

Date 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 Detai

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

Medicine Details:

DOXEPIN HYDROCHLORIDE (Suspected) Reason: Rash

30.0 Dose Unspecified Daily

3atch: **3tarted**: 25/07/1989 **3topped**: 31/07/1989

PROPYLTHIOURACIL (Suspected) Reason: Thyrotoxicosis w/o ment goiter

600.0 Milligram Daily

3atch: 3tarted: 26/07/1989 3topped: 08/08/1989

Laboratory Investigations:

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

Additional Information:

Case Sequenced to: 62758/2



Date 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:
Onset Date: 06/11/1988
Age: 59Y
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

| FELDENE (Suspected) | | Reason: | Unspecified arthrit | is |
|----------------------|---------------------|---------|---------------------|----------|
| Capsule | 20.0 Milligram | Daily | Ora | al |
| 3atch: | Started: 01/12/1986 | | Stopped: 06/ | /11/1988 |
| SINEQUAN (Suspected) | | Reason: | Disturbance of sle | ер |
| Capsule | 50.0 Milligram | Daily | Ora | al |
| 3atch: | Started: 01/01/1983 | | Stopped: | |
| SEREPAX (Suspected) | | Reason: | Disturbance of sle | ер |
| Tablet | 30.0 Milligram | Daily | Ora | al |
| 3atch: | Started: 01/01/1983 | | Stopped: | |

Laboratory Investigations:

| Date | Туре | Range | Date Tested | Result | Details | 3 |
|------|--------------|-------|-------------|--------|--|--|
| | 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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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN,DOXEPIN HYDROCHLORIDE,QUITAXON,SINEQUAN

Report Detail

Case Number: 59076 Seq: 1 Gender: M

Reported: 02/03/1989 Weight: 65.00 Hospitalisation: Age: 53Y

Onset Date: 05/09/1988 **DOB**:

Outcome: Recovered with sequelae Causality: Causality probable

Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------|----------------------------|
| Orthostatic hypotension | | | Sequelae. cuts and bruises |

Medicine Details:

NICORETTE GUM (Other drug) Reason:

Tablet, chewable 8.0 Milligram Daily Oral

3atch: 3tarted: 01/08/1988 3topped:

DOXEPIN HYDROCHLORIDE (Suspected) Reason: Anxiety neurosis

25.0 Milligram 1 time

3atch: 3tarted: 05/09/1988 3topped: 05/09/1988

Laboratory Investigations:

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

Additional Information:

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

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

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 Detai

| touchion polar | | ā | - |
|----------------------|----------|--------------------|--|
| 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

3atch: Started: 01/03/1989 Stopped: CONTIN

Laboratory Investigations:

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

Additional Information:

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

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

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 Detai

| 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 | |
| 3atch: | Started: 01/11/1988 | | Stopped: 18/03/1989 | |
| SINEQUAN (Suspected) | | Reason: | | |
| | 25.0 Milligram | Daily | 1 | |
| 3atch: | Started: | | Stopped: 02/12/1988 | |
| VALIUM (Suspected) | | Reason: | Abnormal involuntary movement | |
| Tablet | 2.0 Milligram | Daily | , Oral | |
| 3atch: | Started: | | Stopped: | |
| DOLOBID (Suspected) | | Reason: | Other disturbance of sensation | |
| | 500.0 Milligram | Daily | 1 | |
| 3atch: | Started: 01/11/1988 | | Stopped: | |

Laboratory Investigations:

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

Additional Information:

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

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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: 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 Detai

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

Medicine Details:

| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | | | |
|-----------------------------------|---------------------|---------|----------|------------|--------|
| | 300.0 Milligram | Daily | | | |
| 3atch: | Started: 01/01/1987 | | Stopped: | 14/12/1988 | |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | | | |
| | 250.0 Milligram | Daily | | | |
| 3atch: | Started: 14/12/1988 | | Stopped: | 28/01/1989 | |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | | | |
| | 200.0 Milligram | Daily | | | |
| 3atch: | Started: | | Stopped: | | CONTIN |

Laboratory Investigations:

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

Additional Information:

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

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Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

| Reported: 09/05/1989 | Case Number | : 60127 | Seq: | 1 | | | Gende | er: M |
|--|----------------|-------------|----------|-------------|---------|-------------|---------|-----------------------|
| Onset Date: Outcome: Recovered Preferred Term Severity Report Description Treatment Diarrhoea Medicine Details: TOLIVON (Other drug) 3 atch: 3 tarted: 3 topped: DEPTRAN (Suspected) 25.0 Milligram Daily 3 atch: 3 tarted: 3 topped: DEPTRAN (Suspected) 25.0 Milligram Daily 3 atch: 3 tarted: 3 topped: DEPTRAN (Suspected) Reason: 25.0 Milligram Daily 3 atch: 3 tarted: 3 topped: DEPTRAN (Suspected) Reason: 25.0 Milligram Daily Date Type Range Date Tested Result Details | Reported | : 09/05/198 | 9 | | | | Weigl | ht: 88.00 |
| Outcome: Recovered Secretiv Report Description Treatment Preferred Term Severity Report Description Treatment Medicine Details: TOLVON (Other drug) Reason: 0.0 3atch: Started: Stopped: MOGADON (Other drug) Reason: 0.0 3atch: Started: Stopped: DEPTRAN (Suspected) Reason: 25.0 Milligram Daily 3atch: Started: Stopped: Deby Reason: 25.0 Milligram Daily 3atch: Started: Stopped: Deby Reason: 25.0 Milligram Daily 3atch: Started: Stopped: | ospitalisation | : | | | | | Ag | je: 68Y |
| Preferred Term Severity Report Description Treatment Medicine Details: TOLVON (Other drug) 3atch: Started: Stopped: MOGADON (Other drug) 3atch: Started: Stopped: DEPTRAN (Suspected) 3atch: Started: Stopped: | Onset Date | : | | | | | | |
| Preferred Term Severity Report Description Treatment Diarrhoea Medicine Details: TOLVON (Other drug) 3 atch: Started: Stopped: MOGADON (Other drug) 3 atch: Started: Stopped: DEPTRAN (Suspected) 25.0 Milligram Daily 3 atch: Started: Stopped: Aboratory Investigations: Date Type Range Date Tested Result Details | Outcome | : Recovere | d | | | | Causali | ty: Causality certain |
| Medicine Details: TOLVON (Other drug) 3 atch: 3 tarted: 3 topped: MOGADON (Other drug) 3 atch: 3 tarted: 3 topped: DEPTRAN (Suspected) 25.0 Milligram Daily 3 atch: 3 tarted: 3 topped: Aboratory Investigations: Date Type Range Date Tested Result Details | | | <u> </u> | | | | | |
| ### Tolvon (Other drug) 3 atch: 3 tarted: 3 topped: MOGADON (Other drug) 3 atch: 3 tarted: 3 topped: DEPTRAN (Suspected) 25.0 Milligram Daily 3 atch: 3 tarted: 3 topped: 25.0 Milligram Daily 3 topped: Aboratory Investigations: Date Type Range Date Tested Result Details | Preferr | ed Term | Sev | erity | Repor | Description | | Treatment |
| TOLVON (Other drug) 3atch: Started: Stopped: MOGADON (Other drug) 3atch: Started: Stopped: 0.0 3atch: Started: Stopped: DEPTRAN (Suspected) 25.0 Milligram Daily 3atch: Started: Stopped: 25.0 Milligram Daily 3atch: Date Type Range Date Tested Result Details | iarrhoea | | | | | | | |
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| Started: Stopped: | | | | | Reas | on: | | |
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| BEPTRAN (Suspected) 25.0 Milligram Daily Batch: Started: Stopped: 25.0 Milligram Daily Stopped: Date Type Range Date Tested Result Details | MOGADON (Othe | r drug) | | | Reas | on: | | |
| DEPTRAN (Suspected) 25.0 Milligram Daily 3atch: Started: Stopped: aboratory Investigations: Date Type Range Date Tested Result Details | | | | | | | | |
| 3atch: Started: Stopped: | | | 3ta | ırted: | | | d: | |
| Aboratory Investigations: Date Type Range Date Tested Result Details | DEPTRAN (Susp | ected) | | | | | | |
| Aboratory Investigations: Date Type Range Date Tested Result Details | 2 atala. | | 24- | | gram | - | J. | |
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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 Detai

| touction Botal | Juditori Detai | | | | | | | |
|------------------------|----------------|--------------------|---------------------------|--|--|--|--|--|
| Preferred Term | Severity | Report Description | Treatment | | | | | |
| Hypertonia | | | lv kcl, normal saline iv, | | | | | |
| Hypotension | | | | | | | | |
| Respiratory depression | | | | | | | | |

Medicine Details:

DOXEPIN HYDROCHLORIDE (Suspected) Reason:

Oral application 50.0 Milligram 1 time Oral

3atch: 3tarted: 10/04/1989 **3topped:**

Laboratory Investigations:

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

Additional Information:

See original report for other drugs.



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

| Report Detail | | | | | |
|------------------------------------|------------|---------------|------------------------------|-------------------------|-----------------------|
| Case Number: | 60592 | Seq: 1 | | Gende | er: F |
| Reported: | 29/05/1989 |) | | Weigl | nt: 64.00 |
| Hospitalisation: | | | | | e : 58Y |
| Onset Date: | | | | DO | |
| | Recovered | | | Causalit | y: Causality possible |
| Reaction Deta Preferre | | Severity | Bonor | Description | Treatment |
| | | Seventy | Repoi | Description | rrealment |
| Increased appet Weight increase | | | | | |
| Medicine Det | | 50.0 | Reas o 0 Milligram | on: Depression Daily | |
| Зatch: | | Started: 2 | | Stopped: | CONTIN |
| Laboratory Ir | | | and the Book | | |
| Date | Туре | Range Date To | ested Result | D | etails |
| | | , | • | | |



Date 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

Hospitalisation:
Onset Date:

Onset Date:

Weight:
Age: 65Y
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

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

Medicine Details:

DEPTRAN (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 01/02/1989 **3topped:**

Laboratory Investigations:

| Date | Туре | Range | Date Tested | Result | Details |
|------|------|-------|-------------|--------|---------|
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Additional Information:

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



Date 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 Detai

| | | - | ā. |
|---------------------------------|----------|--------------------|--|
| Preferred Term | Severity | Report Description | Treatment |
| Coordination abnormal Diplopia | | | Patient stopped deptran and resumed sinequan. symptoms |
| Dysgeusia | | | |
| Visual disturbance | | | |

Medicine Details:

| TENORMIN (Other drug) | | Reason: | Essential benign hypertension |
|-----------------------------|--|------------------|--|
| Tablet | 100.0 Milligram | Daily | Oral |
| 3atch: | Started: 22/07/1982 | | Stopped: |
| MINIPRESS (Other drug) | | Reason: | Essential benign hypertension |
| Tablet | 2.0 Milligram | Daily | Oral |
| 3atch: | Started: 28/06/1985 | | Stopped: |
| | | | |
| ZANTAC (Other drug) | | Reason: | Ulcer of duodenum w/o ment perf |
| ZANTAC (Other drug) Tablet | 150.0 Milligram | Reason: Daily | ' |
| ` " | 150.0 Milligram Started: 02/05/1985 | | ' |
| Tablet | _ | | Oral |
| Tablet 3atch: | _ | Daily | Oral Stopped: Othr&unspec metabolic diseases |

Laboratory Investigations:

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



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Case Number: 6 | 31299 | Seq: 1 | | | Gender: | F | |
|----------------------|--------------|----------------------------|---------|------------|------------|-------------------|---|
| Reported: 0 | 06/07/1989 | | | | Weight: | 60.00 | |
| Hospitalisation: | | | | | Age: | | |
| Onset Date: 1 | 15/05/1989 | | | | DOB: | | |
| Outcome: F | Recovered | | | C | ausality: | Causality probabl | е |
| Reaction Detai | | | | | | | |
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| Medicine Deta | ils: | | | | | | |
| DEPTRAN (Suspect | | | Reason: | Depression | | | |
| Capsule | | 50.0 Milligram | Daily | | Oral | | |
| 3atch: | | 3tarted: 15/05/1989 | | Stopped: | 22/06/1989 | | |
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| Laboratory Inv | estigations: | | | | | | |
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| Additional Info | rmation: | | | | | | |
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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 De | | | | | | |
|-------------------------|------------------------|-----------------------|---------------|---------------|----------------|--------------------------|
| vehour ne | etail | | | | | |
| Case Num | ber: 61421 | Seq: | 1 | | Gene | der: F |
| Repor | ted: 14/07/198 | _ | | | Weig | ght: 51.00 |
| Hospitalisat | | | | | | . ge : 59Y |
| - | oate: 29/04/198 | 9 | | | | OB: |
| Outco | me: Recovered | d | | | Causa | lity: Causality probable |
| Reaction D | | | | | | , ,, |
| | eferred Term | Seve | erity | Repor | Description | Treatment |
| Depression | | | | | · | |
| Nausea | | | | | | |
| | | | | | | |
| Medicine DEPTRAN (S | | | | Reas | on: Depression | |
| , | . , | | 3.0 Dos | e Unspecified | • | |
| 3atcl | h: | Star | ted: 29/04/19 | | Stopped: 14/07 | /1989 |
| | | | | | | |
| Laborator | ry Investigati | ions: | | | | |
| Laborato Date | ry Investigati Type | ions: Range | Date Tested | Result | | Details |
| | T I | | Date Tested | Result | | Details |



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

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 Detai

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

Medicine Details:

| MIDAMOR (Other drug) | | Reason: | Essential beni | gn hypertension | |
|-----------------------|---------------------|--------------|-------------------------|-----------------|--------|
| Tablet | 1.0 Dose Unspe | cified Daily | | Oral | |
| Зatch: | 3tarted: 01/01/1988 | | Stopped: | | CONTIN |
| TRANDATE (Other drug) | | Reason: | Essential beni | gn hypertension | |
| Tablet | 400.0 Milligram | Daily | | Oral | |
| 3atch: | 3tarted: 01/01/1988 | | Stopped: | | CONTIN |
| SINEQUAN (Other drug) | | Reason: | Nervousness | | |
| Capsule | 25.0 Milligram | Daily | | Oral | |
| 3atch: | h | | | | |
| Jaton. | Started: 01/01/1988 | | Stopped: | 17/07/1989 | |
| SEREPAX (Other drug) | Started: 01/01/1988 | Reason: | Stopped: Anxiety neuros | | |
| | 15.0 Milligram | Reason: | - '' | | |

Laboratory Investigations:

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

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. 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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Date Range: 1 Jan 1989 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: DEPTRAN, DOXEPIN HYDROCHLORIDE, QUITAXON, SINEQUAN

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 Detai

Medicine Details:

 DEPTRAN (Suspected)
 Reason:
 Anxiety neurosis

 Capsule
 25.0 Milligram
 1 time
 Oral

 3atch:
 3tarted:
 17/07/1989
 3topped:
 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.

Report Run 30/07/200 03:48PN Database: pusime ADRS004 Page 15 of 307



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

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 Detai

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

Medicine Details:

| TRANSIDERM-NITRO (Suspected) | | | Reason: | Essential ben | ign hypertension |
|-----------------------------------|----------|-----------|---------|----------------|------------------|
| | 0.0 | | | | |
| 3atch: | Started: | | | Stopped: | 13/06/1989 |
| LITHIUM CARBONATE (Suspected) | | | Reason: | Unspecifid aff | ective psychosis |
| Tablet | 1.0 | Gram | Daily | | Oral |
| 3atch: | Started: | | | Stopped: | 08/06/1989 |
| NIFEDIPINE (Suspected) | | | Reason: | Essential ben | ign hypertension |
| Oral application | 40.0 | Milligram | Daily | | Oral |
| 3atch: | Started: | | | Stopped: | 13/06/1989 |
| DOXEPIN HYDROCHLORIDE (Suspected) | | | Reason: | Depression | |
| | 150.0 | Milligram | Daily | | |
| 3atch: | Started: | | | Stopped: | 08/06/1989 |

Laboratory Investigations:

| Laborator | y ilivootigat | | | | |
|-----------|------------------|-------|-------------|--------|---|
| Date | Туре | 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 |



Report Detail

Case Number: 61987

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

| Reported: 16/08/1989 ospitalisation: Onset Date: | | | Weight: 92.00 Age: 64Y DOB: | | |
|--|-------------------|---------------------|-----------------------------|--|--|
| Outcome: Recovered | | Causality: Ca | | | |
| action Detai | County | Deposit Description | Treatment | | |
| Preferred Term | Severity | Report Description | Treatment | | |
| eadache eadache | | | Changed back to sinequan | | |
| | | | | | |
| edicine Details: DEPTRAN (Suspected) | 0.0 | Reason: | | | |
| 3atch: | 0.0 Started: | Stopped: | | | |
| abarataru Invastigation | | | | | |
| aboratory Investigation Date Type | Range Date Tested | Result | Details | | |
| | ŭ | | | | |
| additional Information: | | | | | |
| ort Run 30/07/200 03:48PN I | Database: pusime | ADRS004 | Page 17 of 307 | | |



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

| Rep | oort | Det | ail |
|-----|------|-----|-----|
|-----|------|-----|-----|

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 Detai

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

Medicine Details:

SINEQUAN (Suspected) Reason: Neuroses

 Capsule
 150.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 30/12/1987
 3topped:
 14/04/1989

Laboratory Investigations:

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



Report Detail

Case Number: 62195

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

| Reported: 30/08/1989 Hospitalisation: Onset Date: Outcome: Unknown | 9 | | Weight: Age: DOB: Causality: Causality probable | | | | |
|--|-----------------|------------------|---|------------|------------|-----|--|
| Reaction Detai Preferred Term | Severit | v | Report D | escription | Treatment | | |
| Constipation | 364011 | | . topoit D | | Hodinoni | | |
| Depersonalisation | | | | | | | |
| Dry mouth | | | | | | | |
| Medicine Details: | | | | | | | |
| DEPTRAN (Suspected) | | 0.0 | Reason: | | | | |
| 3atch: | Starte | 0.0 d: | | Stopped: | | | |
| Laboratory Investigati | ons: | | | | | | |
| Date Type | | ate Tested | Result | | Details | | |
| | | | | | | | |
| Additional Information | 1: | | | | | | |
| eport Run 30/07/200 03:48PN | Database: pusim | e | ADR | S004 | Page 19 of | 307 | |



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

| Report D | etai |
|----------|------|
|----------|------|

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 Detai

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

Medicine Details:

| OESTRADIOL (Suspected) | | Reas | on: | | |
|--|----------------------|-------------------|---------|----------|--------------|
| Nasal Drops | 0.0 | | | | Nasal |
| 3atch: | Started: | | | Stopped: | |
| DI-GESIC (Suspected) | | Reas | on: | | |
| Tablet | 0.0 | | | | Oral |
| 3atch: | Started: | | | Stopped: | |
| | | | | | |
| CHOLECALCIFEROL (Suspected) | | Reas | on: | | |
| CHOLECALCIFEROL (Suspected) Oral application | 10.0 | | | | Oral |
| ` ' ' | 10.0 Started: | | Monthly | እtopped: | Oral |
| Oral application | | | Monthly | | Oral |
| Oral application 3atch: | | Thousand Internat | Monthly | Stopped: | Oral Oral |

Laboratory Investigations:

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



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Papartad: | 62292 | Seq: 1 | | | Gender: | F |
|------------------------------------|-------------------|----------------------------------|----------------------|---------|------------|--------------------|
| Reported. | 03/08/1989 | | | | Weight: | |
| Hospitalisation: | | | | | Age: | |
| Onset Date: | 27/06/1989 | | | | | 09/12/1937 |
| Outcome: | Death, maybe dru | ng | | | Causality: | Causality possible |
| eaction Detai | İ | | | | | |
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| Medicine Det | | | | | | |
| PIROXICAM (Susp | ected) | | | Reason: | | |
| Capsule | | | Milligram | Daily | Oral | |
| 3atch: | | Started: | | | Stopped: | |
| OXAZEPAM (Susp | ected) | | | Reason: | | |
| Tablet | | | Milligram | Daily | Oral | |
| 3atch: | | Started: | | | Stopped: | |
| | 00111 0DIDE (0 | ted) | | Reason: | | |
| PETHIDINE HYDR | OCHLORIDE (Suspec | | | Deily | | |
| | OCHLORIDE (Suspec | 100.0 | Milligram | Daily | | |
| Зatch: | | | Milligram | | Stopped: | |
| | | 100.0 Started: | | Reason: | Stopped: | |
| Зatch: | | 100.0 Started: | Milligram Milligram | | | |
| 3atch: | | 100.0 Started: | | Reason: | Stopped: | |
| 3atch: MAXOLON (Suspe 3atch: | ected) | 100.0 Started: 20.0 | | Reason: | | |
| 3atch: MAXOLON (Suspe 3atch: | | 100.0 Started: 20.0 | | Reason: | | |
| 3atch: MAXOLON (Suspe 3atch: | ected) | 100.0 Started: 20.0 | | Reason: | | |
| 3atch: MAXOLON (Suspe 3atch: | ected) | 100.0 Started: 20.0 | | Reason: | | |
| 3atch: MAXOLON (Suspe 3atch: | ected) | 100.0 Started: 20.0 | | Reason: | | |
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| 3atch: MAXOLON (Suspe 3atch: | ected) | 100.0 Started: 20.0 | | Reason: | | |
| 3atch: MAXOLON (Suspe 3atch: | ected) | 100.0 Started: 20.0 | | Reason: | | |
| 3atch: MAXOLON (Suspe 3atch: | ected) | 100.0 Started: 20.0 | | Reason: | | |
| 3atch: MAXOLON (Suspe | ected) | 100.0 Started: 20.0 | | Reason: | | |
| 3atch: MAXOLON (Suspe | ected) | 100.0 Started: 20.0 | | Reason: | | |
| 3atch: MAXOLON (Suspe 3atch: | ected) | 100.0 Started: 20.0 | | Reason: | | |
| 3atch: MAXOLON (Suspe | ected) | 100.0 Started: 20.0 | | Reason: | | |
| 3atch: MAXOLON (Suspe | ected) | 100.0 Started: 20.0 | | Reason: | | |

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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: 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 Detai

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

Medicine Details:

| LITHIUM CARBONATE (Suspected) | | | Reason: | Unspecifid aff | ective psychosis |
|-----------------------------------|----------|-----------|---------|-----------------|------------------|
| Tablet | 1.0 | Gram | Daily | | Oral |
| Зatch: | Started: | | | Stopped: | 17/07/1989 |
| DOXEPIN HYDROCHLORIDE (Suspected) | | | Reason: | Unspecifid aff | ective psychosis |
| | 125.0 | Milligram | Daily | | |
| 3atch: | Started: | | | Stopped: | 17/07/1989 |
| HALOPERIDOL (Suspected) | | | Reason: | Unspecifid aff | ective psychosis |
| | 0.5 | Milligram | Daily | | |
| Зatch: | Started: | | | Stopped: | 17/07/1989 |
| THEO-DUR (Suspected) | | | Reason: | Otr respiratory | y systm diseases |
| | 600.0 | Milligram | Daily | | |
| Зatch: | Started: | | | Stopped: | 17/07/1989 |

Laboratory Investigations:

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



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Case Number: 6 | 2669 | Seq: 1 | | Gender: M | |
|------------------------|--------------|---------------|-------------------------|---------------------|----------|
| Reported: 1 | 4/08/1989 | | | Weight: | |
| Hospitalisation: | | | | Age : 66Y | |
| Onset Date: 1 | 1/07/1989 | | | DOB: | |
| Outcome: F | Recovered | | C | ausality: Causality | possible |
| Reaction Detai | | | | | |
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| Medicine Detai | ils: | | | | |
| MODECATE (Suspe | | | Reason: Unspecifid affe | ective psychosis | |
| Injection | | 6.2 Milligram | Alternate weeks | Intramuscular | |
| 3atch: | | Started: | Stopped: | 17/07/1989 | |
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| Laboratory Inv | estigations: | | | | |
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| Additional Info | rmation: | | | | |
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| 00/07/000 | 00:4001 5 1 | | 100001 | _ | |

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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: 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 Detai

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

Medicine Details:

DEPTRAN (Suspected) Reason: Depression

0.0

3atch: Started: 01/08/1989 Stopped: 30/09/1989

Laboratory Investigations:

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

Additional Information:

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

Report Run 30/07/200 03:48PN Database: pusime ADRS004 Page 24 of 307



Date 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 Detai

| 104011011 20141 | | | |
|--------------------|----------|--------------------|-----------|
| Preferred Term | Severity | Report Description | Treatment |
| Increased appetite | | | |
| Paraesthesia | | | |
| Weight increased | | | |

Medicine Details:

SINEQUAN (Suspected) Reason: Depression

75.0 Milligram Daily

3atch: Started: 01/08/1989 **Stopped:** 09/10/1989

VALIUM (Suspected) Reason: Dependence on unspecifid drugs

1.0 Milligram Daily

3atch: 3tarted: 01/01/1977 3topped:

Laboratory Investigations:

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

Additional Information:

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



Date 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

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detai

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

Medicine Details:

| CARBAMAZEPINE (Suspected) | | Reason: | |
|---------------------------------------|-------------------------|------------------------|--------------|
| Oral application | 600.0 Milligram | Daily | Oral |
| 3atch: | Started: 01/06/1989 | Stopped: | 02/09/1989 |
| ZIDOVUDINE (Suspected) | | Reason: | |
| Oral application | 1.0 Gram | Daily | Oral |
| 3atch: | Started: 21/08/1989 | Stopped: | 30/08/1989 |
| | | | |
| DIAZEPAM (Suspected) | | Reason: Anxiety neuro | osis |
| DIAZEPAM (Suspected) Oral application | 20.0 Milligram | Reason: Anxiety neuro | osis Oral |
| , , , | 20.0 Milligram Started: | • | |
| Oral application | · · | Daily | Oral |
| Oral application 3atch: | · · | Daily Stopped : | Oral |

Laboratory Investigations:

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

Additional Information:

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

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Date 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 Detai

| todotion Dotal | | <u> </u> | |
|-----------------|----------|--------------------|---|
| 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 | |
| 3atch: | Started: 01/11/1988 | Stoppe | d: CONTIN | N |
| SEREPAX (Suspected) | | Reason: | | |
| Oral application | 30.0 Milligram | Daily | Oral | |
| Зatch: | Started: 01/11/1987 | Stoppe | d: CONTIN | N |
| | | | | |
| ANATENSOL (Suspected) | | Reason: Depression | 1 | |
| ANATENSOL (Suspected) Oral application | 2.0 Milligram | Reason: Depression Daily | n Oral | |
| | 2.0 Milligram 3tarted: 05/10/1989 | · | Oral | |
| Oral application | 3 - | Daily | Oral | |
| Oral application 3atch: | 3 - | Daily Stoppe | Oral | |

Laboratory Investigations:

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

Additional Information:

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

Report Run 30/07/200 03:48PN Database: pusime ADRS004 Page 27 of 307



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

| R۵ | no | rt | ח | eta | il |
|----|----|-------|------------------|-----|----|
| UE | νv | יו ני | \boldsymbol{L} | τιa | |

 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 Detai

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

Medicine Details:

| BACLOFEN (Suspected) | | | Reason: | Abnormal involuntary movement |
|-----------------------------------|-----------------------|-----------------------|------------------|--|
| | 30.0 | Milligram | Daily | |
| 3atch: | Started: | | | Stopped: |
| DOXEPIN HYDROCHLORIDE (Suspected) | | | Reason: | Depression |
| | 200.0 | Milligram | Daily | |
| 3atch: | Started: | | | Stopped: |
| | | | | |
| ECOTRIN (Suspected) | | | Reason: | |
| ECOTRIN (Suspected) | 650.0 | Milligram | Reason: Daily | |
| ECOTRIN (Suspected) 3atch: | 650.0 Started: | Milligram | | Stopped: |
| | | Milligram | | Stopped: Other prophylactic procedures |
| 3atch: | | Milligram Dose Unspe | Daily | ••• |

Laboratory Investigations:

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



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Case Number: 63820 Reported: 22/12/1989 Hospitalisation: Onset Date: 21/12/1989 Outcome: Not yet reco Reaction Detai | Seq: 1 | Gender: M Weight: 112.00 Age: 44Y DOB: Causality: Causality possible |
|--|---------------|--|
| Medicine Details: | | |
| VALIUM (Suspected) | | Reason: Abnormal involuntary movement |
| | 5.0 Milligram | Daily |
| 3atch: | Started: | Stopped: |
| | | |
| Laboratory Investigatio | ns: | |
| Additional Information: | | |

Report Run 30/07/200 03:48PN Database: pusime ADRS004 Page 29 of 307



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

Report Detail

Case Number:63885Seq:1Gender:FReported:05/01/1990Weight:70.00Hospitalisation:Admitted to hospitalAge:48Y

Onset Date: 20/11/1989 **DOB**:

Outcome: Recovered with sequelae Causality: Causality possible

Reaction Detai

| 104011011 20141 | | | - |
|------------------------------|----------|--------------------|---|
| Preferred Term | Severity | Report Description | Treatment |
| Supraventricular tachycardia | | | Plendil replaced by lopresor 2 x 50 mg. |

Medicine Details:

| PLENDIL (Interaction) | | Reason: | Essential beni | gn hypertension | |
|-------------------------|----------------------------|---------|----------------|-----------------|--|
| Oral application | 10.0 Milligram | Daily | | Oral | |
| 3atch: | Started: 01/04/1988 | | Stopped: | 21/11/1989 | |
| SINEQUAN (Interaction) | | Reason: | Depression | | |
| SINEQUAN (IIIteraction) | | teason. | Depression | | |
| Oral application | 50.0 Milligram | Daily | Depression | Oral | |

Laboratory Investigations:

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

Additional Information:

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

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Date 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 Detai

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

Medicine Details:

| modicino Botano. | | | |
|-----------------------------------|----------------------------|---------|---------------------------------|
| TAGAMET (Other drug) | | Reason: | Ulcer of duodenum w/o ment perf |
| | 800.0 Milligram | Daily | |
| Заtch: | Started: 01/01/1988 | | Stopped: |
| ZYLOPRIM (Other drug) | | Reason: | Gout |
| | 300.0 Milligram | Daily | |
| 3atch: | Started: 01/01/1975 | | Stopped: |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | Depression |
| | 50.0 Milligram | Daily | |
| Зatch: | Started: 02/06/1989 | | Stopped: |

Laboratory Investigations:

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

Additional Information:

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

Report Run 30/07/200 03:48PN Database: pusime ADRS004 Page 31 of 307



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

| - | \sim | | eta | |
|---|--------|------|-----|--|
| | | | | |
| | | | | |

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 Detai

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

Medicine Details:

SINEQUAN (Suspected) Reason: Depression

25.0 Milligram Daily

3atch: 3tarted: 14/12/1989 3topped: 21/12/1989

Laboratory Investigations:

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



Date 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 Detai

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

Medicine Details:

| SINEQUAN (Suspected) | | Reason: | Depression | |
|--------------------------|---------------------|---------|------------------------------|-----|
| Capsule | 50.0 Milligram | Daily | Oral | |
| 3atch: | Started: 01/01/1990 | | Stopped: | 05D |
| DISOPYRAMIDE (Suspected) | | Reason: | Otr&nos disord of heart rhyt | hm |
| Tablet | 300.0 Milligram | Daily | Oral | |
| | | | | |

Laboratory Investigations:

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

Report Run 30/07/200 03:48PN Database: pusime ADRS004 Page 33 of 307



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

| Severity R | | Gender: F Weight: Age: 42Y DOB: usality: Causality possible |
|------------|-------------------|---|
| Severity R | | DOB: nusality: Causality possible |
| Severity R | | usality: Causality possible |
| Severity R | | |
| Severity R | eport Description | |
| | • | Treatment |
| | | |
| | | |
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| | | |
|) | | |
| 0.0 | Reason: | |
| | Reason: | 05Y |
| 0.0 | | 05Y |
| 0.0 | Stopped: | 05Y Details |
| | | |

Additional Information:

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



Date 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 Detai

| 104041011 20441 | | | - |
|-----------------|----------|--------------------|--|
| Preferred Term | Severity | Report Description | Treatment |
| Hyperhidrosis | | | Stoped deptran and commenced prothiaden. |

Medicine Details:

| VOLTAREN (Other drug) | | Reason: Osteoarthritis | 8 |
|-----------------------|---------------------|------------------------|------------|
| | 100.0 Milligram | Daily | |
| 3atch: | Started: | Stopped: | |
| SEREPAX (Other drug) | | Reason: Depression | |
| Oral application | 15.0 Milligram | Daily | Oral |
| 3atch: | Started: | Stopped: | |
| DEPTRAN (Suspected) | | Reason: Depression | |
| | 50.0 Milligram | Daily | |
| 3atch: | Started: 18/05/1990 | Stopped: | 28/05/1990 |

Laboratory Investigations:

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



Date 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 Detai

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

Medicine Details:

| RIFAMPICIN (Suspected) | | Reason: Bacterial disease nec | |
|-----------------------------------|----------------------------|-------------------------------|--|
| Oral application | 600.0 Milligram | Daily Oral | |
| 3atch: | Started: 15/05/1990 | Stopped: | |
| CIPROFLOXACIN (Suspected) | | Reason: Bacterial disease nec | |
| Oral application | 1.0 Gram | Daily Oral | |
| 3atch: | Started: 15/05/1990 | Stopped: | |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: Bacterial disease nec | |
| Oral application | 50.0 Milligram | Daily Oral | |
| 3atch: | Started: 15/05/1990 | Stopped: | |
| BACTRIM DS (Suspected) | | Reason: | |
| Oral application | 2.0 Dose Unsp | ecified Daily Oral | |
| 3atch: | Started: | Stopped: | |

Laboratory Investigations:

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



Report Detail

Case Number: 65932

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: M

| Reported: | 30/05/1990 | | | | | : 65.00 | |
|--------------------|----------------------|-----------|------------------|---------|-----------|------------------|--------|
| ospitalisation: | | | | | Age | : 46Y | |
| Onset Date: | 26/05/1990 | | | | DOB | : | |
| Outcome: | Not yet recovered | | | | Causality | : Causality poss | ible |
| action Detai | | | | | | | |
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| Medicine Deta | | | | | | | |
| KETOCONAZOLE | | | Reas | | | | |
| Oral applica | ation | | Milligram | Daily | Oral | | |
| 3atch: | | Started: | | | Stopped: | | |
| | ACIDOPHILUS (Suspect | | Reas | | | | |
| Tablet | | 3.0 | Dose Unspecified | Daily | Oral | | |
| 3atch: | | Started: | | | Stopped: | | |
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| _aboratory In | vestigations: | | | | | | |
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| Additional Inf | ormation: | | | | | | |
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| port Run 30/07/200 | 03:48PN Database | e: pusime | , | ADRS004 | | Page 37 | of 307 |



Date 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 Detai

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

Medicine Details:

DOXEPIN HYDROCHLORIDE (Suspected) Reason: Depression

75.0 Milligram Daily

3atch: 3tarted: 3topped: 28/04/1990

Laboratory Investigations:

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

Additional Information:

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



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

| Report Do | etail |
|-----------|-------|
|-----------|-------|

 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 Detai

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

Medicine Details:

SINEQUAN (Suspected)

Oral application

50.0 Milligram

1 time

Oral

3atch: \$tarted: 28/03/1990

\$topped:

Laboratory Investigations:

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



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

| Report Des | Depression | Weig A Do Causal | der: M ght: Age: 34Y OB: lity: Causality probab |
|------------|------------|---------------------------|---|
| Reason: | Depression | Do Causa | OB: lity: Causality probab |
| Reason: | Depression | Causal n Oral | lity: Causality probab |
| Reason: | Depression | n Oral | |
| Reason: | Depression | Oral | Treatment |
| Reason: | Depression | Oral | Healinent |
| | ily | Oral | |
| | ily | Oral | |
| . Daily | | | |
| | лорро | <u></u> | |
| Davis 1 | | | D.M. II. |
| Result | | | Details |
| | | | |
| | | | |



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

| Report D | etail |
|----------|-------|
|----------|-------|

 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 Detai

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

Medicine Details:

3atch:

| RANITIDINE (Suspected) | | | Reason: | Other disease | es of esophagus | |
|-----------------------------------|----------|-----------|---------|---------------|-----------------|--|
| | 0.0 | | | | | |
| 3atch: | Started: | | | Stopped: | 05/06/1990 | |
| PROTHIADEN (Suspected) | | | Reason: | | | |
| | 75.0 | Milligram | Daily | | | |
| 3atch: | Started: | | | Stopped: | 11/06/1990 | |
| DOXEPIN HYDROCHLORIDE (Suspected) | | | Reason: | | | |
| | 50.0 | Milligram | Daily | | | |
| | | | | | | |

Stopped:

05/06/1990

Started:

Laboratory Investigations:

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



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

| _ | - 4 | etai | • |
|---|-----|------|---|
| | | | |
| | | | |
| | | | |

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 Detai

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

Medicine Details:

SINEQUAN (Suspected) Reason: Depression

Capsule 75.0 Milligram Daily Oral

3atch: 3tarted: 12/07/1990 3topped:

Laboratory Investigations:

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



Date 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 Gender: F Seq: 1 Reported: 30/11/1990 Weight: 76.00

Hospitalisation: Age: 71Y Onset Date: 31/10/1990 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

SINEQUAN (Suspected) Reason: Anxiety neurosis 25.0 Milligram Daily 3tarted: 01/01/1980 3atch: Stopped: 28/10/1990 Reason:

ALCOHOL (Suspected)

1.0 Dose Unspecified Daily

3atch: Started: Stopped:

Laboratory Investigations:

| Date | Туре | Range | Date Tested | Result | Details |
|------|--------------------------|-------|-------------|--------|---|
| | Haematology Histology | | | | 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 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.

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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: 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 Detai

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

Medicine Details:

SINEQUAN (Suspected) Reason: Depression

 Capsule
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/11/1990
 3topped:
 21/11/1990

Laboratory Investigations:

| Laborator | y mroongat | invoctigationo: | | | | | | |
|-----------|-------------|-----------------|-------------|--------|---|--|--|--|
| Date | Туре | 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: 2.401.69 -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) | | | |



Date 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

| 104011011 20141 | | | = |
|---------------------------|----------|--------------------|--|
| Preferred Term | Severity | Report Description | Treatment |
| Photosensitivity reaction | | | Ceased mysteclin & given oral prednisone |

Medicine Details:

| VENTOLIN (Other drug) | | Reason: | Asthma | | |
|-----------------------|---|-------------|-----------------|---------------|--------|
| | 1.0 Dose Unspec | ified As ne | cessary | | |
| Зatch: | Started: 01/01/1984 | | Stopped: | | CONTIN |
| BECOTIDE (Other drug) | | Reason: | Asthma | | |
| Inhalation | 4.0 Dose Unspec | ified Daily | | Inhalation | |
| 3atch: | Started: 01/01/1984 | | Stopped: | | CONTIN |
| OFFERAN (OIL I | | 3 | Coorific dicor | dore of cloop | |
| SEREPAX (Other drug) | | Reason: | Specific disord | acis oi sicch | |
| Tablet | 15.0 Milligram | Daily | Specific disort | Oral | |
| ` " | 15.0 Milligram 3tarted: 01/01/1984 | | Stopped: | | CONTIN |
| Tablet | ŭ | | Stopped: | | |
| Tablet 3atch: | ŭ | Daily | Stopped: | Oral | |

Laboratory Investigations:

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

Additional Information:

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

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

| Repo | ort D | etai |
|------|-------|------|
|------|-------|------|

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 Detai

| M | | ine | u | |
|---|--|-----|-------|--|

SINEQUAN (Suspected) Reason: Depression

25.0 Milligram Daily

3atch: 3tarted: 01/01/1980 3topped: 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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 46 of 307



Date 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 Detai

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

Medicine Details:

| KOLPON (Suspected) | | Reason: | Pain | |
|---|---|------------------|--------------------------------|--------|
| Tablet | 1.0 Dose Unspe | ecified Week | dy Vaginal | |
| 3atch: | Started: 12/09/1990 | | Stopped: | CONTIN |
| NOROXIN (Suspected) | | Reason: | Othr diseases of urinary tract | |
| | 800.0 Milligram | Daily | | |
| 3atch: | Started: 12/09/1990 | | Stopped: 17/09/1990 | |
| | | _ | _ | |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | Depression | |
| DOXEPIN HYDROCHLORIDE (Suspected) | 50.0 Milligram | Reason: Daily | Depression | |
| DOXEPIN HYDROCHLORIDE (Suspected) 3atch: | 50.0 Milligram 3tarted: 01/01/1985 | | Stopped: | CONTIN |
| , , , | · · | | · | CONTIN |
| 3atch: | · · | Daily | Stopped: | CONTIN |

Laboratory Investigations:

| Date | Туре | 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 combes 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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 47 of 307



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

| Rej | port | De | tail |
|-----|------|----|------|
|-----|------|----|------|

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 Detai

Medicine Details:

| ASPIRIN (Suspected) | र | leason: | |
|--------------------------|----------------------|------------------|--------|
| | 150.0 Milligram | Daily | |
| 3atch: | Started: | Stopped: | CONTIN |
| DIDYDID AMOUT (O | | | |
| DIPYRIDAMOLE (Suspected) | \$ | leason: | |
| DIPYRIDAMOLE (Suspected) | ع 200.0 Milligram | leason: Daily | |

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.

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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:
 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 Detai

| 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

3atch: Started: 01/11/1990 Stopped:

Laboratory Investigations:

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

Additional Information:

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

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

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 Detai

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

Medicine Details:

| LITHIUM CARBONATE (Suspected) | | | Reason: | | |
|-----------------------------------|------------------|----------------------|------------------|----------|--------------------|
| | 1.0 | Gram | Daily | | |
| 3atch: | Started: | | | Stopped: | 06/03/1990 |
| DOXEPIN HYDROCHLORIDE (Suspected) | | | Reason: | | |
| Tablet | 150.0 | Milligram | Daily | | Oral |
| 3atch: | Started: | | | Stopped: | 06/03/1990 |
| | | | | | |
| TRIFLUOPERAZINE HYDROCHLORIDE (St | uspected) | | Reason: | | |
| TRIFLUOPERAZINE HYDROCHLORIDE (Su | uspected) 5.0 | Milligram | Reason: Daily | | Oral |
| ` | • | Milligram | | Stopped: | Oral 06/03/1990 |
| Tablet | 5.0 | Milligram | | Stopped: | |
| Tablet 3atch: | 5.0 | Milligram Milligram | Daily | Stopped: | |

Laboratory Investigations:

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



Date 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 Detai

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

Medicine Details:

| TRANDATE (Other drug) | ; | Reason: | | |
|-------------------------------|--------------------------------------|------------------|------|--|
| | 600.0 Milligram | Daily | | |
| 3atch: | Started: 01/01/1980 | Stoppe | ed: | |
| NAPROSYN (Other drug) | ; | Reason: | | |
| Oral application | 500.0 Milligram | Daily | Oral | |
| 3atch: | Started: 01/01/1980 | Stoppe | ed: | |
| | | | | |
| ZYLOPRIM (Other drug) | ; | Reason: | | |
| ZYLOPRIM (Other drug) | 300.0 Milligram | Reason: Daily | | |
| ZYLOPRIM (Other drug) 3atch: | | | ed: | |
| , , | 300.0 Milligram Started: 01/01/1988 | Daily | ed: | |
| 3atch: | 300.0 Milligram Started: 01/01/1988 | Daily Stoppe | ed: | |

Laboratory Investigations:

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

Additional Information:

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

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

| Repo | ort D | etai |
|------|-------|------|
|------|-------|------|

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 Detai

Medicine Details:

 SINEQUAN (Suspected)
 Reason:
 Depression

 Oral application
 25.0 Milligram
 Daily
 Oral

 3atch:
 \$tarted:
 01/03/1991
 \$topped:
 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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 52 of 307



Date 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 Detai

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

Medicine Details:

| ENALAPRIL MALEATE (Suspected) | | Rea | son: | Essential ben | ign hypertension |
|-------------------------------|----------|------------------|-------|---------------|------------------|
| Tablet | 10.0 | Milligram | Daily | | Oral |
| 3atch: | Started: | | | Stopped: | 05/12/1990 |
| FRUSEMIDE (Suspected) | | Rea | son: | Essential ben | ign hypertension |
| Oral application | 40.0 | Milligram | Daily | | Oral |
| 3atch: | Started: | | | Stopped: | 05/12/1990 |
| SLOW-K (Suspected) | | Rea | son: | Alkalosis | |
| Tablet | 4.0 | Dose Unspecified | Daily | | Oral |
| 3atch: | Started: | | | Stopped: | 05/12/1990 |
| SINEQUAN (Suspected) | | Rea | son: | | |
| Oral application | 2.0 | Dose Unspecified | Daily | | Oral |
| 3atch: | Started: | | | Stopped: | 05/12/1990 |

Laboratory Investigations:

| | <u> </u> | | | | |
|------|--------------|-------|-------------|--------|---|
| Date | Туре | 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 |



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Case Number: | 70203 | Seq: 1 | | | | Gender: | F | |
|-------------------|---------------|----------|-------------|---------|---------------|---------------|-------------|----------|
| Reported: | 21/03/1991 | | | | | Weight: | | |
| lospitalisation: | | | | | | Age: | 92Y | |
| Onset Date: | | | | | | DOB: | | |
| Outcome: | Recovered | | | | C | ausality: | Causality p | oossible |
| eaction Detai | | | | | | | | |
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| Medicine Deta | aile | | | | | | | |
| ISORDIL (Suspecte | | | | Reason: | Chron isch he | art dis no hy | ner | |
| Tablet | , , | 30.0 | Milligram | Daily | | Oral | PO . | |
| 3atch: | | Started: | wiiiigrairi | Daily | Stopped: | 05/12/1990 |) | |
| Jaton. | | Jantea. | | | noppeu. | 03/12/1990 | | |
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| Laboratory In | vestigations: | | | | | | | |
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| Additional Info | ormation: | | | | | | | |
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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:
 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 Detai

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

Medicine Details:

| BURINEX (Other drug) | | Reason: | Essential benign hypertension |
|-----------------------------|---------------------|--------------|-------------------------------|
| | 2.0 Milligram | Daily | • |
| 3atch: | 3tarted: 04/05/1991 | | Stopped: |
| CARDIZEM (Other drug) | | Reason: | Essential benign hypertension |
| | 360.0 Milligram | Daily | • |
| 3atch: | 3tarted: 01/01/1991 | | Stopped: |
| CAPOTEN (Other drug) | | Reason: | Essential benign hypertension |
| | 25.0 Milligram | Daily | • |
| 3atch: | 3tarted: 01/01/1986 | | Stopped: |
| KINIDIN DURULES (Suspected) | | Reason: | |
| | 3.0 Dose Unspe | cified Daily | 1 |
| 3atch: | 3tarted: 15/06/1991 | | Stopped: 04/07/1991 |

Laboratory Investigations:

| Date | Туре | 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.

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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: 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 Detai

Medicine Details:

SINEQUAN (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 04/06/1991 3topped: 04/07/1991

Laboratory Investigations:

| | y mroonga. | | | | |
|------|--------------|----------------|-------------|--------|---------|
| Date | Туре | 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.

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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: 71597 Seq: 1 Gender: F

Reported: 19/07/1991 Weight:
Hospitalisation: Age: 62Y

Onset Date: 30/06/1991

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Detai

Medicine Details:

| Medicine Betails. | | | | |
|-----------------------------|----------------------------|---------------|-------------------------------|--|
| BURINEX (Other drug) | | Reason: | Essential benign hypertension | |
| | 2.0 Milligram | Daily | | |
| 3atch: | Started: 04/05/1991 | | Stopped: | |
| CARDIZEM (Other drug) | | Reason: | Essential benign hypertension | |
| | 360.0 Milligram | Daily | | |
| 3atch: | Started: 01/01/1991 | | Stopped: | |
| CAPOTEN (Other drug) | | Reason: | Essential benign hypertension | |
| | 25.0 Milligram | Daily | | |
| 3atch: | Started: 01/01/1986 | | Stopped: | |
| KINIDIN DURULES (Suspected) | | Reason: | | |
| | 3.0 Dose Unspe | ecified Daily | | |
| 3atch: | 3tarted: 15/06/1991 | | Stopped: 04/07/1991 | |

Laboratory Investigations:

| Date | Туре | Range | Date Tested | Result | Details |
|------|--------------|----------|-------------|--------|--|
| | GGT = SGGT = | 5-65 U/L | 19/07/1991 | 189 | |
| | GGT = SGGT = | 5-65 U/L | 07/07/1991 | 596 | |
| | GGT = SGGT = | 5-65 U/L | 05/07/1991 | 515 | |
| | ĜĜT = SGGT = | 5-65 U/L | 09/08/1991 | 74 | |
| | Other data | | | | 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. |

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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 57 of 307



Date 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

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Detai

Medicine Details:

SINEQUAN (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 04/06/1991 3topped: 04/07/1991

Laboratory Investigations:

| Date | Туре | 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.

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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: 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 Detai

| · (0401:0:: 2014: | | | |
|------------------------------|--------------------------|--------------------|-----------|
| 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 | | | Oral |
| 3atch: | Started: 11/03/1991 | | Stopped: | 19/04/1991 |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | | |
| Oral application | 20.0 Milligram | Daily | | Oral |
| Зatch: | Started: 01/01/1980 | | Stopped: | |
| SOLPRIN (Suspected) | | Reason: | | |
| Tablet | 125.0 Milligram | Daily | | Oral |
| 3atch: | 3tarted: 01/01/1989 | | Stopped: | |

Laboratory Investigations:

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

Additional Information:

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

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Date Range: 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 Detai

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

Medicine Details:

DEPTRAN (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: **3tarted**: 01/01/1986 **3topped**:

Laboratory Investigations:

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

Additional Information:

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

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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

| | | • | | 4 | |
|--------------|--------|---|---|-----|--|
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| R P | | | | -14 | |
| | \sim | | _ | eta | |

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 Detai

| · (oaotioii Dotai | | | |
|------------------------------|----------|--------------------|-----------|
| Preferred Term | Severity | Report Description | Treatment |
| Affect lability | | | |
| Agitation | | | |

Medicine Details:

| LIPEX (Suspected) | Reason: | | | |
|------------------------|-----------------|----------------------------|-------|----------|
| | 10.0 | Milligram | Daily | |
| 3atch: | Started: 30/ | 07/1991 | | Stopped: |
| SINEQUAN (Suspected) | | Reas | on: | |
| | 50.0 | Milligram | Daily | |
| 3atch: | Started: | L TERM | | Stopped: |
| NORMISON (Suspected) | | Reas | on: | |
| (ouspecteu) | | \cus | on. | |
| Northinoon (daspected) | 2.0 | Dose Unspecified | | |
| 3atch: | 2.0 Started: | | | Stopped: |
| , , , | | Dose Unspecified | Daily | Stopped: |
| 3atch: | Started: | Dose Unspecified L TERM | Daily | }topped: |

Laboratory Investigations:

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



Report Detail

Case Number: 73440

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

| Reported: 18/09/1991 | _ | | | | | |
|--|------------------|----------------------------------|------------|---|--------|--|
| ospitalisation: Onset Date: | | | | Age: 72Y DOB: | | |
| Onset Date: Outcome: Recovered | | | Car | יטסא: יו sality: Causality possil | hla | |
| eaction Detai | | | Cal | i santy. Causanty possii | DIE. | |
| Preferred Term | Severity | Report D | escription | Treatment | | |
| onstipation | 1 | | · · · | | | |
| icturition disorder | | | | | | |
| | | | | | | |
| edicine Details: DOXEPIN HYDROCHLORIDE (Susp | | Reason :) Milligram D | : aily | | | |
| 3atch: | Started: | , willingram | Stopped: | | | |
| | | | | | | |
| aboratory Investigation Date Type | S: Range Date Te | ested Result | | Details | | |
| раце туре | Range Date 16 | ested Result | | Details | | |
| Additional Information: | l | | | | | |
| oort Run 30/07/200 03:49PN D | atabase: pusime | ADF | 2S004 | Page 62 | of 307 | |



Date 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 Detai

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

Medicine Details:

ORTHOCLONE OKT3 (Suspected) Reason: Complicatins of transplant orgn

0.0

3atch: 3tarted: 28/09/1991 3topped:

IMURAN (Suspected) Reason:

0.0

 3atch:
 3tarted:
 3topped:
 30/09/1991

SANDIMMUN (Suspected) Reason: Complicates of transplant orgn

 Solution
 5.6 Millilitre
 Daily
 Oral

 3atch:
 3tarted:
 18/09/1991
 \$topped:
 30/09/1991

PREDNISOLONE (Suspected) Reason:

Tablet 30.0 Milligram Daily Oral

3atch: 3tarted: 16/09/1991 **3topped:** 30/09/1991

Laboratory Investigations:

| Date | Туре | Range | Date Tested | Result | Details |
|------|------------|-------|-------------|--------|--|
| | Other data | | | | Post martem revealed pneumontic consdidation. no bacteria seen. blood cultures: no growth. |

Additional Information:

Patient died on 30/09/1991.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 63 of 307



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

 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 Detai

Medicine Details:

| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | | |
|-----------------------------------|---------------------|---------|----------|------------|
| Capsule | 100.0 Milligram | Daily | | Oral |
| 3atch: | Started: 21/08/1991 | | Stopped: | 30/09/1991 |
| RANITIDINE (Suspected) | | Reason: | | |
| Tablet | 150.0 Milligram | Daily | | Oral |
| 3atch: | Started: 23/08/1991 | | Stopped: | 30/09/1991 |
| ACICLOVIR (Suspected) | | Reason: | | |
| | 400.0 Milligram | Daily | | |
| 3atch: | 3tarted: 23/09/1991 | | Stopped: | 26/09/1991 |

Laboratory Investigations:

Additional Information:

Patient died on 30/09/1991.



Date 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
Onset Date: 13/05/1991
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

| 104011011 20141 | | | |
|-----------------|----------|--------------------|------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Abdominal pain | | | |
| Constipation | | | Pethidine and ex-prep. |

Medicine Details:

| THYMOL (Suspected) | | Reason: | | | |
|-----------------------------------|---------------------|---------|---------------|-----------------|--------|
| Mouthwash | 0.0 | As n | ecessary | Buccal | |
| Зatch: | Started: | | Stopped: | | CONTIN |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | Depression | | |
| | 50.0 Milligram | Daily | 1 | | |
| Зatch: | Started: 01/04/1991 | | Stopped: | 13/05/1991 | |
| RANITIDINE (Suspected) | | Reason: | Other disease | es of esophagus | |
| | 600.0 Milligram | Daily | 1 | | |
| 3atch: | Started: | | Stopped: | | CONTIN |

Laboratory Investigations:

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

Additional Information:

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

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Date 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 Detai

| todotion Botal | | | |
|----------------------|----------|--------------------|-----------|
| 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 |
| Зatch: | 3tarted: 21/11/1991 | | Stopped: | 30/11/1991 |
| DEPTRAN (Suspected) | | Reason: | Pain | |
| Oral application | 150.0 Milligram | Daily | | Oral |
| Зatch: | 3tarted: 01/01/1990 | | Stopped: | |
| ZANTAC (Suspected) | | Reason: | Ulcer of duod | enum w/o ment perf |
| Tablet | 300.0 Milligram | Daily | | Oral |
| 3atch: | 3tarted: 01/01/1986 | | Stopped: | |
| EPILIM (Suspected) | | Reason: | Pain | |
| Oral application | 150.0 Milligram | Daily | | Oral |
| 3atch: | Started: 01/07/1990 | | Stopped: | |

Laboratory Investigations:

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

Additional Information:

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

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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: 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 Detai

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

Medicine Details:

SINEQUAN (Suspected) Reason: Depression

25.0 Milligram Daily

3atch: 3tarted: 07/08/1991 3topped: 09/12/1991

Laboratory Investigations:

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

Additional Information:

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

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 67 of 307



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

DOB:

Report Detail

Case Number: 75296 Seq: 1 Gender: F

Reported: 23/01/1992 **Weight:** 76.00 **Hospitalisation: Age:** 67Y

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Onset Date: 12/01/1992

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

Medicine Details:

| DILTIAZEM HYDROCHLORIDE (Suspected | d) | Reason: | Angina pectoris | 3 |
|------------------------------------|--------------------------------------|------------------|-----------------|---------------------------|
| Tablet | 120.0 Milligram | Daily | | Oral |
| Batch: | 3tarted: 04/01/1992 | | Stopped: | 12/01/1992 |
| SIMVASTATIN (Suspected) | | Reason: | Othr&unspec n | netabolic diseases |
| Tablet | 10.0 Milligram | Daily | | Oral |
| 3atch: | 3tarted: 01/01/1990 | | Stopped: | CONTIN |
| | | | | |
| CIMETIDINE (Suspected) | | Reason: | Ulcer of duode | num w/o ment perf |
| CIMETIDINE (Suspected) Tablet | 800.0 Milligram | Reason: Daily | Ulcer of duode | num w/o ment perf Oral |
| ` ' ' | 800.0 Milligram Started: 01/01/1990 | | Ulcer of duode | • |
| Tablet | · · | | | Oral |
| Tablet 3atch: | · · | Daily | | Oral |

Laboratory Investigations:

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

Additional Information:

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

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 68 of 307



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

Report Detail

Case Number: 75296 Seq: 1 Gender: F

Reported: 23/01/1992 Weight: 76.00 Hospitalisation: Age: 67Y

Onset Date: 12/01/1992 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

| SINEQUAN (Suspected) | | Reason: | Depression | |
|------------------------|---------------------|--------------|---------------------------|--------|
| Oral application | 75.0 Milligram | Daily | Oral | |
| 3atch: | 3tarted: 01/01/1990 | | Stopped: | CONTIN |
| NITRAZEPAM (Suspected) | | Reason: | Specific disorders of sle | еер |
| Tablet | 5.0 Milligram | Daily | Oral | |
| 3atch: | 3tarted: 01/01/1990 | | Stopped: | CONTIN |
| BECOTIDE (Suspected) | | Reason: | Asthma | |
| Inhalation | 200.0 Microgram | Daily | Inhalatio | on |
| 3atch: | Started: 01/01/1990 | | Stopped: | CONTIN |
| VENTOLIN (Suspected) | | Reason: | Asthma | |
| Inhalation | 8.0 Dose Unspe | cified Daily | Inhalatio | on |
| 3atch: | Started: 01/01/1990 | | 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. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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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

Case Number: 75296 Seq: 1 Gender: F
Reported: 23/01/1992 Weight: 76.00
Hospitalisation: Age: 67Y

Onset Date: 12/01/1992 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

 DIAZEPAM (Suspected)
 Reason:
 Specific disorders of sleep

 Oral application
 5.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/01/1990
 3topped:
 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. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

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Date Range: 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:

 Reported:
 06/02/1992
 Weight:

 Hospitalisation:
 Age: 57Y

 Onset Date:
 05/11/1991
 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

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

Medicine Details:

| modionio Botano. | | | | | | | |
|-----------------------------------|----------|------|-----------|-----------|-------|----------------------------|--------|
| ENALAPRIL MALEATE (Suspected) | | | | Reaso | n: | Essential benign hypertens | ion |
| | : | 5.0 | Milligram | I | Daily | | |
| Зatch: | Started: | 05/0 | 02/1990 | | | Stopped: | CONTIN |
| DOXEPIN HYDROCHLORIDE (Suspected) | | | | Reaso | n: | | |
| | 5 | 0.0 | Milligram | 1 | Daily | | |
| Зatch: | Started: | | | | | Stopped: | CONTIN |
| DYAZIDE (Suspected) | | | | Reaso | n: | Essential benign hypertens | ion |
| | | 1.0 | Dose Unsp | ecified I | Daily | | |
| Зatch: | Started: | 01/0 | 05/1989 | | | 3topped: 23/11/1991 | |

Laboratory Investigations:

| Date | Туре | 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.

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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 D | etai |
|----------|------|
|----------|------|

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 Detai

| 104011011 20141 | | _ | = |
|-----------------|------------|----------------------|-----------|
| Preferred Term | Severity | Report Description | Treatment |
| Hyperhidrosis | | Profuse diaphoresis. | |
| Tremor | Trembling. | | |

Medicine Details:

| PARACETAMOL (Other drug) | | Reason: | | | |
|-----------------------------------|---------------------|--------------|------------|--|--|
| | 1.0 Gram | As necessary | | | |
| 3atch: | Started: 03/06/1991 | Stopped: | | | |
| LACTULOSE (Other drug) | | Reason: | | | |
| | 20.0 Millilitre | Daily | | | |
| Зatch: | Started: 05/06/1991 | Stopped: | | | |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | | | |
| | 100.0 Milligram | Total | | | |
| 3atch: | 3tarted: 07/06/1991 | Stopped: | 09/06/1991 | | |

Laboratory Investigations:

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



Date 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 Detai

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

Medicine Details:

| ZYLOPRIM (Suspected) | Reason: Unspecified arthritis | |
|-----------------------|---|--|
| | 300.0 Milligram Daily | |
| 3atch: | Started: L TERM Stopped: 18/02/1992 | |
| MINIPRESS (Suspected) | Reason: Essential benign hypertension | |
| | 2.5 Milligram Daily | |
| Зatch: | Started: 01/01/1985 Stopped: | |
| SLOW-K (Suspected) | Reason: Essential benign hypertension | |
| | 1.0 Dose Unspecified Daily | |
| Зatch: | Started: 01/01/1985 Stopped: | |
| ECOTRIN (Suspected) | Reason: | |
| | 1.0 Dose Unspecified Daily | |
| Зatch: | Started: Stopped: 18/02/1992 | |

Laboratory Investigations:

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

Additional Information:

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

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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

 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 Detai

Medicine Details:

MODURETIC (Suspected)

1.0 Dose Unspecified Daily

3atch: Started: 01/01/1985 Stopped:

DEPTRAN (Suspected)

Reason: Specific disorders of sleep

1.0 Dose Unspecified Daily

3atch: 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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 74 of 307



Date 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

| todotion Botal | | E | |
|----------------|----------|--------------------|---------------|
| 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

 3atch:
 3tarted:
 01/01/1992
 3topped:
 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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 75 of 307



Date 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 Detai

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

Medicine Details:

| STEMETIL (Suspected) | Reason: Nausea and vomiting |
|---|--|
| Injection | 12.5 Milligram As necessary Intramuscular |
| 3atch: | Started: 10/02/1992 Stopped: |
| PANADOL (Suspected) | Reason: Other disturbance of sensation |
| Oral application | 2.0 Dose Unspecified As necessary Oral |
| 3atch: | Started: 10/02/1992 Stopped: |
| | |
| BACTRIM DS (Suspected) | Reason: |
| BACTRIM DS (Suspected) Oral application | Reason: 2.0 Dose Unspecified Daily Oral |
| ` ' ' | |
| Oral application | 2.0 Dose Unspecified Daily Oral |
| Oral application 3atch: | 2.0 Dose Unspecified Daily Oral Started: 10/02/1992 Stopped: 13/02/1992 |

Laboratory Investigations:

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



Case Number: 75719

Reported: 13/02/1992

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: M

Weight: 85.00

| Onset Date: 13/02/1992 Outcome: Not yet recovered eaction Detai | | | Age: (DOB: Causality: (| 64Y Causality possi | ble |
|---|---------------------|---------|--------------------------------|------------------------|--------|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| ledicine Details: NAPROSYN (Suspected) | | Reason: | Unspecified arthritis | | |
| Oral application | 500.0 Milligram | Daily | Oral | | |
| Batch: | 3tarted: 10/02/1992 | Dany | Stopped: | | |
| MPRACE (Suspected) | | Reason: | Essential benign hypertensi | on | |
| Tablet | 5.0 Milligram | Daily | | | |
| 3atch: | Started: 10/02/1992 | , | Stopped: | | |
| aboratory Investigations: | | | | | |
| dditional Information: | | | | | |
| ort Run 30/07/200 03:49PN Databas | e: pusime | ADRS00 |)4 | Page 77 | of 307 |



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

| Report | Detai∣ |
|--------|--------|
|--------|--------|

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 Detai

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

Medicine Details:

| DEPTRAN (Suspected) | Reason: | |
|----------------------|------------------------------|--|
| | 100.0 Milligram Daily | |
| 3atch: | Started: 19/02/1992 Stopped: | |
| TEGRETOL (Suspected) | Reason: | |

 400.0
 Milligram
 Daily

 3atch:
 \$tarted:
 19/02/1992
 \$topped:

Laboratory Investigations:

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



Date 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 Detai

| · ···································· | | _ | <u> </u> |
|--|----------|--------------------|------------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Aggression | | | |
| Confusional state | | | Valium 10mg im, rivotril 2mg |
| Dementia | | | |
| Dry mouth | | | |
| Tachycardia | | | |

Medicine Details:

| TOBRAMYCIN (Other drug) | Reason: Keratitis no mention of ulcer |
|--------------------------------|---|
| | 12.0 Dose Unspecified Daily |
| 3atch: | Started: 31/03/1992 Stopped: 09/04/1992 |
| CEPHAZOLIN SODIUM (Other drug) | Reason: Keratitis no mention of ulcer |
| | 12.0 Dose Unspecified Daily |
| 3atch: | Started : 31/03/1992 Stopped : 09/04/1992 |
| ATROPINE (Suspected) | Reason: Keratitis no mention of ulcer |
| | 2.0 Dose Unspecified Daily |
| 3atch: | Started: 31/03/1992 Stopped: 02/04/1992 |
| PLENDIL (Suspected) | Reason: Essential benign hypertension |
| Tablet | 2.5 Milligram Daily Oral |
| 3atch: | Started : 31/03/1992 Stopped : 03/04/1992 |

Laboratory Investigations:

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



Case Number: 76649

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: F

| Reported: | 10/04/1992 | | | | Weight: 61. | 00 | |
|--------------------|----------------|-----------------|---------|---------------|---------------------|---------------|--------|
| Hospitalisation: | | | | | Age : 75 | (| |
| Onset Date: | 02/04/1992 | | | | DOB: | | |
| Outcome: | Recovered | | | C | ausality: Ca | usality possi | ible |
| Reaction Deta | i | | | | | | |
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| Medicine Det | | | | | | | |
| RENITEC (Suspec | cted) | | Reason: | Essential ben | ign hypertension | | |
| Tablet | | 5.0 Milligram | Daily | | Oral | | |
| 3atch: | | 31/03/1992 | | Stopped: | 03/04/1992 | | |
| SINEQUAN (Susp | | | Reason: | Anxiety neuro | | | |
| Oral applic | cation | 150.0 Milligram | Daily | | Oral | | |
| 3atch: | | 31/03/1992 | | Stopped: | 03/04/1992 | | |
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| Laboratory in | vestigations: | | | | | | |
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| Additional In | formation: | | | | | | |
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| eport Run 30/07/20 | 0 03:49PN Data | abase: pusime | ADRS00 |)4 | | Page 80 | of 207 |



Case Number: 76987

Reported: 13/05/1992

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: M

Weight: 85.00

| Onset Date: 01/05/199 Outcome: Unknown | | | | | Age: 27 | |
|--|----------------|--------------|--------|-------------|---------------|------------------|
| Outcome: Unknown | | | | | DOB: | |
| | l | | | 1 | Causality: Ca | usality probable |
| action Detai | | | | | <u> </u> | |
| Preferred Term | Seve | erity | Report | Description | | Treatment |
| onstipation | | | | | | |
| y mouth | | | | | | |
| ntigue | | | | | | |
| omnolence | | | | | | |
| | | | | | | |
| edicine Details: | (2) | | | | | |
| OOXEPIN HYDROCHLORIDE (| (Suspected) | 0.0 | Reaso | on: | | |
| 3atch: | 240 | 0.0 rted: | | Stopped: | | |
| Saton: METHADONE HYDROCHLORI | | rtea: | Reaso | | | |
| Tablet | DE (Suspecteu) | 45.0 Mill | | Daily | Oral | |
| 3atch: | | rted: | igram | Stopped: | Olai | |
| | | | | | | |
| aboratory Investigat | tions: | | | | | |
| aboratory Investigate Date Type | Range | Date Tested | Result | | Details | |
| aboratory Investigat Date Type dditional Information | Range | Date Tested | Result | | Details | |



Date 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 Detai

| todotion Botal | | _ | |
|----------------|----------|--------------------|--|
| Preferred Term | Severity | Report Description | Treatment |
| Psoriasis | | | Metoprolol ceased, nifedipine,20 mg twice daily |

Medicine Details:

| PANADOL (Suspected) | | Reason: | Pain | | |
|---|---------------------|------------------|----------------------|------------------|--------|
| Tablet | 500.0 Milligram | As ne | ecessary | Oral | |
| 3atch: | Started: | | Stopped: | | CONTIN |
| METOPROLOL TARTRATE (Suspected) | | Reason: | Essential beni | ign hypertension | |
| Oral application | 100.0 Milligram | Daily | | Oral | |
| 3atch: | Started: 20/11/1991 | | Stopped: | 24/01/1992 | |
| | | | | | |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | Depression | | |
| DOXEPIN HYDROCHLORIDE (Suspected) Oral application | 25.0 Milligram | Reason: Daily | Depression | Oral | |
| ` ' ' | 25.0 Milligram | | Depression Stopped: | Oral | CONTIN |
| Oral application | 3 - | | · | | CONTIN |
| Oral application 3atch: | 3 - | Daily | Stopped: | | CONTIN |

Laboratory Investigations:

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



Date 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 Detai

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

Medicine Details:

 MESALAZINE (Suspected)
 Reason:
 Ulcerative colitis

 Tablet
 1.5 Gram
 Daily
 Oral

 3atch:
 3tarted:
 18/05/1992
 3topped:
 CONTIN

DOXEPIN HYDROCHLORIDE (Suspected) Reason: Specific disorders of sleep

Oral application 25.0 Milligram Daily Oral **3atch: 3tarted:** 01/01/1991 **3topped:**

Laboratory Investigations:

| Date | Туре | 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.

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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: 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--------------------|--|
| Fielelieu Tellii | Seventy | Report Description | Healment |
| Bradycardia | | | |
| Hyperkalaemia | | | |
| Syncope | | | lv dextrose and insulin. isoprenaline infusion |

Medicine Details:

| TRANSIDERM-NITRO (Other drug) | | Reason: | | |
|-----------------------------------|---------------------|--------------|----------------|------------------|
| Cream | 1.0 Dose Unspe | cified Daily | | Topical |
| 3atch: | Started: 01/05/1992 | | Stopped: | CONTIN |
| RENITEC (Suspected) | | Reason: | Essential beni | gn hypertension |
| Tablet | 10.0 Gram | Daily | | Oral |
| 3atch: | 3tarted: 01/05/1992 | | Stopped: | 06/08/1992 |
| VERAPAMIL HYDROCHLORIDE (Suspecto | ed) | Reason: | Essential beni | gn hypertension |
| Tablet | 320.0 Gram | Daily | | Oral |
| 3atch: | 3tarted: 01/05/1992 | | Stopped: | 06/08/1992 |
| DYAZIDE (Suspected) | | Reason: | Essential beni | ign hypertension |
| Tablet | 2.0 Dose Unspe | cified Daily | | Oral |
| 3atch: | 3tarted: 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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 84 of 307



Date 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 S | Seq: 1 | | | | Gender: | F |
| | 14/08/1992 | • | | | | Weight: | 60.00 |
| Hospitalisation: | | | | | | Age: | 82Y |
| Onset Date: | 06/08/1992 | | | | | DOB: | |
| Outcome: | Recovered | | | | C | Causality: | Causality possible |
| Reaction Detai | | | | | | | |
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| Medicine Deta | AIIS: CHLORIDE (Suspected | ` | Reas | on: | Disturbance o | of sloop | |
| Tablet | SHEORIDE (Suspected | | Milligram | Daily | Disturbance C | Oral | |
| 3atch: | | Started: | L TERM | | Stopped: | | 2 |
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| Laboratory In | vestigations: | | | | | | |
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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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 85 of 307



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

| Repo | ort D | etai |
|------|-------|------|
|------|-------|------|

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 Detai

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

Medicine Details:

| ROHYPNOL (Other drug) | | Reason: | Specific disor | ders of sleep | |
|-----------------------|---------------------|---------|----------------|---------------|--------|
| Tablet | 2.0 Milligram | Daily | | Oral | |
| 3atch: | Started: | L TERM | Stopped: | | CONTIN |
| ORUDIS SR (Suspected) | | Reason: | Osteoarthritis | | |
| Capsule | 200.0 Milligram | Daily | | Oral | |
| 3atch: | Started: 02/09/1992 | | Stopped: | 04/09/1992 | |
| SINEQUAN (Suspected) | | Reason: | Depression | | |
| Tablet | 25.0 Milligram | Daily | | Oral | |
| 3atch: | Started: 19/11/1991 | | Stopped: | | CONTIN |

Laboratory Investigations:

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



Date 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 Detai

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

Medicine Details:

| PREMARIN (Suspected) | | Reas | on: | |
|----------------------|----------|--------------------|--------------|--|
| | 0. | 0 | | |
| 3atch: | Started: | L TERM | Stopped: | |
| PROVERA (Suspected) | | Reas | on: | |
| | 0. | 0 | | |
| Зatch: | Started: | L TERM | Stopped: | |
| VALIUM (Suspected) | | Reas | on: | |
| | 1. | 0 Dose Unspecified | As necessary | |
| Заtch: | Started: | | Stopped: | |
| MOGADON (Suspected) | | Reas | on: | |
| | 1. | 0 Dose Unspecified | As necessary | |
| 3atch: | Started: | | Stopped: | |

Laboratory Investigations:

| Date | Туре | 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.



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

| Report Deta | İ |
|-------------|---|
|-------------|---|

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 Detai

Medicine Details:

| Medicine Details: | | | | | | |
|-----------------------|-----------------------------------|------------------------|------------|--|--|--|
| SINEQUAN (Suspected) | Reason: | | | | | |
| | 1.0 Dose Unspecified As necessary | | | | | |
| 3atch: | Started: | Stopped: | | | | |
| ORUDIS SR (Suspected) | | Reason: Osteoarthritis | | | | |
| Capsule | 200.0 Milligram | Daily | Oral | | | |
| 3atch: | 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.

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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:
 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 Detai

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

Medicine Details:

| CAPOTEN (Suspected) | | | | Reaso | n: | Congestive heart failure | |
|--------------------------|----------|------|------------|--------|-------|--------------------------------|--------|
| Tablet | 5 | 0.0 | Milligram | | Daily | Oral | |
| Зatch: | Started: | 03/ | /06/1992 | | | Stopped: | CONTIN |
| LASIX (Suspected) | | | | ₹easo | n: | Congestive heart failure | |
| Tablet | 8 | 30.0 | Milligram | | Daily | Oral | |
| Зatch: | Started: | 03/ | /06/1992 | | | Stopped: | CONTIN |
| SLOW-K (Suspected) | | | | ₹easo | n: | Congestive heart failure | |
| Tablet, modified release | | 2.0 | Dose Unspe | cified | Daily | Oral | |
| Зatch: | Started: | 03/ | /06/1992 | | | Stopped: | CONTIN |
| DIGOXIN (Suspected) | | | | Reaso | n: | Otr&nos disord of heart rhythi | m |
| Tablet | | 1.0 | Dose Unspe | cified | Daily | Oral | |
| Зatch: | Started: | 19/ | /06/1992 | | | Stopped: | CONTIN |

Laboratory Investigations:

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Case Number: 7 | 79337 | Seq: 1 | | | | Gender: | M | |
|----------------------|--------------|----------|-----------|---------|------------|------------|------------------|-----|
| Reported: 2 | 26/06/1992 | | | | | Weight: | 92.00 | |
| Hospitalisation: | | | | | | Age: | 67Y | |
| Onset Date: 2 | 24/06/1992 | | | | | DOB: | | |
| Outcome: F | Recovered | | | | (| Causality: | Causality possib | ole |
| Reaction Detai | | | | | | | | |
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| Medicine Deta | ils: | | | | | | | |
| SINEQUAN (Suspec | | | | Reason: | Depression | | | |
| Capsule | | 25.0 | Milligram | Daily | | Oral | | |
| 3atch: | | Started: | | | Stopped: | | CONTIN | |
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| Laboratory Inv | estigations: | | | | | | | |
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| Additional Info | rmation: | | | | | | | |
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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: 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 Detai

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

Medicine Details:

| LITHIUM CARBONATE (Suspected) | | | Reason: | Unspecifid affective psychosi | s |
|-----------------------------------|---------------|-----------|---------|-------------------------------|--------|
| | 1.0 | Gram | Daily | | |
| Зatch: | Started: | | | Stopped: | CONTIN |
| DOXEPIN HYDROCHLORIDE (Suspected) | | | Reason: | | |
| | 150.0 | Milligram | Daily | | |
| Зatch: | 3tarted: 20/0 | 2/1992 | | Stopped: | CONTIN |
| THIAMINE (Suspected) | | | Reason: | | |
| | 100.0 | Milligram | Daily | | |
| 3atch: | 3tarted: 15/0 | 2/1992 | | Stopped: | CONTIN |

Laboratory Investigations:

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

Additional Information:

Cystic lesions on face.



Date 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 Detai

| 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

 3atch:
 3tarted:
 16/01/1992
 3topped:
 08/09/1992

Laboratory Investigations:

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

Additional Information:

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

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 92 of 307



Date 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 Detai

| 104011011 20141 | | - | - |
|---------------------|----------|--------------------|-----------|
| Preferred Term | Severity | Report Description | Treatment |
| Rash maculo-papular | | | |

Medicine Details:

SINEQUAN (Suspected) Reason: Depression

20.0 Milligram Daily

3atch: 3tarted: 12/06/1992 3topped:

Laboratory Investigations:

| Date | Туре | 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.



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

| Report Detail | il | | | | | | | |
|-------------------------------|------------------|--|------------|-----------------|--------|----------------|-----------------|---|
| Hospitalisation Onset Date | : 04/11/199 : | 92 | 1 | | | c | Weig A Do | der: M ght: .ge: 77Y OB: lity: Causality possible |
| Reaction Deta | = | | | | | _ | | |
| | ed Term | Sev | erity | Repor | Desc | cription | | Treatment |
| Duodenal ulcer | | | - | • | | • | | |
| Gastric ulcer | | | | | | | | |
| Oesophagitis | | | | | | | | Omeprazole, gaviscon, |
| Oesophagitis ul | cerative | | | | | | | transfused 2 units packed cells |
| Modicino Do | taile | | | | | | | |
| Medicine De KETOROLAC (SI | | | | Reas | on. | | | |
| Injection | aopootou, | | 30.0 N | | 4 time | es | Intran | nuscular |
| 3atch: | | 3ta | rted: | J - | | Stopped: | 01/11 | |
| ASPIRIN SOLUB | LE (Suspecte | d) | | Reas | on: | Transient cere | eb isch | no hypert |
| Tablet | | | 1.0 D | ose Unspecified | Daily | | Oral | |
| 3atch: | | 3ta | rted: | | | Stopped: | | |
| ZYLOPRIM (Susp | pected) | | | Reas | | | | |
| Tablet 3atch: | | 240 | 1.0 D | ose Unspecified | Daily | \\ | Oral | |
| DOXEPIN HYDRO | OCHI ORIDE (| | rteu. | Reas | on. | Stopped: | | |
| Capsule | JOINEON DE (| ouspecteu) | 25.0 N | | Daily | | Oral | |
| 3atch: | | 3ta | rted: | J - | - , | Stopped: | | |
| l abayataw. I | n rooting | ······································ | | | | | | |
| Laboratory I | Type | Range | Date Teste | d Result | | | | Details |
| I | | | | | | | | |
| Additional Ir | nformatio | on: | | | | | | |



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Case Number: | 80701 | Seq: 1 | | | Gender: M | 1 | |
|------------------|-------------------|-------------|--|---------|--------------|-----------------|-----|
| Reported: | 04/11/1992 | - | | | Weight: | | |
| Hospitalisation: | | | | | Age: 7 | 7Y | |
| Onset Date: | 01/11/1992 | | | | DOB: | | |
| Outcome: | Not yet recovered | t | | | Causality: C | ausality possil | ble |
| Reaction Detai | | | | | | | |
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| | | | | | | | |
| Medicine Deta | | | | | | | |
| FRAGMIN (Suspec | ted) | | | ison: | | | |
| Injection | | | 5.0 Thousand Interna | | Subcutaneou: | S | |
| 3atch: | | Started | <u>: </u> | Stopped | l : | | |
| | | | | | | | |
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| Laboratory In | vestigations: | | | | | | |
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| Additional Inf | ormation: | | | | | | |
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| | 03:40PN Datak | aso: nusimo | | ADDS004 | | | |

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THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Repor | ber: 80863 | Seq: | 1 | | | Gender: F | |
|-------------------------------|---------------------------------|-------------|---------------------|---------|----------------|------------------------|---------|
| - | ted: 11/11/19 | 92 | | | | Weight: | |
| ospitalisat | | | | | | Age: AD | |
| Onset D | | | | | | DOB: | |
| | me: Recovere | ed | | | С | ausality: Causality po | ossible |
| eaction D | | | | | _ | 1 | |
| | eferred Term | Sev | erity | Repor | Description | Treatme | ent |
|)yspepsia | | | | | | Losec | |
| | | | | | | | |
| ledicine PROVERA (C | | | | Reas | | | |
| | | | 10.0 Mil | ligram | Daily | | |
| 3atch | | 3ta | arted: | _ | Stopped: | | |
| PREMARIN (| Other drug) | | 605.0 14 | Reas | | | |
| 3atch | n· | 24. | 625.0 Mid arted: | crogram | Daily Stopped: | | |
| ZANTAC (Ot | | 310 | | Reas | | | |
| | - ~3/ | | 300.0 Mil | | Daily | | |
| 3atch | 1: | Sta | arted: | - | Stopped: | | |
| FELDENE (O | ther drug) | | | Reas | | | |
| | | | 20.0 Mil | ligram | Daily | | |
| 3atch: | | 3ta | arted: | | Stopped: | | |
| 3atch | | | | | | | |
| | v Investina | tions: | | | | | |
| | ry Investiga _{Type} | Range | Date Tested | Result | | Details | |



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Case Number: Reported: Hospitalisation: Onset Date: Outcome: Reaction Detai | 11/11/1992 Recovered | Seq: 1 | | | Gender: Weight: Age: DOB: Causality: | | |
|--|-------------------------|--------|-----------|---------|--|----|---|
| Medicine Deta | | | | | | | _ |
| DEPTRAN (Suspec | cted) | | | Reason: | | | |
| 3atch: | | 150.0 | Milligram | Daily | Stopped: | 2Y | |
| Jaten. | | Janea. | | | Moppeu. | 21 | |
| Laboratory In | vestigations: | | | | | | |
| Additional Inf | ormation: | | | | | | |

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 97 of 307



Date 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 Detai

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

Medicine Details:

| RULIDE (Suspected) | | Reason: | |
|---------------------|---------------------|--------------------------------|---------|
| | 300.0 Milligram | Daily | |
| 3atch: | Started: 28/10/1992 | Stopped: 02/ | 11/1992 |
| DOLOBID (Suspected) | | Reason: Unspecified arthritis | 3 |
| | 1.0 Gram | Daily | |
| 3atch: | Started: 01/01/1990 | Stopped: | CONTIN |
| DEPTRAN (Suspected) | | Reason: Depression | |
| | 100.0 Milligram | Daily | |
| 3atch: | Started: 01/01/1990 | Stopped: | CONTIN |
| BURINEX (Suspected) | | Reason: Left ventricular failu | ıre |
| | 1.0 Milligram | Daily | |
| | | | |

Laboratory Investigations:

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

Additional Information:

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

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 98 of 307



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

| Report Detail | | | | | | |
|--|-----------------------|---|---|---|--|--|
| Case Number: Reported: Hospitalisation: Onset Date: | 11/11/1992 | Seq: 1 | | | Gender: Weight: Age: DOB: | 72.00 |
| | Not yet recovered | d | | | | Causality possible |
| Reaction Detai | | | | | • | , , |
| | | | | | | |
| Medicine Deta | aile: | | | | | |
| SPAN-K (Suspecte | | | | Reason: | | |
| | | 60 | 0.0 Milligram | Daily | | |
| 3atch: | | Started: | 01/01/1985 | | Stopped: | CONTIN |
| | | | | | | |
| Laboratory In | vestigations: | | | | | |
| Additional Inf the dosage start da accurate but indica occurred sometime year. | ate is not accurate b | ut indicates ed sometime e dosage sta | that start occurr e during the yea art date is not ac | ed sometime r. the dosage ccurate but inc | during the year. the do start date is not accur licates that start occur | osage start date is not ate but indicates that start red sometime during the |

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 99 of 307



Date 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 Detai

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

Medicine Details:

SINEQUAN (Suspected)

Capsule

1.0 Dose Unspecified Daily

Oral

Batch: Started: Stopped:

Laboratory Investigations:

| Date | Туре | 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 |



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

Case Number:81768Seq:1Gender:MReported:18/12/1992Weight:78.00Hospitalisation:Admitted to hospitalAge:63Y

Onset Date: 08/12/1992 DOB:

Outcome: Death, maybe drug Causality: Causality possible

Reaction Detai

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

Medicine Details:

| DOXEPIN HYDROCHLORIDE (Suspected) | • | | Reason: | | |
|-----------------------------------|----------|------------|---------|----------|------|
| Tablet | | 0.0 | | | Oral |
| Зatch: | Started: | 07/12/1992 | | Stopped: | |
| DIGOXIN (Suspected) | | | Reason: | | |
| | | 0.0 | | | |
| Зatch: | Started: | 07/12/1992 | | Stopped: | |
| CIPROXIN (Suspected) | | | Reason: | | |
| Tablet | | 1.0 Gram | Total | | Oral |
| 3atch: | Started: | 07/12/1992 | | Stopped: | |

Laboratory Investigations:

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



Date 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 Detai

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

Medicine Details:

| VALIUM (Other drug) | | Reason: | Anxiety neuro | sis | |
|-----------------------|---------------------|-------------|---------------|------------------|--------|
| Tablet | 20.0 Milligram | Daily | | Oral | |
| 3atch: | Started: 01/01/1980 | | Stopped: | | CONTIN |
| MODURETIC (Suspected) | | Reason: | Essential ben | ign hypertension | |
| Tablet | 1.0 Dose Unspec | ified Daily | | Oral | |
| 3atch: | Started: 16/12/1992 | | Stopped: | 22/12/1992 | |
| SINEQUAN (Suspected) | | Reason: | Depression | | |
| | 175.0 Milligram | Daily | | | |
| 3atch: | Started: 15/11/1992 | | Stopped: | 24/12/1992 | |

Laboratory Investigations:

| Date | Туре | 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.

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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: 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 Detai

Medicine Details:

| VALIUM (Other drug) | | Reason: | Anxiety neuro | osis | |
|-----------------------|---------------------|--------------|---------------|------------------|--------|
| Tablet | 20.0 Milligram | Daily | | Oral | |
| 3atch: | Started: 01/01/1980 | | Stopped: | | CONTIN |
| MODURETIC (Suspected) | | Reason: | Essential ben | ign hypertension | |
| Tablet | 1.0 Dose Unspec | cified Daily | | Oral | |
| 3atch: | Started: 16/12/1992 | | Stopped: | 22/12/1992 | |
| SINEQUAN (Suspected) | | Reason: | Depression | | |
| | 175.0 Milligram | Daily | | | |
| 3atch: | Started: 15/11/1992 | | Stopped: | 24/12/1992 | |

Laboratory Investigations:

| Date | Туре | Range | Date Tested | Result | Details |
|------|--------------|-----------|-------------|--------|---|
| | Creatinine | 0.06-0.13 | 07/12/1992 | 0.093 | |
| | Creatinine | 0.06-0.13 | 22/12/1992 | 0.093 | |
| | Creatinine | 0.06-0.13 | 23/12/1992 | 0.093 | |
| | Creatinine | 0.06-0.13 | 30/12/1992 | 0.069 | |
| | Creatinine | 0.06-0.13 | 04/01/1993 | 0.075 | |
| | Electrolytes | | | | Serum osmolarity 24/12/92 - 265 (range 285-295) |
| | Potassium | 3.4-4.8 | 02/07/1992 | 5.0 | |

Additional Information:

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

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 103 of 307



Date 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 Detai

Medicine Details:

| VALIUM (Other drug) | | Reason: | Anxiety neuro | sis | |
|-----------------------|---------------------|--------------|---------------|------------------|--------|
| Tablet | 20.0 Milligram | Daily | | Oral | |
| 3atch: | Started: 01/01/1980 | | Stopped: | | CONTIN |
| MODURETIC (Suspected) | | Reason: | Essential ben | ign hypertension | |
| Tablet | 1.0 Dose Unspec | cified Daily | | Oral | |
| 3atch: | Started: 16/12/1992 | | Stopped: | 22/12/1992 | |
| SINEQUAN (Suspected) | | Reason: | Depression | | |
| | 175.0 Milligram | Daily | | | |
| 3atch: | Started: 15/11/1992 | | Stopped: | 24/12/1992 | |

Laboratory Investigations:

| Date | Туре | 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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 104 of 307



Date 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 Detai

Medicine Details:

| modicino Botano. | | | | | |
|-----------------------|---------------------|-------------|---------------|------------------|--------|
| VALIUM (Other drug) | | Reason: | Anxiety neuro | sis | |
| Tablet | 20.0 Milligram | Daily | | Oral | |
| 3atch: | Started: 01/01/1980 | | Stopped: | | CONTIN |
| MODURETIC (Suspected) | | Reason: | Essential ben | ign hypertension | |
| Tablet | 1.0 Dose Unspec | ified Daily | | Oral | |
| 3atch: | Started: 16/12/1992 | | Stopped: | 22/12/1992 | |
| SINEQUAN (Suspected) | | Reason: | Depression | | |
| | 175.0 Milligram | Daily | | | |
| 3atch: | Started: 15/11/1992 | | Stopped: | 24/12/1992 | |

Laboratory Investigations:

| Date | Туре | 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.

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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: 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 Detai

Medicine Details:

| VALIUM (Other drug) | | Reason: | Anxiety neuro | sis | |
|-----------------------|---------------------|--------------|---------------|------------------|--------|
| Tablet | 20.0 Milligram | Daily | | Oral | |
| 3atch: | Started: 01/01/1980 | | Stopped: | | CONTIN |
| MODURETIC (Suspected) | | Reason: | Essential ben | ign hypertensior | 1 |
| Tablet | 1.0 Dose Unspe | cified Daily | | Oral | |
| 3atch: | Started: 16/12/1992 | | Stopped: | 22/12/1992 | |
| SINEQUAN (Suspected) | | Reason: | Depression | | |
| | 175.0 Milligram | Daily | | | |
| 3atch: | Started: 15/11/1992 | | Stopped: | 24/12/1992 | |

Laboratory Investigations:

| Date | Туре | 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.

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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

| Case Number: 82395 Seq: 1 Reported: 02/02/1993 Ospitalisation: Admitted to hospital Onset Date: 06/01/1993 Outcome: Recovered | | | | Gender: F Weight: 60.00 Age: 49Y DOB: Causality: Causality possible | | | | |
|---|--|--------|-------------|---|-------|----------|------|-----------|
| | ferred Term | Sev | erity | Report | Descr | iption | | Treatment |
| latulence Diarrhoea eus | | | Diste | nded abdome | en. | | | |
| | | | | | | | | |
| ledicine ORUDIS (Oth | | | | ₹eas | on: | | | |
| Caps | | | 200.0 Milli | | Daily | | Oral | |
| 3atch | | Sta | rted: | J. 4111 | Juny | Stopped: | Oiui | |
| OGEN (Other | | | | Reas | on: | | | |
| ` Table | | | 2.0 Dos | e Unspecified | Daily | | Oral | |
| 3atch | n: | Sta | rted: | | | Stopped: | | |
| DEPTRAN (S | uspected) | | | Reas | on: | | | |
| Caps | sule | | 25.0 Milli | gram | Daily | | Oral | |
| 3atch | n: | Sta | rted: | L TERM | | Stopped: | | |
| .aborator | 'y Investiga ^{Type} | tions: | Date Tested | Result | | | | Details |
| | | | | | | | | |
| | | | | | | | | |



Date 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 Detai

| 100000000000000000000000000000000000000 | | | - |
|---|----------|--------------------|-----------------|
| Preferred Term | Severity | Report Description | Treatment |
| Blood alkaline phosphatase incre | | | |
| Confusional state | | | |
| Neutropenia | | | Antibiotics iv. |
| Vomiting | | | |

Medicine Details:

DOXEPIN HYDROCHLORIDE (Suspected) Reason:

25.0 Milligram Daily

3atch: 3tarted: 01/06/1992 3topped: 16/07/1992

Laboratory Investigations:

| Date | Туре | 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.

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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:
 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 Detai

Medicine Details:

DOXEPIN HYDROCHLORIDE (Suspected) Reason:

25.0 Milligram Daily

3atch: 3tarted: 01/06/1992 **3topped:** 16/07/1992

Laboratory Investigations:

| Date | Туре | Range | Date Tested | Result | Details |
|------|-------------------|----------|-------------|--------|---------|
| | SAP = ALP | 35 - 135 | 22/07/1992 | 238 | |
| | SAP = ALP | 35 - 135 | 27/07/1992 | 195 | |
| | SAP = ALP | 35 - 135 | 19/07/1992 | 291 | |
| | White blood cells | 4 - 11 | 14/05/1992 | 6.6 | |
| | White blood cells | 4 - 11 | 16/07/1992 | 0.9 | |
| | White blood cells | 4 - 11 | 19/07/1992 | 1.4 | |
| | White blood cells | 4 - 11 | 22/07/1992 | 4.6 | |

Additional Information:

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

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 109 of 307



Date 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 Detai

Medicine Details:

DOXEPIN HYDROCHLORIDE (Suspected) Reason:

25.0 Milligram Daily

3atch: 3tarted: 01/06/1992 **3topped:** 16/07/1992

Laboratory Investigations:

| Date | Туре | 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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 110 of 307



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| - | | | | | | |
|------------------|-------------------|----------|-----------|----------------|------------|--------------------|
| Case Number: | 83578 | Seq: 1 | | | Gender: | F |
| Reported: | 25/03/1993 | | | | Weight: | |
| Hospitalisation: | | | | | _ | 69Y |
| Onset Date: | 03/06/1992 | | | | DOB: | |
| | Not yet recovered | d | | | Causality: | Causality possible |
| Reaction Detai | - | | | | | , , , |
| Preferre | | Severity | F | Report Descrip | otion | Treatment |
| Rash | | | | | | |
| Medicine Deta | ails: | | | | | |
| PREDNISOLONE (| | | | Reason: | | |
| | | 10.0 | Milligram | Daily | | |
| 3atch: | | Started: | | | Stopped: | |

OMEPRAZOLE (Suspected) Reason:

Reason: Other diseases of esophagus 20.0 Milligram Daily

Stopped:

Reason:

3atch:3tarted:02/06/19923topped:04/06/1992ATARAX (Suspected)Reason:Other puritis conditions

0.0

25.0 Milligram Daily

Started:

3atch: Started: Stopped: 2W

Laboratory Investigations:

DOXEPIN HYDROCHLORIDE (Suspected)

3atch:

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Case Number: | 83578 | Seq: 1 | | | Gender: | F | |
|------------------|-------------------|----------|-----------|----------------|------------|--------------------|--|
| Reported: | 25/03/1993 | | | | Weight: | | |
| Hospitalisation: | | | | | Age: | | |
| Onset Date: | 03/06/1992 | | | | DOB: | | |
| | Not yet recovered | d | | | Causality: | Causality possible | |
| Reaction Detai | | | | | - | | |
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| Medicine Deta | ails: | | | | | | |
| CYCLOPHOSPHAN | | | | Reason: | | | |
| | | 50.0 | Milligram | Alternate days | | | |
| 3atch: | | Started: | | Stoppe | d: | | |
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| Laboratory In | vestigations: | | | | | | |
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| Additional Inf | ormation: | | | | | | |
| Additional | ormation. | | | | | | |
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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

| _ | | 4 | | 4 | - 1 |
|---------------------|--------|----|----|-----|-----|
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| | \sim | | _ | - | |

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 Detai

| 154511511 25141 | | - | |
|---------------------|----------|--------------------------------|---------------------------|
| 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 | As necessary | | |
| Зatch: | Started: | Stopped: | CONTIN | |
| DIGOXIN (Other drug) | Reason: | | | |
| | 1.0 Dose Unspe | ecified Alternate days | | |
| 3atch: | Started: | Stopped: | CONTIN | |
| ALLOPURINOL (Suspected) | | Reason: Gout | | |
| | 0.0 | | | |
| 3atch: | Started: 08/03/1993 | Stopped: | | |
| STEMETIL (Suspected) | Reason: | | | |
| | 5.0 Milligram | As necessary | | |
| 3atch: | Started: | Stopped: | | |

Laboratory Investigations:

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



Case Number: 85194

Reported: 09/06/1993

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

Weight:

| ospitalisation: Admitted to hospita | | | | | Age: | 92Y | |
|-------------------------------------|------------------|-------------|---------|----------|------------|--------------------|---|
| Onset Date: 14/03/1993 | | | | | DOB: | | |
| Outcome: Recovered | | | | C | ausality: | Causality possible | 9 |
| action Detai | | | | | | | |
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| ledicine Details: | | | _ | | | | |
| FRUSEMIDE (Suspected) | | | Reason: | | | | |
| | | Milligram | Daily | | 00/04/4000 | | |
| BINEOUAN (Sugmented) | Started: | | 2 | Stopped: | 03/04/1993 | | |
| SINEQUAN (Suspected) | 25.0 | | Reason: | | | | |
| 3atch: | 25.0 Started: | Milligram | Daily | Stopped: | | | |
| ASPIRIN (Suspected) | Starteu. | | Reason: | stopped. | | | |
| AOF IKIN (Suspected) | 150.0 | Milligram | Daily | | | | |
| 3atch: | Started: | wiiiigram | Daily | Stopped: | | | |
| MOGADON (Suspected) | 7.0 | | Reason: | жерреш. | | | |
| | 1.0 | Dose Unspec | | | | | |
| 3atch: | Started: | , | , | Stopped: | | | |
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| aboratory Investigations: | | | | | | | |
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| dditional Information: | | | | | | | |
| additional Information: | | | | | | | |
| additional Information: | | | | | | | |
| dditional Information: | | | | | | | |

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Case Number: 85194

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: F

| Reported: 09/06/1993 ospitalisation: Admitted to he Onset Date: 14/03/1993 | ospital | | Weight Age DOB | : 92Y | |
|--|-----------------|---------|----------------------|----------------------|---|
| Outcome: Recovered | | | | : Causality possible | |
| eaction Detai | | | - uu-u | r caucamy possible | |
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| Medicine Details: | | | | | |
| CAPTOPRIL (Suspected) | | Reason: | | | |
| | 18.7 Milligram | Daily | | | |
| 3atch: | Started: | | Stopped: | | _ |
| ZYLOPRIM (Suspected) | 000 0 14111 | Reason: | | | |
| 3atch: | 300.0 Milligram | Daily | Stopped: | | |
| Jaton. | Janteu. | | лоррец. | | |
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| Laboratory Investigation | s: | | | | |
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| Additional Information: | | | | | |
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| port Run 30/07/200 03:49PN D | atabase: pusime | ADRS004 | | Page 115 of 30' | 7 |



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

| Re | por | t D | etail |
|----|-----|-----|-------|
|----|-----|-----|-------|

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 Detai

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

Medicine Details:

| TEMAZEPAM (Other drug) | | Reason: | Specific disorders of sleep | |
|------------------------|---------------------------------------|--------------|-------------------------------|--|
| | 20.0 Milligram | Daily | | |
| Зatch: | Started: 13/07/1993 | | Stopped: | |
| APRINOX (Other drug) | | Reason: | Essential benign hypertension | |
| | 1.0 Dose Unspe | cified Daily | | |
| 3atch: | Started: 07/10/1987 | | Stopped: | |
| MELLEDII (Othor days) | | Reason: | | |
| MELLERIL (Other drug) | | Veason. | | |
| MELLERIL (Other drug) | 50.0 Milligram | Daily | | |
| 3atch: | 50.0 Milligram Started: 12/07/1988 | | Stopped: | |
| , • | · · | | | |
| Batch: | · · | Daily | Stopped: Depression | |

Laboratory Investigations:

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Case Number: | 86342 | Seq: 1 | | Gender: | | |
|------------------|--------------|----------------------------|--------------------|------------|--------------------|--|
| Reported: | 28/07/1993 | | | Weight: | | |
| ospitalisation: | | | | Age: | | |
| Onset Date: | | | | DOB: | | |
| Outcome: | Recovered | | | Causality: | Causality possible | |
| eaction Detai | | | | | | |
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| ledicine Deta | ils: | | | | | |
| PROZAC (Suspecte | | | Reason: Depression | | | |
| | | 20.0 Milligram | n Daily | | | |
| | | | | | | |
| Заtch: | | 3tarted: 15/07/1993 | Stopped: | 18/07/1993 | 3 | |
| 3atch: | | | | 18/07/1993 | 3 | |
| 3atch: | | | | 18/07/1993 | 3 | |
| 3atch: | | | | 18/07/1993 | 3 | |
| 3atch: | | | | 18/07/1993 | 3 | |
| Заtch: | | | | 18/07/1993 | 3 | |
| 3atch: | | | | 18/07/1993 | 3 | |
| 3atch: | | | | 18/07/1993 | 3 | |
| 3atch: | | | | 18/07/1993 | 3 | |
| Заtch: | | | | 18/07/1993 | 3 | |
| | vestigations | 3tarted: 15/07/1993 | | 18/07/1993 | 3 | |
| | vestigations | 3tarted: 15/07/1993 | | 18/07/1993 | 3 | |
| | vestigations | 3tarted: 15/07/1993 | | 18/07/1993 | 3 | |
| | vestigations | 3tarted: 15/07/1993 | | 18/07/1993 | 3 | |
| | vestigations | 3tarted: 15/07/1993 | | 18/07/1993 | 3 | |
| | vestigations | 3tarted: 15/07/1993 | | 18/07/1993 | 3 | |
| | vestigations | 3tarted: 15/07/1993 | | 18/07/1993 | 3 | |
| | vestigations | 3tarted: 15/07/1993 | | 18/07/1993 | 3 | |
| aboratory Inv | | 3tarted: 15/07/1993 | | 18/07/1993 | 3 | |
| aboratory Inv | | 3tarted: 15/07/1993 | | 18/07/1993 | 3 | |
| aboratory Inv | | 3tarted: 15/07/1993 | | 18/07/1993 | 3 | |
| aboratory Inv | | 3tarted: 15/07/1993 | | 18/07/1993 | 3 | |

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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: 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 Detai

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

Medicine Details:

| GENTAMICIN SULPHATE (Suspected) | | | | Reason: | Unspecified a | rthritis |
|------------------------------------|----------|------|-----------|---------|---------------|--------------------|
| | | 0.0 | | | | |
| Зatch: | Started: | 05 | 08/1993 | | Stopped: | 05/08/1993 |
| FLUCLOXACILLIN SODIUM (Suspected) | | | | Reason: | Unspecified a | rthritis |
| Oral application | | 2.0 | Gram | Daily | | Oral |
| 3atch: | Started: | 05 | 08/1993 | | Stopped: | 18/08/1993 |
| PREDNISOLONE (Suspected) | | | | Reason: | Otr mus rheur | m,fibrosit&myalgia |
| Oral application | | 8.5 | Milligram | Daily | | Oral |
| Зatch: | Started: | | | L TERM | Stopped: | CONTIN |
| VERAPAMIL HYDROCHLORIDE (Suspected | ed) | | | Reason: | Otr&nos disor | d of heart rhythm |
| Oral application | 18 | 30.0 | Milligram | Daily | | Oral |
| 3atch: | Started: | | | L TERM | Stopped: | CONTIN |

Laboratory Investigations:

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



Hospitalisation:

Case Number: 87430

Reported: 02/09/1993

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

Age: 74Y

Weight:

| Outcome: Not yet recovered action Detai | | | | C | ausality: C | ausality poss | ible |
|---|-------|---------------|-----------|------------------|--------------------|---------------|------|
| action Detai | | | | | | | |
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| edicine Details: DIGOXIN (Suspected) | | 3 | eason: | Otr&noe dieor | d of heart rhyth | m | |
| SIOOMIN (Guspecteu) | 125.0 | Microgram | Daily | Circuitos distri | u oi neari mylli | 111 | |
| 3atch: Starte | | 3 - | - , | Stopped: | 10/08/1993 | | |
| OOXEPIN HYDROCHLORIDE (Suspected) | | ? | eason: | Pain | | | |
| Oral application | | Milligram | Daily | | Oral | | |
| 3atch: Starte | d: | | | Stopped: | | CONTIN | |
| CAPADEX (Suspected) | • | | eason: | Pain | 0.1 | | |
| Capsule 3atch: Starte | | Dose Unspecif | ied Daily | Stopped: | Oral 19/08/1993 | | |
| Starte | u. | | | Moppea. | 19/00/1993 | | |



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

| Rep | 00 | rt | D | eta | il |
|-----|----|----|---|-----|----|
|-----|----|----|---|-----|----|

 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 Detai

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

Medicine Details:

SINEQUAN (Suspected)

Oral application

Reason: Depression

Oral

Oral

3atch: **3tarted**: 27/05/1993 **3topped**: 02/08/1993

Laboratory Investigations:

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



Date 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 Detai

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

Medicine Details:

SOLPRIN (Other drug)

150.0 Milligram Daily

3atch: Started: L TERM Stopped:

DOXEPIN HYDROCHLORIDE (Suspected) Reason: Specific disorders of sleep

10.0 Milligram Daily

3atch: 3tarted: 03/09/1993 3topped: 14/09/1993

Laboratory Investigations:

| Date | Туре | 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.



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

| Report D | etail | | | | | | | |
|-------------|---------|-----------|------------|---------------|----------|----------------|-----------------------------|--------|
| Case Num | nber: | 88962 | Seq: | 1 | | Geno | der: F | |
| Repo | rted: | 01/11/199 | _ | | | Weig | ght: 63.00 | |
| Hospitalisa | | | | | | | ge: 72Y | |
| Onset D | Date: | | | | | D | OB: | |
| Outco | ome: | Recovere | d | | | Causal | l ity: Causality pro | obable |
| Reaction D | | | | i | | - | | |
| | eferrec | d Term | Seve | erity | Report | Description | Treatme | ent |
| Dyspepsia | | | | | | | | |
| Flatulence | | | | | | | | |
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| Medicine | Doto | ilo | | | | | | |
| DOXEPIN H | | | Suspected) | | Reaso | on: Depression | | |
| | | | , | 10.0 Milli | | Daily | | |
| 3atc | :h: | | 3ta | rted: 13/08/1 | | Stopped: | | |
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| Date | | Туре | Range | Date Tested | Result | | Details | |
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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:
 89237
 Seq:
 1
 Gender:
 M

 Reported:
 12/11/1993
 Weight:

Hospitalisation: Age: 50Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

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

Medicine Details:

DOXEPIN HYDROCHLORIDE (Suspected) Reason:

25.0 Milligram 2 times

3atch: 3tarted: 01/04/1990 **3topped:**

Laboratory Investigations:

| Date | Туре | Range | Date Tested | Result | Details |
|------|---------------------------|-------|-------------|--------|--|
| | Bilirubin Liver biopsy | | | | 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 aminotransfera se activity was greater than 1500 II/l (0-40) Active acute hepatits with portal and acinar inflammation. |

Additional Information:

Patient was rechallenged on doxepin hydrochloride 8/90 and again 3/92 with same reaction occuring. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

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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: 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 Detai

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

Medicine Details:

| Medicine Betails. | | | | |
|-----------------------------------|---------------------|------------|-----------------|-------------|
| CLAFORAN (Suspected) | | Reason: Ot | ther cellulitis | and abscess |
| Injection | 4.0 Gram | Daily | | Intravenous |
| 3atch: | Started: 02/08/1993 | | Stopped: | 06/08/1993 |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: De | epression | |
| | 100.0 Milligram | Daily | | |
| 3atch: | Started: 01/01/1991 | | Stopped: | 09/08/1993 |

Laboratory Investigations:

| | . , | | | | |
|------|-------------------|-------|-------------|--------|---------|
| Date | Туре | 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.

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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: 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 Detai

Medicine Details:

| Medicine Betails. | | | | |
|-----------------------------------|---------------------|------------|-----------------|-------------|
| CLAFORAN (Suspected) | | Reason: Ot | ther cellulitis | and abscess |
| Injection | 4.0 Gram | Daily | | Intravenous |
| 3atch: | Started: 02/08/1993 | | Stopped: | 06/08/1993 |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: De | epression | |
| | 100.0 Milligram | Daily | | |
| 3atch: | Started: 01/01/1991 | | Stopped: | 09/08/1993 |

Laboratory Investigations:

| Date | Туре | 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.

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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: 89374 Seq: 1 Gender: M

Reported: 24/11/1993 Weight: 78.00 Hospitalisation: Age: 38Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

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

Medicine Details:

DOXEPIN HYDROCHLORIDE (Suspected) Reason: Depression

 Oral application
 25.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/04/1993
 3topped:
 28/05/1993

Laboratory Investigations:

| Date | Туре | 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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 126 of 307



Date 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 Detai

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

Medicine Details:

DESERIL (Suspected) Reason: Migraine

3.0 Milligram Daily

3atch: 3tarted: 30/11/1991 L TERM 3topped: 27/11/1993

SINEQUAN (Suspected) Reason:

25.0 Milligram Daily

3atch: 3tarted: 30/11/1991 Stopped:

Laboratory Investigations:

| Date | Туре | 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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 127 of 307



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

| | er: 89584 ed: 01/12/1993 on: | Seq: 1 | | | Gender: M Weight: 60.00 Age: 77Y | | | |
|---|------------------------------------|------------|---------------------------------------|---|-------------------------------------|---------------------------|-----------|--------------------|
| Onset Da | te: | | | | | | DOB: | |
| | ne: Recovered | | | | | C | ausality: | Causality possible |
| action De | | 1 | i | | | | - | |
| | erred Term | Sev | erity | | t Descri | ption | | Treatment |
| ash | | | Red | d blotches on le | eg. | | | |
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| | | | | ₹eas | | | | |
| PANADOL (Su | | 24:2 | 0.0 | ₹eas | on: As neces | | | |
| PANADOL (Su 3atch: | spected) | Sta | 0.0 arted: | | As neces | ssary 3topped : | | |
| PANADOL (Su 3atch: | spected) | Sta | | Reas | As neces | | | |
| ledicine E PANADOL (Su 3atch: LASIX (Suspec | spected) | | arted: | Reas | As neces | | | |
| PANADOL (Su 3atch: LASIX (Suspec 3atch: | spected) cted) | | arted: 40.0 Mi arted: | ₹eas illigram ₹eas | As neces on: Daily on: | Stopped: | | |
| PANADOL (Su 3atch: LASIX (Suspec 3atch: SLOW-K (Susp | spected) cted) | Sta | 40.0 Mi arted: 2.0 Do | Reas illigram | As neces on: Daily on: | Stopped: | | |
| PANADOL (Su 3atch: LASIX (Suspec 3atch: SLOW-K (Susp 3atch: | spected) | Sta | arted: 40.0 Mi arted: | ₹eas illigram ₹eas ose Unspecified | As neces on: Daily on: Daily | Stopped: | | |
| PANADOL (Su 3atch: LASIX (Suspec 3atch: SLOW-K (Susp | spected) | Sta | 40.0 Mi arted: 2.0 Do arted: | Reas illigram Reas use Unspecified Reas | As neces on: Daily on: Daily on: | Stopped: | | |
| PANADOL (Su 3atch: LASIX (Suspect 3atch: SLOW-K (Suspect 3atch: | spected) | Sta Sta | 40.0 Mi arted: 2.0 Do arted: 20.0 Mi | Reas illigram Reas use Unspecified Reas | As neces on: Daily on: Daily | Stopped: Stopped: | | |
| PANADOL (Su 3atch: LASIX (Suspect 3atch: SLOW-K (Suspect 3atch: FELDENE (Suspect) | spected) pected) | Sta Sta | 40.0 Mi arted: 2.0 Do arted: | Reas illigram Reas use Unspecified Reas | As neces on: Daily on: Daily on: | Stopped: | | |
| PANADOL (Su 3atch: LASIX (Suspect 3atch: SLOW-K (Suspect 3atch: FELDENE (Suspect) | spected) | Sta Sta | 40.0 Mi arted: 2.0 Do arted: 20.0 Mi | Reas illigram Reas use Unspecified Reas illigram | As neces on: Daily on: Daily on: | Stopped: Stopped: | Deta | sila |



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Case Number: Reported: | 89584 01/12/1993 | Seq: 1 | | | Gender: Weight: | | |
|------------------------|---------------------|--------------|-----------|---------|--------------------|--------------------|---|
| Hospitalisation: | | | | | Age: | | |
| Onset Date: | _ | | | | DOB: | | |
| | Recovered | | | | Causality: | Causality possible | |
| Reaction Detai | | | | | | | |
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| Madiaina Dat | -!! | | | | | | |
| Medicine Deta | alls: | | | Reason: | | | |
| | | 100.0 | Milligram | Daily | | | |
| 3atch: | | Started: | 3 | , | Stopped: | | |
| SINEQUAN (Suspe | ected) | | | Reason: | | | |
| | | 25.0 | Milligram | Daily | | | |
| 3atch: | | Started: | | | Stopped: | | |
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| Laboratory In | vestigations: | | | | | | |
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| Additional Inf | formation: | | | | | | |
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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 Det | :aii |
|------------|------|
|------------|------|

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 Detai

| <u> </u> | | | |
|-------------------|----------|--------------------|-----------|
| Preferred Term | Severity | Report Description | Treatment |
| Myalgia | | | |
| Oedema peripheral | | | |

Medicine Details:

SINEQUAN (Suspected) Reason: Depression

Oral application 125.0 Milligram Daily Oral

3atch: 3tarted: 09/11/1993 **3topped:** CONTIN

Laboratory Investigations:

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



Date 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 Detai

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

Medicine Details:

| PREPULSID (Suspected) | | Reason: | Abdominal pain | |
|-----------------------|---------------------|---------|-------------------------------|--|
| | 30.0 Milligram | Daily | | |
| 3atch: | Started: 01/06/1993 | | Stopped: 28/11/1993 | |
| INDERAL (Suspected) | | Reason: | Abnormal involuntary movement | |
| Tablet | 80.0 Milligram | Daily | Oral | |
| 3atch: | 3tarted: 01/01/1986 | | Stopped: | |
| SINEQUAN (Suspected) | | Reason: | Abnormal involuntary movement | |
| | 50.0 Milligram | Daily | | |
| 3atch: | Started: 01/01/1986 | | Stopped: | |

Laboratory Investigations:

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

Additional Information:

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

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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: 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 Detai

| todotion Botal | | | <u> - </u> |
|----------------|----------|--------------------|--|
| Preferred Term | Severity | Report Description | Treatment |
| Bronchospasm | | | |

Medicine Details:

SINEQUAN (Suspected) Reason:

125.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

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

Additional Information:

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

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Date Range: 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 Detai

| 104011011 20141 | | | |
|--------------------|----------|--------------------|-----------|
| Preferred Term | Severity | Report Description | Treatment |
| Tardive dyskinesia | | | |

Medicine Details:

| PRAMIN (Suspected) | | | Reason: | Nausea and v | omiting | |
|--|------------------|------------------------|------------------|---------------|--------------------------|--------|
| Tablet | 30.0 | Milligram | Daily | | Oral | |
| Зatch: | Started: 01 | /01/1986 | | Stopped: | 26/03/1993 | |
| ISOPTIN SR (Suspected) | | | Reason: | Essential ben | ign hypertension | |
| Tablet, modified release | 240.0 | Milligram | Daily | | Oral | |
| Зatch: | Started: | | L TERM | Stopped: | | CONTIN |
| | | | | | | |
| FRUSEMIDE (Suspected) | | | Reason: | Essential ben | ign hypertension | |
| FRUSEMIDE (Suspected) Oral application | 40.0 | Milligram | Reason: Daily | Essential ben | ign hypertension Oral | |
| ` ' / | 40.0 Started: | Milligram | | Essential ben | Oral | CONTIN |
| Oral application | | Milligram | Daily | 3topped: | Oral | |
| Oral application 3atch: | | Milligram Milligram | Daily L TERM | 3topped: | Oral | |

Laboratory Investigations:

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

Additional Information:

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

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 133 of 307



Date 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 Detai

Medicine Details:

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

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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 134 of 307



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

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|----|--------|--------|------|---|
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| Re | \sim | _ | U LU | ш |

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 Detai

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

Medicine Details:

| DOXEPIN HYDROCHLORIDE (Suspected) | | | Reason: | Depression | |
|-----------------------------------|----------|-----------|---------|------------|-------------|
| Oral application | 50.0 | Milligram | Daily | | Oral |
| Зatch: | Started: | | | Stopped: | |
| PREDNISOLONE (Suspected) | | | Reason: | | |
| Oral application | 37.5 | Milligram | Daily | | Oral |
| Зatch: | Started: | | | Stopped: | |
| TIMENTIN (Suspected) | | | Reason: | | |
| Injection | 12.4 | Gram | Daily | | Intravenous |
| Зatch: | Started: | | | Stopped: | |
| RANITIDINE (Suspected) | | | Reason: | | |
| Tablet | 300.0 | Milligram | Daily | | Oral |
| 3atch: | Started: | | | Stopped: | |

Laboratory Investigations:

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



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

| 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 poss | ible |
| Reaction Detai | i | | | | | | | |
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| Medicine Det | | | | | | | | |
| SPIRONOLACTON | IE (Suspected) | | | eason: | | | | |
| Tablet | | 200.0 M | lilligram | Daily | | Oral | | |
| 3atch: | | Started: | | | Stopped: | | | |
| AMIODARONE HY | DROCHLORIDE (Sus | | | eason: | | | | |
| | | 600.0 M | filligram | Daily | | | | |
| 3atch: | | 3tarted: 19/01 | /1994 | | Stopped: | | | |
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| I aboratory In | vestigations: | | | | | | | |
| Laboratory III | ivestigations. | | | | | | | |
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| Additional Inf | formation: | | | | | | | |
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| eport Run 30/07/200 | 0 03:49PN Data | ıbase: pusime | | ADRS004 | | | Page 136 | of 307 |



Date 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 Detai

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

Medicine Details:

| MIANSERIN HYDROCHLORIDE (Su | spected) | Reason: | | |
|-----------------------------|---------------------|-------------|----------|------------|
| | 20.0 Milligram | Daily | | |
| 3atch: | Started: 14/01/1994 | | Stopped: | 24/01/1994 |
| DEPTRAN (Suspected) | | Reason: | | |
| | 25.0 Milligram | Daily | | |
| Зatch: | Started: 10/01/1994 | | Stopped: | 28/01/1994 |
| COLOXYL (Suspected) | | Reason: | | |
| | 4.0 Dose Unspec | ified Daily | | |
| 3atch: | Started: | | Stopped: | CONTIN |
| AMLODIPINE (Suspected) | | Reason: | | |
| | 10.0 Milligram | Daily | | |
| 3atch: | Started: | | Stopped: | CONTIN |

Laboratory Investigations:

| <u> </u> | i ji iii vootigat | | | | |
|----------|-------------------|-------|-------------|--------|---------|
| Date | Туре | 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 | |



Date 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:
Onset Date: 20/01/1994
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

| Medicine Details. | | | | |
|-----------------------|-----------------|----------|--------|--|
| ZANTAC (Suspected) | ; | Reason: | | |
| | 150.0 Milligram | Daily | | |
| Зatch: | Started: | Stopped: | CONTIN | |
| PREPULSID (Suspected) | | Reason: | | |
| | 15.0 Milligram | Daily | | |
| 3atch: | Started: | Stopped: | CONTIN | |

Laboratory Investigations:

| Date | Туре | 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 | |



Date 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 Detai

Medicine Details:

| MIANSERIN HYDROCHLORIDE (Susp | ected) | Reason: | | | |
|-------------------------------|---------------------|------------|------------|--------|--|
| | 20.0 Milligram | Daily | | | |
| 3atch: | Started: 14/01/1994 | €top | ped: 24/01 | /1994 | |
| DEPTRAN (Suspected) | | Reason: | | | |
| | 25.0 Milligram | Daily | | | |
| Зatch: | Started: 10/01/1994 | Stop | ped: 28/01 | /1994 | |
| COLOXYL (Suspected) | | Reason: | | | |
| | 4.0 Dose Unspeci | fied Daily | | | |
| 3atch: | Started: | 3400 | ped: | CONTIN | |
| Jaicii. | Starteu. | Stop | peu. | CONTIN | |
| AMLODIPINE (Suspected) | | Reason: | peu. | CONTIN | |
| | | · | ppeu. | CONTIN | |

Laboratory Investigations:

| Date | Туре | 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 | |



Date 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 Detai

Medicine Details:

| ZANTAC (Suspected) | Reason: | | | | |
|-----------------------|----------------------|-----------------|--------|--|--|
| | 150.0 Milligram | Daily | | | |
| Зatch: | Started: | Stopped: | CONTIN | | |
| | | | | | |
| PREPULSID (Suspected) | र | eason: | | | |
| PREPULSID (Suspected) | રત 15.0 Milligram | eason: Daily | | | |

Laboratory Investigations:

| Date | Туре | 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 | |



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

| Report Do | etail |
|-----------|-------|
|-----------|-------|

Case Number:91376Seq:1Gender:FReported:02/03/1994Weight:Hospitalisation:Admitted to hospitalAge:54Y

Onset Date: 22/02/1994 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--------------------|-----------|
| Hypotension | | | |
| Rash erythematous | | | |
| Tachycardia | | | |
| Urticaria | | | |

Medicine Details:

| OGEN (Suspected) | | Reason: Menopausal symptoms |
|----------------------|---------------------|---------------------------------------|
| | 0.0 | |
| 3atch: | Started: | Stopped: 22/02/1994 |
| SINEQUAN (Suspected) | | Reason: |
| | 50.0 Milligram | Daily |
| 3atch: | Started: 15/02/1994 | Stopped: 22/02/1994 |
| CARDIZEM (Suspected) | | Reason: Essential benign hypertension |
| | 180.0 Milligram | Daily |
| 3atch: | Started: 17/02/1994 | Stopped : 22/02/1994 |

Laboratory Investigations:

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



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

| Report De | tail | | | | | | | |
|--|--|----------------|----------------------|--------------|------------------|-------------|---|-----------|
| Case Numb Report Ospitalisatio Onset Da Outcor | eer: 91455 ed: 08/03/199 on: Admitted to ate: ne: Not yet re | to hospital | 1 | | | W ei | ider: ight: Age: OB: ality: | |
| eaction De | erred Term | Seve | rity | Renord | Description | <u> </u> | | Treatment |
| Dizziness Urticaria | circa reiiii | Severe | , ity | Тероп | Besonption | • | | Trodution |
| Medicine [| | | | | | | | |
| CARDIZEM (C | ther drug) | | 400 0 14:00 | Reaso | | | | |
| 3atch: | : | Star | 180.0 Millio ted: | gram | Daily Stop | pped: | | |
| SINEQUAN (S | uspected) | | 50.0 Millig | Reaso | | | | |
| 3atch: | | 3tar | ted: | | 3to _l | pped: | | |
| _aboratory | y Investigat Type | ions: Range | Date Tested | Result | | | Detai | ils |
| Additional | Information | n: | | | | | | |



Date 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 Detai

| 104011011 20141 | | | | |
|-------------------------|--------|--------------------|-----------|--|
| Preferred Term Severity | | Report Description | Treatment | |
| Thrombocytopenia | Severe | | | |

Medicine Details:

| LOSEC (Other drug) | Reason: | | | | | |
|----------------------|----------------------------|-----------|---------|----------|------------|--|
| | 40.0 | Milligram | Daily | | | |
| 3atch: | Started: | L | TERM | Stopped: | CONTIN | |
| SEREPAX (Other drug) | Reason: | | | | | |
| | 30.0 | Milligram | Daily | | | |
| 3atch: | Started: | L | TERM | Stopped: | CONTIN | |
| PANADOL (Other drug) | Reason: | | | | | |
| | 8.0 Dose Unspecified Daily | | | | | |
| 3atch: | Started: | | | Stopped: | CONTIN | |
| TEGRETOL (Suspected) | | | Reason: | Pain | | |
| | 600.0 | Milligram | Daily | | | |
| 3atch: | 3tarted: 01 | /04/1994 | | Stopped: | 30/04/1994 | |

Laboratory Investigations:

| Date | Туре | 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 | |



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Hospitalisation: Onset Date: Outcome: Reaction Detai | 16/05/1994 26/04/1994 Recovered | Seq: 1 | | | Gender: Weight: Age: DOB: ausality: | | |
|---|---------------------------------------|----------|---------|----------|---|---|--|
| Medicine Deta | | | | | | | |
| SINEQUAN (Suspe | ected) | | Reason: | | | | |
| D-4-h | | | | aily | 00/05/4004 | | |
| 3atch: | | Started: | L TERM | Stopped: | 03/05/1994 | • | |
| Laboratory In | vestigations: | | | | | | |
| Additional Inf | ormation: | | | | | | |

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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:
 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 Detai

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

Medicine Details:

| AUGMENTIN FORTE (Suspected) | | Reason: | Acute bronchitis | &bronchiolitis |
|-----------------------------|----------------------------|---------------|------------------|-------------------|
| | 3.0 Dose Unspe | cified Daily | | |
| 3atch: | Started: 13/05/1994 | | Stopped: 1 | 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 |
| 3atch: | Started: 01/01/1984 | | Stopped: | CONTIN |
| ZOCOR (Suspected) | | Reason: | Othr&unspec me | etabolic diseases |
| | 1.0 Dose Unspe | cified Alterr | nate days | |
| Зatch: | Started: 01/01/1991 | | }topped: | CONTIN |

Laboratory Investigations:

| Date | Туре | 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.

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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: 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 Detai

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

Medicine Details:

| ALPRAZOLAM (Suspected) | | Reason: | |
|-----------------------------------|----------------------------|--------------|------------|
| | 500.0 Microgram | As necessary | |
| 3atch: | Started: | Stopped: | |
| TEGRETOL (Suspected) | | Reason: | |
| | 200.0 Milligram | Daily | |
| 3atch: | Started: 22/02/1994 | Stopped: | 15/04/1994 |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | |
| | 250.0 Milligram | Daily | |
| | | Daily | |
| 3atch: | Started: 01/01/1992 | Stopped: | |
| 3atch: PREMARIN (Suspected) | · · | • | |
| | · · | Stopped: | |

Laboratory Investigations:

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

Additional Information:

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

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

Report Detail

Case Number: 93776 Gender: M Seq: 1

Reported: 17/06/1994 Weight: 90.00 Hospitalisation: Age: 74Y

Onset Date: 09/06/1994 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

| 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 | / | |
| 3atch: | Started: 01/01/1994 | | Stopped: | |
| SULPHUR (Other drug) | | Reason: | Other prophylactic procedures | |
| | 50.0 Milligram | Daily | / | |
| 3atch: | Started: 01/01/1994 | | Stopped: | |
| VOLTAREN (Other drug) | | Reason: | Unspecified arthritis | |
| | 100.0 Milligram | Daily | / | |
| 3atch: | Started: 01/01/1994 | | Stopped: | |
| CLARATYNE (Other drug) | | ₹eason: | | |

1.0 Dose Unspecified Daily

CONTIN 3tarted: 01/03/1994 3atch: Stopped:

Laboratory Investigations:

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

Additional Information:

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

Medicine Details:

| Medicine Details. | | | | | |
|---------------------|----------------------------|---------|----------------|------------|--|
| RULIDE (Suspected) | | Reason: | Bronchitis,und | qualified | |
| Tablet | 10.0 Milligram | Daily | | Oral | |
| 3atch: | Started: 07/06/1994 | | Stopped: | 09/06/1994 | |
| DEPTRAN (Suspected) | | Reason: | Depression | | |
| | 125.0 Milligram | Daily | | | |
| 3atch: | 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 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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Date 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 Detai

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

Medicine Details:

| FERRO-GRADUMET (Other drug) | | Reason: | |
|-----------------------------------|---------------------|-----------------------|-------------------|
| Tablet | 350.0 Milligram | Daily | Oral |
| Зatch: | Started: 15/04/1994 | Stopped: | CONTIN |
| MEGAFOL (Other drug) | | Reason: | |
| Oral application | 500.0 Microgram | Daily | Oral |
| 3atch: | 3tarted: 18/04/1994 | Stopped: | CONTIN |
| FLUCLOXACILLIN SODIUM (Suspected) | | Reason: Otr&nos infec | ¶sit diseases |
| Injection | 2.0 Gram | Daily | Intravenous |
| Зatch: | Started: 08/04/1994 | Stopped: | 14/04/1994 |
| STAPHYLEX (Suspected) | | Reason: Unspecified s | epticemia |
| Oral application | 1.0 Gram | Daily | Oral |
| Зatch: | Started: 14/04/1994 | Stopped: | 03/05/1994 |

Laboratory Investigations:

| Date | Туре | 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.

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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:
 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 Detai

Medicine Details:

| AMOXIL (Suspected) | 2 | leason: | Otr&nos infec¶sit diseases |
|----------------------|---------------------|---------|--------------------------------|
| Injection | 1.5 Gram | Daily | Intravenous |
| Зatch: | Started: 09/04/1994 | | Stopped: 14/04/1994 |
| ROCEPHIN (Suspected) | 3 | leason: | Otr&nos infec¶sit diseases |
| Injection | 1.0 Gram | Daily | Intravenous |
| 3atch: | 3tarted: 07/04/1994 | | Stopped: 09/04/1994 |
| DEPTRAN (Suspected) | ? | leason: | Unspecified psychosis |
| Oral application | 25.0 Milligram | Daily | Oral |
| 3atch: | Started: 27/04/1994 | | Stopped: 27/04/1994 |
| TOFRANIL (Suspected) | ? | leason: | Unspecified psychosis |
| Tablet | 20.0 Milligram | Daily | Oral |
| | | | |

Laboratory Investigations:

| Date | Туре | 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.

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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:
 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 Detai

Medicine Details:

| FERRO-GRADUMET (Other drug) | | Reason: | |
|-----------------------------------|---------------------|-----------------------|-------------------|
| Tablet | 350.0 Milligram | Daily | Oral |
| 3atch: | 3tarted: 15/04/1994 | Stopped: | CONTIN |
| MEGAFOL (Other drug) | | Reason: | |
| Oral application | 500.0 Microgram | Daily | Oral |
| 3atch: | 3tarted: 18/04/1994 | Stopped: | CONTIN |
| FLUCLOXACILLIN SODIUM (Suspected) | | Reason: Otr&nos infec | ¶sit diseases |
| Injection | 2.0 Gram | Daily | Intravenous |
| 3atch: | 3tarted: 08/04/1994 | Stopped: | 14/04/1994 |
| STAPHYLEX (Suspected) | | Reason: Unspecified s | epticemia |
| Oral application | 1.0 Gram | Daily | Oral |
| 3atch: | 3tarted: 14/04/1994 | Stopped: | 03/05/1994 |

Laboratory Investigations:

| Date | Туре | 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.

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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:
 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 Detai

Medicine Details:

| AMOXIL (Suspected) | | Reason: | Otr&nos infec | ¶sit diseases |
|----------------------|-----------------------------|---------|---------------|-------------------|
| Injection | 1.5 Gram | Daily | | Intravenous |
| Зatch: | Started: 09/04/1994 | | Stopped: | 14/04/1994 |
| ROCEPHIN (Suspected) | | Reason: | Otr&nos infec | ¶sit diseases |
| Injection | 1.0 Gram | Daily | | Intravenous |
| Зatch: | Started: 07/04/1994 | | Stopped: | 09/04/1994 |
| DEPTRAN (Suspected) | | Reason: | Unspecified p | sychosis |
| Oral application | 25.0 Milligram | Daily | | Oral |
| Зatch: | Started: 27/04/1994 | | Stopped: | 27/04/1994 |
| TOFRANIL (Suspected) | | Reason: | Unspecified p | sychosis |
| Tablet | 20.0 Milligram | Daily | | Oral |
| 3atch: | Started : 28/04/1994 | | Stopped: | 06/05/1994 |

Laboratory Investigations:

| Date | Туре | 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.

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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:
 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 Detai

| todotion Botai | | | <u> - </u> |
|----------------|----------|--|--|
| 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: | |
|-----------------------------|----------------------------|----------------------|-----------------------|
| | 0.0 | As necessary | |
| 3atch: | Started: | Stopped | d: |
| SINEQUAN (Suspected) | | Reason: Depression | n |
| | 75.0 Milligram | Daily | Oral |
| Зatch: | Started: 01/02/1988 | Stopped | d: 28/07/1994 |
| DIPENTUM (Suspected) | | Regional e | enteritis |
| | 3.0 Dose Unspe | cified Daily | Oral |
| 3atch: | 3tarted: 01/04/1994 | Stopped | d: |
| VOLTAREN (Suspected) | | Reason: Pain in join | nt |
| | 2.0 Dose Unspe | cified Daily | Oral |
| Зatch: | Started: 01/12/1993 | Stopped | d : 28/07/1994 |

Laboratory Investigations:

| Date | Туре | 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.

Report Run 30/07/200 03:49PN Database: pusime ADRS004 Page 153 of 307



Date 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 Detai

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

Medicine Details:

| LAMISIL (Suspected) | | Reason: | Dermatophyte | osis | |
|------------------------------|-----------------|-------------------------------|----------------------|-------------------|--|
| Tablet | 250.0 | Milligram Dai | ly | Oral | |
| 3atch: | Started: 25 | /04/1994 | Stopped: | 25/07/1994 | |
| SINEQUAN (Suspected) | | Reason: | Depression | | |
| Oral application | 35.0 | Milligram Dai | ly | Oral | |
| 3atch: | Started: | L TERM | Stopped: | | |
| | | | | | |
| DI-GESIC (Suspected) | | Reason: | Other disturb | ance of sensation | |
| DI-GESIC (Suspected) | 4.0 | Reason: Dose Unspecified Dai | | ance of sensation | |
| DI-GESIC (Suspected) 3atch: | 4.0 Started: | | | ance of sensation | |
| | | Dose Unspecified Dai | ly | | |
| 3atch: | | Dose Unspecified Dai | Stopped: Menopausal | | |

Laboratory Investigations:

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

Additional Information:



Date 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 Detai

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

Medicine Details:

| NORIDAY (Other drug) | | Reaso | n: Contraception | on |
|-----------------------|--------------|--------------------|------------------|--------------|
| | 1.0 | Dose Unspecified I | Daily | |
| Зatch: | Started: | L TERM | Stopped: | : |
| BECOTIDE (Other drug) | | Reason | n: Asthma | |
| Inhalation | 4.0 | Dose Unspecified I | Daily | Inhalation |
| Зatch: | Started: | L TERM | Stopped: | : |
| SINEQUAN (Suspected) | | Reaso | n: Migraine | |
| Tablet | 25.0 | Milligram I | Daily | Oral |
| 3atch: | Started: 19/ | 07/1994 | Stopped: | : 14/08/1994 |

Laboratory Investigations:

| Date | Туре | 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.



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

| _ | | 4 | | 4 | - 1 |
|---------------------|--------|----|----|-----|-----|
| $oldsymbol{\omega}$ | nn | r. | | eta | |
| RH | | | ., | -14 | |
| | \sim | | _ | - | |

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 Detai

| 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

 Заtch:
 Started:
 09/08/1994
 Эторред:
 CONTIN

Laboratory Investigations:

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

Additional Information:



Date 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: | = |
| Reported: 07/11/1994 | | | | | Weight: | 58.00 |
| lospitalisation: | | | | | Age: 4 | 46Y |
| Onset Date: 29/10/1994 | | | | | DOB: | |
| Outcome: Recovered | | | | C | ausality: (| Causality possible |
| eaction Detai | | | | | _ | |
| Preferred Term | Severity | | Report Des | cription | | Treatment |
| Anticholinergic syndrome | | | | | | |
| Confusional state | | | | | | |
| Dystonia | | | | | | |
| Extrapyramidal disorder | | | | | | |
| Hyperhidrosis | | | | | | |
| Hyperthermia malignant | | | | | | |
| Hypertonia | | | | | | |
| Pyrexia | | | | | | |
| Tachycardia | | | | | | |
| Tremor | | | | | | |
| | | | | | | |
| Medicine Details: | | | | | | |
| HEROIN (Other drug) | | | Reason: | | | |
| | 0.0 | | | | | |
| 3atch: | Started: | | | Stopped: | | |
| VALIUM (Other drug) | | | Reason: | Anxiety neuro | sis | |
| | 10.0 | Milligram | Daily | | | |
| 3atch: | Started: | | | Stopped: | | CONTIN |
| MAXOLON (Suspected) | | | Reason: | Nausea and v | omiting | |
| | 20.0 | Milligram | Total | | | |
| 3atch: | Started: 29 | /10/1994 | | Stopped: | | |
| AROPAX (Suspected) | | | Reason: | Depression | | |
| Tablet | 20.0 | Milligram | Daily | | Oral | |
| 3atch: | Started: 20 | /10/1994 | | Stopped: | 31/10/1994 | |

Additional Information:

Туре

Range

Date Tested

Date

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.

Result

Details



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

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 Detai

Medicine Details:

 DEPTRAN (Suspected)
 Reason:
 Depression

 Oral application
 100.0
 Milligram
 Daily
 Oral

 3atch:
 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.

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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:
 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 Detai

| todotion Botai | | _ | |
|-----------------------|----------|--|-----------|
| 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

3atch: **3tarted**: 01/07/1994 **3topped**: CONTIN

Laboratory Investigations:

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

Additional Information:

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

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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: 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 Detai

| teaction Detai | | - | |
|-----------------------|----------|--------------------------|------------------|
| 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

 3atch:
 3tarted:
 29/11/1994
 3topped:

Laboratory Investigations:

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

Additional Information:



Date 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 Detai

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

Medicine Details:

| DAPSONE (Suspected) | | Reason: | |
|--------------------------------|--|--------------------------|------------|
| | 200.0 Milligram | Weekly | |
| 3atch: | Started: 29/03/1994 | Stopped: | CONTIN |
| FLUCONAZOLE (Suspected) | | Reason: Moniliasis | |
| Capsule | 200.0 Milligram | Daily | Oral |
| 3atch: | 3tarted: 20/07/1994 | Stopped: | CONTIN |
| | | | |
| DIDANOSINE (Suspected) | | Reason: Hiv infection | |
| DIDANOSINE (Suspected) | 400.0 Milligram | | |
| DIDANOSINE (Suspected) 3atch: | 400.0 Milligram 3tarted: 24/11/1993 | | 24/08/1994 |
| | · · | Daily | 24/08/1994 |
| 3atch: | · · | Daily Stopped: | 24/08/1994 |

Laboratory Investigations:

| Date | Туре | 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.



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

| Report Detail | | | | | | |
|---|--------------------------|--------------|----------------------------------|------------------|---|--------------------|
| Case Number: Reported: ospitalisation: Onset Date: | 01/12/1994 20/07/1994 | eq: 1 | | | Gender: Weight: Age: DOB: | 38.00 49Y |
| Outcome: eaction Detai | Death, maybe drug | | | | Causality: | Causality possible |
| | | | | | | |
| ledicine Deta CLONAZEPAM (Su | | | 200.0 Microgram | Reason: | Anxiety neurosis | |
| | | Started | l: 27/10/1993 | 2 | | CONTIN |
| F.G.F. (Suspected) | | ; | 270.0 Milligram | Reason: Daily | Iron deficiency anemias | |
| 3atch: | | Started | l: 27/10/1993 | | Stopped: | CONTIN |
| | | Started | 1: 27/10/1993 270.0 Milligram | Reason: | Stopped: Iron deficiency anemias Stopped: | CONTIN |
| Laboratory Inv | vestigations: | | | | | |
| Additional Info | | | | | | |

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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: 97547 Seq: 1 Gender: M

Reported: 05/12/1994 Weight: 86.00
Hospitalisation: Age: 61Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

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

Medicine Details:

| inculcine Details. | | | | |
|-----------------------|-----------------------------|---------|--------------------------------|--|
| PEPCIDINE (Suspected) | | Reason: | Otr disorders stomach function | |
| | 60.0 Milligram | Daily | | |
| 3atch: | Started: 01/08/1994 | | Stopped: | |
| SINEQUAN (Suspected) | | Reason: | Otr disorders stomach function | |
| | 50.0 Milligram | Daily | | |
| 3atch: | Started : 01/09/1993 | | Stopped: 28/11/1994 | |

Laboratory Investigations:

| Date | Туре | 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.

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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: 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 Detai

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

Medicine Details:

| CLOZARIL (Suspected) | | Reason: | Unspecified schizophre | enia |
|----------------------|---------------------|---------|------------------------|--------|
| Oral application | 400.0 Milligram | Daily | Oral | |
| 3atch: | Started: 01/04/1994 | | Stopped: | CONTIN |
| SINEQUAN (Suspected) | | Reason: | Depression | |
| Tablet | 75.0 Milligram | Daily | Oral | |
| 3atch: | Started: | L TERM | Stopped: | CONTIN |

Laboratory Investigations:

| Date | Туре | 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.

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 164 of 307



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

| Case Number | : 98836 | Seq: | 1 | | (| Gender: M | |
|-------------------|----------------|--------------|-------------|--------|---------------|------------------------|--------|
| | l: 08/02/1995 | - | | | • | Weight: | |
| Hospitalisatior | | | | | | Age: | |
| Onset Date | | | | | | DOB: | |
| Outcome | : Recovered | | | | Ca | usality: Causality pos | sible |
| Reaction Det | ai | <u> </u> | | | | | |
| Prefer | red Term | Seve | erity | Repor | t Description | Treatmen | t |
| Psychotic disor | der | | | | | | |
| | | | | | | | |
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| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Medicine De | etails: | | | | | | |
| | OCHLORIDE (Sus | pected) | | Reas | on: | | |
| | | | 0.0 | | | | |
| 3atch: | | 3ta | rted: | | Stopped: | | |
| | | | | | | | |
| | | | | | | | |
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| | | | | | | | |
| Laboratory | Investigatio | ns: | | | | | |
| Date | Туре | Range | Date Tested | Result | | Details | |
| | | | | | | | |
| | | | | | | | |
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| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Additional I | nformation: | | | | | | |
| Additional | iioiiiiatioii. | | | | | | |
| | | | | | | | |
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| | | | | | | | |
| eport Run 30/07/2 | 00 03:50PN | Database: pu | sime | А | DRS004 | Page 165 | of 307 |
| | | | - | • | | 1 agc 100 | 01 001 |



Date 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 Detai

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

Medicine Details:

| LIPEX (Suspected) | | Reason: | |
|---------------------|----------|----------|--|
| | 0.0 | | |
| Зatch: | Started: | Stopped: | |
| IMDUR (Suspected) | | Reason: | |
| | 0.0 | | |
| Зatch: | Started: | Stopped: | |
| DEPTRAN (Suspected) | | Reason: | |
| | 0.0 | | |
| Зatch: | Started: | Stopped: | |

Laboratory Investigations:

| Date | Туре | 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.

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 166 of 307



| Report Detail | | | | |
|--|------------------------------------|------------|--------------------------|------------|
| Case Number: 99321 Reported: 06/03/199 Hospitalisation: Onset Date: 17/02/199 Outcome: Not yet red | 5 | | DOB: | : : 55Y |
| Preferred Term | Severity | Report Des | cription | Treatment |
| Orthostatic hypotension Tachycardia | | · | | |
| Medicine Details: SINEQUAN (Suspected) Tablet 3atch: | 50.0 Mil Started: 23/01/ | | Depression Oral Stopped: | |
| Laboratory Investigat | | Result | Deta | :: - |
| Date Type | Range Date Tested | Result | Deta | alis |
| Additional Information | n: | | | |



Date 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 Detai

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

Medicine Details:

PROZAC (Suspected) Reason: Depression

40.0 Milligram Daily

3atch: 3tarted: 01/02/1994 **3topped:** 28/04/1995

DOXEPIN HYDROCHLORIDE (Suspected) Reason: Depression

 Oral application
 75.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/02/1994
 3topped:
 28/03/1994

Laboratory Investigations:

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

Additional Information:

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

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 168 of 307



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

Causality: Causality possible

Report Detail

 Case Number:
 103055
 Seq: 1
 Gender: M

 Reported:
 28/08/1995
 Weight:
 118.00

 Hospitalisation:
 Age: 35Y

Onset Date: DOB:

Reaction Detai

Outcome: Recovered

| touction betai | | <u>-</u> | |
|--------------------------|----------|---------------------------------|-----------|
| Preferred Term | Severity | Report Description | Treatment |
| Hallucination | | Hypnagogic hallucinations-as if | |
| Drug withdrawal syndrome | | | |
| Hyperhidrosis | | | |
| Nightmare | | | |

Medicine Details:

| MEGICINE DELANS. | | | |
|-----------------------------------|----------------|--------------------|------------|
| PAROXETINE HYDROCHLORIDE (Suspect | ted) | Reason: Depression | |
| Tablet | 30.0 Milligram | Daily | Oral |
| 3atch: | Started: | Stopped: | 28/02/1995 |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | |
| | 25.0 Milligram | Daily | |
| Batch: | Started: | Stopped: | 28/02/1995 |

Laboratory Investigations:

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

Additional Information:

Reaction occured two days after ceasing paroxetine and resolved when restared 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.

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 169 of 307



| eport Detail | | | | | | | | | |
|------------------------------------|-----------|------|---------------------|-----------------------------------|-------------------------|--------|-------------------------|-----------------|----------|
| Case Number: 1 | | Seq: | 1 | | | Gend | | | |
| Reported: 0 | 9/11/1995 | | | | | _ | ht: 60.0 | | |
| ospitalisation: Onset Date: | | | | | | | ge: 64Y) B : | | |
| Outcome: F | Recovered | | | | (| | | ısality possibl | 6 |
| eaction Detai | (00010100 | | | | ` | Jaaoan | Oud | loanty pocolo | • |
| Preferred | Term | Seve | erity | Report De | scription | | | Treatment | |
| Orug ineffective | | | | · | • | | | | |
| | | | | | | | | | |
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| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| Medicine Detai | | | | | | | | | |
| ESTRADERM (Other | drua) | | | | | | | | |
| (~ | arag, | | - | Reason: | | | | | |
| | u. ug/ | 340 | 25.0 Micr | | | | | | |
| 3atch: | | \$ta | 25.0 Micr | rogram Dai | Stopped: | | | | |
| 3atch: | | Sta | rted: | rogram Dai | Stopped: Depression | | | | |
| 3atch: | | | | rogram Dai Reason: gram Dai | Stopped: Depression | 05/11/ | 1995 | | |
| Batch: DEPTRAN (Suspector Batch: | ed) | €ta | rted: 50.0 Milli | rogram Dai Reason: gram Dai | Stopped: Depression y | 05/11/ | 1995 | | |
| 3atch: DEPTRAN (Suspectors) 3atch: | ed) | €ta | rted: 50.0 Milli | rogram Dai Reason: gram Dai | Stopped: Depression y | | 1995 Details | | |



Date 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 Detai

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

Medicine Details:

| VOLTAREN (Suspected) | | Reason: | |
|------------------------|----------------------------|----------|-----|
| | 0.0 | | |
| 3atch: | Started: 18/07/1995 | Stopped: | |
| SINEQUAN (Suspected) | | Reason: | |
| | 0.0 | | |
| 3atch: | 3tarted: 19/08/1995 | Stopped: | |
| FORD PILLS (Suspected) | | Reason: | |
| | 0.0 | | |
| 3atch: | Started: | Stopped: | |
| ZOCOR (Suspected) | | Reason: | |
| | 0.0 | | |
| 3atch: | Started: | Stopped: | 02Y |

Laboratory Investigations:

| Date | Туре | 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:



Date 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 Detai

Medicine Details:

FLUCLOXACILLIN SODIUM (Suspected) Reason:

2.0 Gram Daily

3atch: **3tarted**: 06/07/1995 **3topped**:

Laboratory Investigations:

| Date | Туре | 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:



| Casa Numba | | | | | | | |
|---|---|---------------------|---|--|----------------------------------|---|-------------------|
| Reported espitalisation Onset Date | r: 104653 d: 15/11/199 n: e: 02/09/199 e: Not yet re | 5 | 1 | | , | Gender: Weight: Age: DOB: ausality: | 70.00 56Y |
| action Det | | | | | - | | caucanty peconare |
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| | | | | Reaso | n: | | |
| | | | 0.0 | Reaso | n: | | |
| OLTAREN (Su 3atch: | spected) | Sta | 0.0 arted: 18/07/19 | | n: Stopped: | | |
| OLTAREN (Su 3atch: | spected) | Sta | arted: 18/07/19 | | Stopped: | | |
| OLTAREN (Su 3atch: INEQUAN (Sus | spected) | | 0.0 | 995 Reasc | Stopped: n: | | |
| OLTAREN (Su 3atch: INEQUAN (Sus 3atch: | spected) | | arted: 18/07/19 | 995 Reasc | Stopped: n: Stopped: | | |
| OLTAREN (Su 3atch: INEQUAN (Sus 3atch: | spected) | | 0.0 | 995 Reas c | Stopped: n: Stopped: | | |
| 3atch: INEQUAN (Sustant) 3atch: ORD PILLS (Sustant) | spected) uspected) | Sta | 0.0 arted: 19/08/19 | 995 Reaso 995 Reaso | Stopped: n: Stopped: n: Stopped: | | |
| 3atch: INEQUAN (Sustant) 3atch: ORD PILLS (Sustant) | spected) uspected) | Sta | 0.0 arted: 19/08/19 0.0 0.0 arted: | 995 Reas c | Stopped: n: Stopped: n: Stopped: | | |
| 3atch: INEQUAN (Sustantial 3atch: ORD PILLS (Sustantial 3atch: OCOR (Suspection) | spected) uspected) | Sta Sta | 0.0 arted: 19/08/19 0.0 arted: 0.0 arted: | 995 Reaso 995 Reaso | Stopped: n: Stopped: n: Stopped: | | 02Y |
| 3atch: INEQUAN (Sustantial Batch: ORD PILLS (Sostantial Batch: OCOR (Suspection Batch: Batch: | spected) uspected) | Sta Sta | 0.0 arted: 19/08/19 0.0 0.0 arted: | 995 Reaso 995 Reaso | Stopped: n: Stopped: n: Stopped: | | 02Y |
| 3atch: INEQUAN (Sustantial Batch: ORD PILLS (Sostantial Batch: OCOR (Suspection Batch: | spected) uspected) | Sta Sta | 0.0 arted: 19/08/19 0.0 arted: 0.0 arted: | 995 Reaso 995 Reaso | Stopped: n: Stopped: n: Stopped: | Deta | |
| 3atch: INEQUAN (Suspendent) ORD PILLS (Suspendent) OCOR (Suspendent) 3atch: Aboratory Date GG | spected) spected) uspected) cted) Investigat Type GT = SGGT = | Sta Sta ions: | 0.0 arted: 19/08/19 0.0 arted: 0.0 arted: 0.0 arted: 0.0 arted: 0.0 | 995 Reaso Reaso | Stopped: n: Stopped: n: Stopped: | Detai | |
| 3atch: GORD PILLS (Some states) 3atch: COCOR (Suspendent) 3atch: Aboratory Date GG | spected) uspected) cted) Investigat Type | Sta Sta ions: | 0.0 arted: 19/08/19 0.0 arted: 0.0 arted: 0.0 arted: Date Tested | 995 Reaso | Stopped: n: Stopped: n: Stopped: | Deta | |



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

| Case Number: | 104653 | Seq : 1 | | | Gender: | F | |
|------------------|-------------------|----------------|-----------------------|---------------|------------|--------------------|--|
| | 15/11/1995 | | | | Weight: | | |
| lospitalisation: | | | | | Age: | | |
| Onset Date: | | | | | DOB: | | |
| | Not yet recovered | į | | | Causality: | Causality possible | |
| eaction Detai | | | | | | | |
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| Medicine Deta | ails: | | | | | | |
| | SODIUM (Suspected |) | | Reason: | | | |
| | | | 2.0 Gram | Daily | | | |
| 3atch: | | 3tarte | d : 06/07/1995 | | Stopped: | | |
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| Laboratory In | vestigations: | | | | | | |
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| Additional Inf | ormation | | | | | | |
| Additional inf | ormation: | | | | | | |
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| Report Detail | | | | | |
|---|----------------------|--------------------------|-------------------------------|--|--|
| Nopoli Dotali | | | | | |
| Case Number: 104852 | Seq: 1 | | Gender: F | | |
| Reported: 24/11/19 | • | | Weight: | | |
| | | | _ | | |
| Hospitalisation: Admitted | | Age: | | | |
| Onset Date: 14/11/19 | 95 | | DOB: | | |
| Outcome: Unknown | n | | Causality: Causality possible | | |
| eaction Detai | | | | | |
| Preferred Term | Severity | Report Descripti | on Treatment | | |
| Psychotic disorder | | Acute psychotic reaction | Diazepam, serenace | | |
| Delirium | | | · | | |
| Delusion | | | | | |
| | | | | | |
| Paranoia | | | | | |
| | | | | | |
| Medicine Details: SINEQUAN (Suspected) | | Reason: Dep | ression | | |
| SINEQUAN (Suspected) | 0.0 | veason. Dep | 6551011 | | |
| 3atch: | Started: | 31 | topped: 13/11/1995 | | |
| SERTRALINE HYDROCHLOR | | | ression | | |
| SERTIME IT DROCTEOR | | | C551011 | | |
| | | | | | |
| Datab. | | Milligram Daily | 15/44/400F | | |
| 3atch: | 50.0 Started: 14/ | | topped: 15/11/1995 | | |
| 3atch: Laboratory Investiga Date Type | Started: 14/ | 11/1995 | copped: 15/11/1995 Details | | |



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

 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 Detai

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

Medicine Details:

| SINEQUAN (Suspected) | | Reas | on: | | |
|--------------------------|----------|------------------|--------|----------|--|
| | 0.0 | | | | |
| 3atch: | Started: | L TERM | | Stopped: | |
| TIGASON (Suspected) | | Reas | on: | | |
| | 0.0 | | | | |
| Зatch: | Started: | L TERM | | Stopped: | |
| GOLD NOS (Suspected) | | Reas | on: | | |
| | 1.0 | Dose Unspecified | Weekly | | |
| 3atch: | Started: | | | Stopped: | |
| PREDNISOLONE (Suspected) | | Reas | on: | | |
| | 25.0 | Milligram | Daily | | |
| 3atch: | Started: | L TERM | | Stopped: | |

Laboratory Investigations:

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

Additional Information:



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

| Case Number: 105483 Reported: 21/12/1995 Hospitalisation: Onset Date: 15/11/1995 Outcome: Recovered Reaction Detai | Seq: 1 | | Gender: Weight: Age: DOB: Causality: | 74.00 |
|--|----------|------------------------|--|-------|
| Medicine Details: | | | | |
| BECLOFORTE (Suspected) | | Reason: | | |
| | 8.0 | Dose Unspecified Daily | | |
| 3atch: | Started: | L TERM | Stopped: | |
| Laboratory Investigations: | | | | |
| Laboratory investigations. | | | | |
| Additional Information: | | | | |



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

| Report Detail | Re | po | rt C | 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 Detai

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

Medicine Details:

DEPTRAN (Suspected) Reason: Depression

75.0 Milligram Daily

3atch: Started: 19/10/1990 Stopped: 29/04/1994

Laboratory Investigations:

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

Additional Information:



Date 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 Detai

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

Medicine Details:

 AROPAX (Suspected)
 Reason:

 0.0
 3atch:
 3tarted:
 01/01/1995
 3topped:
 21/08/1995

SINEQUAN (Suspected) Reason:

0.0

3atch: 3tarted: 01/07/1995 3topped:

Laboratory Investigations:

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

Additional Information:

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



Date 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 Detai

| 104011011 D 0141 | ā | | |
|--------------------------|----------|-----------------------|-----------|
| Preferred Term | Severity | Report Description | Treatment |
| Pruritus | | Itching ears and eyes | |
| Drug withdrawal syndrome | | | |
| Insomnia | | | |

Medicine Details:

SINEQUAN (Suspected) Reason: Depression

75.0 Milligram Daily

3atch: 3tarted: 01/01/1994 3topped: 28/02/1996

Laboratory Investigations:

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

Additional Information:

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



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

| Report Detail | | | |
|---|---------------------------------|----------------------------------|-----------|
| Case Number: 10972 Reported: 04/07/ ospitalisation: Onset Date: 06/06/ Outcome: Unkno | 1996 1996 | DO | |
| eaction Detai | 1 2 11 | | |
| Preferred Term | | Report Description | Treatment |
| Cerebellar syndrome | | Cerebellar degeneration | |
| Thinking abnormal Gait disturbance | | Cognitive impairment Sait ataxia | |
| Coordination abnormal | | dali alaxia | |
| Medicine Details: SINEQUAN (Suspected) | | Reason: | |
| | | Milligram Daily | |
| 3atch: | Started: | Stopped: | |
| | | | |
| Laboratory Investio Date Type | gations: Range Date Test | ted Result D | etails |
| Laboratory Investio Date Type | | ted Result D | etails |



Date 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 Detai

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

Medicine Details:

VALIUM (Other drug) Reason: Anxiety neurosis

30.0 Milligram Daily

3atch: 3tarted: 01/01/1995 3topped:

DOXEPIN HYDROCHLORIDE (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 01/03/1996 3topped: 28/06/1996

Laboratory Investigations:

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

Additional Information:

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

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 182 of 307



Date 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 Detai

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

Medicine Details:

| PLENDIL (Other drug) | | Reason: | Essential benign hyperten | sion |
|------------------------|----------------|---------------------|---------------------------|--------|
| Tablet | 10.0 N | Milligram Da | ily Oral | |
| 3atch: | 3tarted: 01/01 | 1/1994 | Stopped: | CONTIN |
| GRISOVIN (Suspected) | | Reason: | Dermatophytosis | |
| | 500.0 N | Milligram Da | ily | |
| 3atch: | Started: | | Stopped: | |
| FUCIDIN (Suspected) | | Reason: | | |
| Ointment | 2.0 [| Dose Unspecified Da | ily Topical | |
| 3atch: | Started: | | Stopped: | |
| ARISTOCORT (Suspected) | | Reason: | | |
| Ointment | 2.0 [| Dose Unspecified Da | ily Topical | |
| 3atch: | Started: | | Stopped: | |

Laboratory Investigations:

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

Additional Information:

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



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

| Report Detail | | | | | | |
|---------------------------------|---|------------|------------------------|--------------------|--|-------|
| Hospitalisation: Onset Date: | 15/07/1996 06/07/1996 Not yet recovered | Seq: | 1 | | Gender: Weight: Age: DOB: Causality: | 60.00 |
| | | | | | | |
| Medicine Det | | | | Reason: Rash | | |
| Capsule | , | | 10.0 Milligram | Daily | Oral | |
| 3atch: | | 3tar | ted: 07/05/1996 | | pped: | |
| Laboratory In | vestigations: | | | | | |
| Additional Int | | out indica | ates that start occurr | red sometime durir | ng the year. | |

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 184 of 307



Date 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 Detai

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

Medicine Details:

| PEPCIDINE (Other drug) | | Reason: Other diseases of esophagus | |
|------------------------|-----------------|-------------------------------------|--|
| | 0.0 | | |
| 3atch: | Started: | Stopped: | |
| OGEN (Other drug) | | Reason: | |
| | 0.0 | | |
| 3atch: | Started: | Stopped: | |
| CALTRATE (Other drug) | | Reason: | |
| | 0.0 | | |
| 3atch: | Started: | Stopped: | |
| PANAMAX (Other drug) | | Reason: Pain | |
| Oral application | 500.0 Milligram | As necessary Oral | |
| 3atch: | Started: | Stopped: | |

Laboratory Investigations:

| Date | Туре | 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.

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 185 of 307



Date 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 Detai

Medicine Details:

| Micalcinic Details. | | | |
|---------------------|---------------------|-------------------------------------|--|
| CARTIA (Other drug) | | Reason: | |
| Tablet | 100.0 Milligram | Daily Oral | |
| 3atch: | Started: | Stopped: | |
| DEPTRAN (Suspected) | | Reason: Specific disorders of sleep | |
| Capsule | 25.0 Milligram | Daily Oral | |
| 3atch: | 3tarted: 01/01/1993 | Stopped: 13/06/1996 | |

Laboratory Investigations:

| Date | Туре | 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.

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 186 of 307



Date 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 Detai

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

Medicine Details:

| DEPTRAN (Suspected) | | 3 | eason: | Pain | |
|-----------------------|------------|----------------|----------|----------|------------|
| Oral application | 10.0 | 0 Milligram | Daily | | Oral |
| 3atch: | Started: 2 | 3/09/1996 | | Stopped: | 30/09/1996 |
| PANADEINE (Suspected) | | 3 | eason: | Pain | |
| Oral application | 2.0 | Dose Unspecifi | ed Daily | | Oral |
| 3atch: | Started: | L TEI | RM | Stopped: | |
| FELDENE (Suspected) | | Reason: | | Pain | |
| | 1.0 | Dose Unspecifi | ed Daily | | |
| 3atch: | Started: | L TEI | RM | Stopped: | |

Laboratory Investigations:

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

Additional Information:



Date 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

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

DOXEPIN HYDROCHLORIDE (Suspected) Reason: Depression

125.0 Milligram Daily

3atch: **3tarted**: 01/05/1995 **3topped**: CONTIN

Laboratory Investigations:

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

Additional Information:

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



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

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|------------|--------|---|----|------|---|
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| R P | | | ., | -14 | |
| Re | \sim | | _ | U LU | ш |

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 Detai

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

Medicine Details:

SINEQUAN (Suspected) Reason:

0.0

3atch: Started: Stopped:

Laboratory Investigations:

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

Additional Information:

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



Date 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 Detai

| todotion Botal | | | |
|------------------|----------|--------------------|-----------|
| Preferred Term | Severity | Report Description | Treatment |
| Leukopenia | | | |
| Thrombocytopenia | | | |

Medicine Details:

| SORBITOL (Other drug) | | Reas | son: | |
|---------------------------------|----------|------------------|--------------|--|
| | 0.0 | | | |
| 3atch: | Started: | | Stopped: | |
| PARACETAMOL (Other drug) | | Reas | son: | |
| | 1.0 | Gram | As necessary | |
| 3atch: | Started: | | Stopped: | |
| COLOXYL WITH SENNA (Other drug) | | Reas | son: | |
| | 4.0 | Dose Unspecified | Daily | |
| 3atch: | Started: | | Stopped: | |
| PHENYTOIN SODIUM (Suspected) | | Reas | son: | |
| | 400.0 | Milligram | Daily | |

Laboratory Investigations:

3atch:

| Date | Туре | 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 | |

Stopped:

28/11/1996

3tarted: 03/11/1996

Additional Information:



Report Detail

Case Number: 113993

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: M

| Reported: 18/12/1996 | | | | | Weight: | | |
|-----------------------------------|--------------|-----------|---------|----------|-------------|----------------|------|
| ospitalisation: | | | | | Age: 8 | | |
| Onset Date: 28/11/1996 | | | | | DOB: 1 | 7/12/1911 | |
| Outcome: Recovered | | | | C | ausality: (| Causality poss | ible |
| eaction Detai | | | | | | | |
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| | | | | | | | |
| Medicine Details: | | | | | | | |
| DOXEPIN HYDROCHLORIDE (Suspected) | | | Reason: | | | | |
| | 25.0 | Milligram | Daily | | | | |
| 3atch: | Started: | | L TERM | Stopped: | 28/11/1996 | | |
| NORFLOXACIN (Suspected) | | | Reason: | | | | |
| | 800.0 | Milligram | Daily | | | | |
| 3atch: | Started: 20/ | | · | Stopped: | 28/11/1996 | | |
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| aboratory Investigations: | | | | | | | |
| aboratory investigations. | | | | | | | |
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| dditional Information: | | | | | | | |
| dultional information. | | | | | | | |
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Report Detail

Case Number: 115022

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

| Report | ed: 06/02/1997 | 7 | | | | Ţ | Neight: | | | |
|------------------------------|----------------|---------------|-------------|------------------|----------|-----------------|-------------|---------------|--------|--|
| lospitalisation: | | | | Age : 49Y | | | | | | |
| Onset Date: Outcome: Unknown | | | | DOB: | | | | | | |
| | | | | | | Ca | usality: Ca | ausality poss | ible | |
| eaction De | | | ., | | | | | | | |
| | erred Term | Sev | erity | Repor | t Descri | ption | | Treatment | | |
| allucination | 1 | | | | | | | | | |
| nsomnia Veight increa | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| ledicine I | | | | Reas | on: A | nxiety neurosis | | | | |
| Capsı | | | 10.0 Milli | | Daily | | Oral | | | |
| 3atch: | | Sta | irted: | gram | Daily | Stopped: | Jiui | | | |
| | | | | | | | | | | |
| aboratory Date | y Investigati | ons: Range | Date Tested | Result | | | Details | | | |
| Date | Туре | Nange | Date Tested | Result | | | Details | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| dditional | Information | n: | | | | | | | | |
| | | | | | | | | | | |
| out Due 2000 | 7/200 02:5054 | Dotoboss | roim o | | DDC004 | | | D | -100= | |
| ort Run 30/0 | 7/200 03:50PN | Database: pu | ısıme | Д | DRS004 | | | Page 192 | ot 307 | |



Date 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 Detai

| Caction Detai | - | | |
|----------------|----------|--|-----------|
| Preferred Term | Severity | Report Description | Treatment |
| Angioedema | | Face oedema including tongue and pharyngeal oedema | |

Medicine Details:

| SINEQUAN (Suspected) | | Reason: | |
|----------------------|---------------------|---------------------------------------|--|
| | 0.0 | | |
| 3atch: | Started: | Stopped: | |
| ESTIGYN (Suspected) | | Reason: | |
| | 0.0 | | |
| 3atch: | Started: | Stopped: | |
| RENITEC (Suspected) | | Reason: Essential benign hypertension | |
| | 20.0 Milligram | Daily | |
| 3atch: | Started: 01/01/1992 | Stopped: | |

Laboratory Investigations:

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

Additional Information:

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



Date 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 Detai

| Preferred Term | rred Term Severity Report Description | | Treatment | | |
|----------------|---------------------------------------|--|-----------|--|--|
| Glossitis | | | | | |

Medicine Details:

SINEQUAN (Suspected) Reason: Otr ecz&der due otr&unsp cause

Capsule 25.0 Milligram Daily Oral

3atch: Started: L TERM Stopped:

Laboratory Investigations:

| Date | Туре | 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.

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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

| ospitalisation: Onset Date: | Seq: 1 | | Wei A D | .ge: 70Y OB: |
|--------------------------------|---------------------|--------------------|----------------------------|-------------------------------|
| Outcome: Unknown eaction Detai | | | Causa | lity: Causality possible |
| Preferred Term | Severity | Repo | rt Description | Treatment |
| sthenia | С | ould not lift legs | to get out of bed. | _ |
| | | | | |
| ledicine Details: | | 7 | | |
| SEREPAX (Other drug) Tablet | 0.0 | Reas | son: Anxiety neurosis Oral | |
| Batch: | Started: | | Stopped: | |
| SINEQUAN (Suspected) | Juitou. | Rea | son: Depression | |
| Capsule | 20.0 | Milligram | Total Oral | |
| 3atch: | Started: | | Stopped: | |
| | | | | |
| _aboratory Investigation | S: Range Date Teste | ed Result | | Details |



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

| Case Number: 115939 Reported: 12/03/1997 ospitalisation: Onset Date: | Seq: 1 | | Gender: M Weight: Age: 83Y DOB: | | | | |
|--|----------------------------|---------------------|--|----------------------------|--|--|--|
| Outcome: Unknown | | | Cau | sality: Causality possible | | | |
| action Detai Preferred Term | Severity | Repor | t Description | Treatment | | | |
| somnia | | • | | | | | |
| | | | | | | | |
| | | | | | | | |
| edicine Details: SINEQUAN (Suspected) | | Reas | on. | | | | |
| Capsule | 10.0 | Milligram | | ral | | | |
| Batch: | Started: | 3 - - | Stopped: | | | | |
| aboratory Investigation Date Type | IS: Range Date Test | ed Result | | Details | | | |
| | | | | | | | |
| dditional Information: | | | | | | | |
| | | | | | | | |



Report Detail

Case Number: 115940

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

| Reported: 12/03/1997 | 7 | | | | | Weig | ht: | | |
|--|--------------|-----------------|---------------|----------|----------|------|-------------------|-----------|--------|
| ospitalisation: | | Age: 27Y | | | | | | | |
| Onset Date: | | DOB: | | | | | | | |
| Outcome: Unknown | | | Causality: Ca | | | | ausality possible | | |
| eaction Detai | 1 0 | ., 1 | | | | - | | | |
| Preferred Term | Sev | erity | | t Descr | iption | | | Treatment | |
| ingivitis | | Blee | ding gums. | | | | | | |
| pistaxis | | | | | | | | | |
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| | | | | | | | | | |
| ledicine Details: SINEQUAN (Suspected) | | | Reas | on: | | | | | |
| Capsule | | 75.0 Milli | | Daily | | Oral | | | |
| 3atch: | 2ta | rted: | gram | Daily | Stopped: | Olai | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| aboratory Investigati | | • | | | | | | | |
| Date Type | Range | Date Tested | Result | | | | Details | | |
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| dditional Information |): | | | | | | | | |
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| ort Run 30/07/200 03:50PN | | | | | | | | | |
| oort Run 30/07/200 03:50PN | Database: pu | sime | А | DRS004 | | | | Page 197 | of 307 |



Date 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 Detai

| todotion Dotal | | | <u> - </u> | |
|----------------|----------|--------------------|--|--|
| Preferred Term | Severity | Report Description | Treatment | |
| Chest pain | | | | |

Medicine Details:

| SINEQUAN (Suspected) | | Reason: | Anxiety neurosi | is |
|----------------------|---------------------|---------|-----------------|------------|
| Capsule | 25.0 Milligram | Daily | | Oral |
| 3atch: | Started: 26/03/1997 | | Stopped: | 07/04/1997 |
| SINEQUAN (Suspected) | | Reason: | Anxiety neurosi | is |
| Capsule | 20.0 Milligram | Daily | | Oral |
| 3atch: | Started: 08/04/1997 | | Stopped: | |
| SINEQUAN (Suspected) | | Reason: | Anxiety neurosi | is |
| Capsule | 10.0 Milligram | Daily | | Oral |
| 3atch: | Started: 09/04/1997 | | }topped: | |

Laboratory Investigations:

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

Additional Information:



Date 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Hypertonia | Severe | | |
| Myalgia | | | |

Medicine Details:

| ISORDIL (Other drug) | | Reason: | Chron isch heart dis | s no hyper |
|---------------------------|----------------|----------------------|----------------------|------------|
| | 2.0 | Dose Unspecified Dai | ly | |
| 3atch: | Started: | | Stopped: | CONTIN |
| BETALOC (Other drug) | | Reason: | Chron isch heart dis | s no hyper |
| | 50.0 N | Milligram Dai | ly | |
| 3atch: | Started: | | Stopped: | CONTIN |
| MURELAX (Other drug) | | Reason: | Anxiety neurosis | |
| | 30.0 N | Milligram Dai | ly | |
| Зatch: | Started: | | Stopped: | CONTIN |
| KENACORT-A 10 (Suspected) | | Reason: | | |
| | 0.0 | | | |
| Зatch: | 3tarted: 07/05 | 5/1997 | Stopped: | |

Laboratory Investigations:

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

Additional Information:

History of allergy to stemetil and stelazine.



Date 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:
Onset Date: 07/05/1997

Weight: 74.00
Age: 73Y
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

| Micarchic Details. | | | | |
|------------------------|----------------------|-----------------------|--------|--|
| LIGNOCAINE (Suspected) | Rea | son: | | |
| Injection | 1.0 Dose Unspecified | I 1 time Intraart | cular | |
| 3atch: | Started: 07/05/1997 | Stopped: | | |
| SINEQUAN (Suspected) | Rea | son: Anxiety neurosis | | |
| | 50.0 Milligram | Daily | | |
| 3atch: | Started: | Stopped: | CONTIN | |

Laboratory Investigations:

Additional Information:

History of allergy to stemetil and stelazine.



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

| Onset Date: Outcome: Unknown | Seq: 1 | | | | |
|---|---------------|-------------|-----------------|---------|-----------------------|
| ospitalisation: Onset Date: Outcome: Unknown action Detai | | | | Gende | |
| Onset Date: Outcome: Unknown eaction Detai | | | | Weigl | |
| Outcome: Unknown action Detai | | | | Ag | |
| eaction Detai | | | | DO | |
| | | | | Causain | y: Causality possible |
| i iciciica iciiii | Severity | Ren | ort Description | | Treatment |
| gitation | Coverity | rtop | ort Description | | Treatment |
| | | | | | |
| edicine Details: SINEQUAN (Suspected) | | | ason: Anxiety r | eurosis | |
| Capsule | 25.0 | Milligram | Daily | Oral | |
| 3atch: | Started: | | €topp | ed: | |
| NDERAL (Suspected) | | ₹e | ason: | | |
| Tablet | 20.0 | Milligram | Daily | Oral | |
| 3atch: | Started: | | }topp | ed: | |
| | s : | sted Result | | D | etails |
| aboratory Investigations Date Type R | Range Date Te | | 1 | D | |



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

Report Detail

Case Number:117774Seq:1Gender:FReported:23/05/1997Weight:Hospitalisation:Age:

Onset Date: 24/04/1997 **DOB**:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

| FOSAMAX (Suspected) | | Reason: | Osteoporosis | |
|--|--|------------------|-------------------------|------------|
| Tablet | 10.0 Milligram | Daily | | Oral |
| Зatch: | 3tarted: 15/03/1997 | | Stopped: | 01/05/1997 |
| SINEQUAN (Suspected) | | Reason: | Anxiety neuros | is |
| Capsule | 20.0 Milligram | Daily | | Oral |
| Зatch: | 3tarted: 19/04/1996 | | Stopped: | |
| | | | | |
| TEMAZEPAM (Suspected) | | Reason: | | |
| TEMAZEPAM (Suspected) