

Unknown if Cialis was taken.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 210435 **Seq:** 1 **Gender:** F
Reported: 05/08/2005 **Weight:** 60.00
Hospitalisation: **Age:** 72
Onset Date: 27/01/2001 **DOB:** 21/06/1928
Outcome: Recovered 15/05/2001 **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---------------------|----------|---|-----------|
| Hypokalaemia | Life | Patient was unwell for 2 weeks, vomiting constantly 2-3 times weekly, developed hypokalaemia and acute on chronic renal failure | |
| Renal failure acute | Life | | |
| Vomiting | Life | | |

Medicine Details:

| | |
|--|---|
| FELODIPINE (Suspected) | Reason: |
| Batch: | Started: Stopped: 27/01/2001 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| Batch: | Started: Stopped: 27/01/2001 |
| CYANOCOBALAMIN (Suspected) | Reason: |
| Batch: | Started: Stopped: 27/01/2001 |
| METFORMIN HYDROCHLORIDE (Suspected) | Reason: Diabetes mellitus |
| Tablet 1.5 Gram Daily Oral | |
| Batch: | Started: Stopped: 27/01/2001 0 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------------|------------------|-------|-------------|--------|---|
| 05/08/2005 | Creatinine | | 27/01/2001 | 0.72 | 08/2000 - 0.35 and 11/2000 - 0.41. |
| 05/08/2005 | Creatinine | | 28/01/2004 | 0.47 | 08/2000 - 0.35 and 11/2000 - 0.41. |
| 05/08/2005 | Other data | | | | Ca 2+ ccorr: 27/01/01 - 1.96 and 28/01/01 - 2.12. |
| 05/08/2005 | Phosphate 1 | | 27/01/2001 | 2.87 | |
| 05/08/2005 | Phosphate 1 | | 28/01/2004 | 1.41 | |
| 05/08/2005 | Serum osmolality | | 27/01/2001 | 329 | |
| 05/08/2005 | Serum osmolality | | 28/01/2004 | 325 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 210435

Seq: 1

Gender: F

Reported: 05/08/2005

Weight: 60.00

Hospitalisation:

Age: 72

Onset Date: 27/01/2001

DOB: 21/06/1928

Outcome: Recovered

15/05/2001

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|------------------------|-----------------|----------|------|
| RANITIDINE (Suspected) | | Reason: | |
| Tablet | 150.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------------|-------------|-------|-------------|--------|---------|
| 05/08/2005 | Urea | | 27/01/2001 | 60 | |
| 05/08/2005 | Urea | | 28/01/2001 | 39.4 | |
| 05/08/2005 | bicarbonate | | 27/01/2001 | 12 | |
| 05/08/2005 | bicarbonate | | 28/01/2004 | 17 | |
| 05/08/2005 | pH | | 27/01/2001 | 7.30 | |

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------------|---------------|--------------------------------------|
| Case Number: 212062 | Seq: 1 | Gender: F |
| Reported: 28/09/2005 | | Weight: 70.00 |
| Hospitalisation: | | Age: 56 |
| Onset Date: 01/09/2005 | | DOB: 29/01/1949 |
| Outcome: Not yet recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--|-----------------------------|
| Musculoskeletal stiffness Agitation Clonus Hyperhidrosis Hypertonia Serotonin syndrome | | Patient experienced stiffness, agitation, sweating, clonus ++ increased tone, serotonin syndrome or NMS. | Ceased all medication, ICU. |

Medicine Details:

| | |
|---|---|
| OLANZAPINE (Suspected) | Reason: Manic-depression psycho,manic |
| Batch: | Started: 18/08/2005 Stopped: 08/09/2005 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: |
| Batch: | Started: Stopped: 08/09/2005 |
| AMITRIPTYLINE HYDROCHLORIDE (Suspected) | Reason: |
| Batch: | Started: Stopped: 08/09/2005 |
| MELLERIL (Suspected) | Reason: |
| Batch: | Started: Stopped: 08/09/2005 0 |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 212062 **Seq:** 1

Gender: F

Reported: 28/09/2005

Weight: 70.00

Hospitalisation:

Age: 56

Onset Date: 01/09/2005

DOB: 29/01/1949

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | |
|--------------------------------------|--|
| RISPERIDONE (Suspected) | Reason: Otr spec symp psychopathol nec |
| Batch: | Started: 28/08/2005 Stopped: 08/09/2005 |
| LITHIUM CARBONATE (Suspected) | Reason: Manic-depression psycho,manic |
| Tablet | 1.0 Gram Daily Oral |
| Batch: | Started: 18/08/2005 Stopped: 08/09/2005 0 |

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 215247 | Seq: 1 | Gender: F |
| Reported: 24/01/2006 | | Weight: 0.00 |
| Hospitalisation: | | Age: 70Y |
| Onset Date: | | DOB: |
| Outcome: Unknown | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------------|----------|---|---|
| Serotonin syndrome | | Patient developed severe serotonergic features, including confusion, nausea, fever, clonus, hyperreflexia, hypertonia, shivering and tachycardia, serotonin syndrome, restless, agitated, febrile, atrial fibrillation, incoordination, mydriasis and elevated CK level | Ceased Fluvoxamine, Oxycodone, Doxepin. |
| Agitation | | | |
| Atrial fibrillation | | | |
| Blood creatine phosphokinase in | | | |
| Chills | | | |
| Clonus | | | |
| Confusional state | | | |

Medicine Details:

| | | | |
|--|-----------------|-----------------|------|
| OXYCODONE HYDROCHLORIDE (Interaction) | | Reason: | |
| Tablet | 80.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | 0 |
| FLUVOXAMINE MALEATE (Interaction) | | Reason: | |
| Tablet | 200.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |
| DOXEPIN HYDROCHLORIDE (Interaction) | | Reason: | |
| Capsule | 50.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | |
| DICLOFENAC SODIUM (Other drug) | | Reason: | |
| Batch: | Started: | Stopped: | |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------------|----------|-------|-------------|--------|---|
| 24/01/2006 | Creatine | | | | Creatine kinase (SK) level was 485 units/L. |

Additional Information:

Literature Reference: Karunatilake H, Buckley NA. Serotonin syndrome induced by Fluvoxamine and Oxycodone. The annals of Pharmacotherapy 2005; 40 (1); 155-157. Following admission, the patient's thyroid indices were normal. Also published: Serotonin syndrome due to fluvoxamine-oxycodone interaction. Psychopharmacology Reviews, Primary Psychiatry 2006; May: 25-26.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2009 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 215247 **Seq:** 1 **Gender:** F
Reported: 24/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|---|----------|--------------------|-----------|
| Coordination abnormal Hyperreflexia Hypertonia Mydriasis Nausea Pyrexia Restlessness Tachycardia | | | |

Medicine Details:

| | | |
|---------------------------------------|-----------------|-----------------|
| RALOXIFENE (Other drug) | Reason: | |
| Batch: | Started: | Stopped: |
| CALCIUM CARBONATE (Other drug) | Reason: | |
| Batch: | Started: | Stopped: |
| Dilzem CD (Other drug) | Reason: | |
| Batch: | Started: | Stopped: |
| SIMVASTATIN (Other drug) | Reason: | |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

Additional Information:

Literature Reference: Karunatilake H, Buckley NA. Serotonin syndrome induced by Fluvoxamine and Oxycodone. The annals of Pharmacotherapy 2005; 40 (1); 155-157. Following admission, the patient's thyroid indices were normal. Also published: Serotonin syndrome due to fluvoxamine-oxycodone interaction. Psychopharmacology Reviews, Primary Psychiatry 2006; May: 25-26.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 222959 | Seq: 1 | Gender: M |
| Reported: 08/11/2006 | | Weight: 0.00 |
| Hospitalisation: | | Age: 58Y |
| Onset Date: | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------------|------------------|---|--|
| Neuroleptic malignant syndrome | Life threatening | Patient experienced parkinsonism-hyperpyrexia syndrome, fever agitation, confusion, autonomic instability, psychotic features, diaphoresis, marked rigidity, disorientation and visual hallucinations, whilst taking oxycodone. | Oxycodone, doxepin hydrochloride, selegeline and dexamethasone were ceased on admission and empiric acyclovir, ceftriaxone and paracetamol given. Four days after admission bromocriptine 5mg three times daily and apomorphine 3mg subcutaneously daily were commenced. Additionally cooling fans were used, with deep vein thrombosis prophylaxis, intravenous fluid support and close monitoring of |

Medicine Details:

| | |
|---|--|
| DIAZEPAM (Other drug) | Reason: |
| 15.0 Milligram Daily | |
| Batch: | Started: L TERM Stopped: |
| OXYCODONE HYDROCHLORIDE (Suspected) | Reason: |
| 40.0 Milligram Daily Oral | |
| Batch: | Started: Stopped: 0 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| 100.0 Milligram Daily Oral | |
| Batch: | Started: Stopped: 0 |
| SELEGILINE HYDROCHLORIDE (Suspected) | Reason: Paralysis agitans |
| Tablet 10.0 Milligram Daily Oral | |
| Batch: | Started: Stopped: 0 |

Laboratory Investigations:

| Date | Type | Range | Date Tested | Result | Details |
|------------|-------------------|-------|-------------|--------|--|
| 08/11/2006 | Creatine | | | | Creatine peaked at 1466 U/L |
| 08/11/2006 | Electroencephalog | | | | EEG on second day of admission was diffusely slowed with encephalopathic features. |
| 08/11/2006 | White blood cells | | | | White cell count peaking at 13.9 x 10 ⁹ /L |

Additional Information:

J.Clin. Neurosci. 2006; 13(7):857-859.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 222959 **Seq:** 1 **Gender:** M
Reported: 08/11/2006 **Weight:** 0.00
Hospitalisation: **Age:** 58Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--|----------|--------------------|-----------|
| Agitation | Life | | |
| Autonomic nervous system imbalance | Life | | |
| Blood creatine phosphokinase increased | Life | | |
| Blood pressure increased | Life | | |
| Confusional state | Life | | |
| Disorientation | Life | | |
| Hallucination, visual | Life | | |
| Hyperhidrosis | Life | | |
| Hyperpyrexia | Life | | |
| Leukocytosis | Life | | |
| Muscle rigidity | Life | | |

Medicine Details:

| | |
|--------------------------------|------------------------------------|
| DEXMETHSONE (Suspected) | Reason: Cervicalgia |
| Tablet | 4.0 Milligram Daily Oral |
| Batch: | Started: Stopped: 0 |

Laboratory Investigations:

Additional Information:

J.Clin. Neurosci. 2006; 13(7):857-859.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-----------------------------|---------------|--------------------------------------|
| Case Number: 222959 | Seq: 1 | Gender: M |
| Reported: 08/11/2006 | | Weight: 0.00 |
| Hospitalisation: | | Age: 58Y |
| Onset Date: | | DOB: |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------|--------------------|-----------|
| Parkinsonian rest tremor | Life | | |
| Parkinsonism | Life | | |
| Psychotic disorder | Life | | |
| Pyrexia | Life | | |
| Tremor | Life | | |

Medicine Details:

| | |
|---|--|
| DIAZEPAM (Other drug) | Reason: |
| 15.0 Milligram Daily | |
| Batch: | Started: L TERM Stopped: |
| OXYCODONE HYDROCHLORIDE (Suspected) | Reason: |
| 40.0 Milligram Daily | Oral |
| Batch: | Started: Stopped: 0 |
| DOXEPIN HYDROCHLORIDE (Suspected) | Reason: Depression |
| 100.0 Milligram Daily | Oral |
| Batch: | Started: Stopped: 0 |
| SELEGILINE HYDROCHLORIDE (Suspected) | Reason: Paralysis agitans |
| Tablet 10.0 Milligram Daily | Oral |
| Batch: | Started: Stopped: 0 |

Laboratory Investigations:

Additional Information:

J.Clin. Neurosci. 2006; 13(7):857-859.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 222959

Seq: 1

Gender: M

Reported: 08/11/2006

Weight: 0.00

Hospitalisation:

Age: 58Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | | |
|-------------------------|---------------|-------------|------|
| DEXMETHSONE (Suspected) | reason: | Cervicalgia | |
| Tablet | 4.0 Milligram | Daily | Oral |
| Batch: | Started: | Stopped: | 0 |

Laboratory Investigations:

Additional Information:

J.Clin. Neurosci. 2006; 13(7):857-859.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 224326 **Seq:** 1 **Gender:** F
Reported: 28/12/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Glaucoma | | glaucoma | |

Medicine Details:

| | |
|-----------------------------|---|
| SINEQUAN (Suspected) | Reason: Specific disorders of sleep |
| Batch: | Started: L TERM Stopped: Oral |

Laboratory Investigations:

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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

| | | |
|-------------------------------|---------------|--------------------------------------|
| Case Number: 224542 | Seq: 1 | Gender: F |
| Reported: 10/01/2007 | | Weight: 0.00 |
| Hospitalisation: | | Age: 60 |
| Onset Date: 12/09/2006 | | DOB: 11/07/1946 |
| Outcome: Recovered | | Causality: Causality possible |

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------|---|----------------------|--|
| Coordination abnormal | Caused or prolonged inpatient hospitalisation | Ataxia and confusion | Admitted to hospital for management. Tramadol ceased |
| Confusional state | Caused or prolonged inpatient hospitalisation | | |

Medicine Details:

| | | |
|--|-----------------|---|
| TRAMAL SR (Interaction) | | Reason: Otr&unsp vertebrogen pain synd |
| Tablet | 100.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: 0 |
| DOXEPIN HYDROCHLORIDE (Interaction) | | Reason: Pain |
| Capsule | 25.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: 0 |
| Sensipar (Interaction) | | Reason: Hyperparathyroidism |
| Tablet | 30.0 Milligram | Daily Oral |
| Batch: | Started: | Stopped: 0 |
| LITHIUM CARBONATE (Other drug) | | Reason: |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:

Tramad ceased and symptoms resolved. When tramadol recommenced for back pain, symptoms returned.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 224542

Seq: 1

Gender: F

Reported: 10/01/2007

Weight: 0.00

Hospitalisation:

Age: 60

Onset Date: 12/09/2006

DOB: 11/07/1946

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

| | | |
|----------------------------------|----------|----------|
| THYROXINE SODIUM (Other drug) | Reason: | |
| Batch: | Started: | Stopped: |
| QUININE SULPHATE (Other drug) | Reason: | |
| Batch: | Started: | Stopped: |
| NITRAZEPAM (Other drug) | Reason: | |
| Batch: | Started: | Stopped: |
| ALUMINIUM HYDROXIDE (Other drug) | Reason: | |
| Batch: | Started: | Stopped: |

Laboratory Investigations:

Additional Information:

Tramad ceased and symptoms resolved. When tramadol recommenced for back pain, symptoms returned.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 226742 **Seq:** 1 **Gender:** F
Reported: 20/03/2007 **Weight:** 65.00
Hospitalisation: Required a visit to the doctor **Age:** 33
Onset Date: 16/01/2007 **DOB:** 11/01/1974
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Nightmare | | Nightmares | |

Medicine Details:

| | | | |
|------------------------------|---------------------------------|-----------------|------------|
| DIAZEPAM (Other drug) | Reason: | | |
| Batch: | Started: | Stopped: | 0 |
| DEPTRAN (Suspected) | Reason: Anxiety neurosis | | |
| Tablet | 50.0 Milligram | Daily | Oral |
| Batch: | Started: 16/01/2007 | Stopped: | 02/02/2007 |

Laboratory Investigations:

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

Additional Information: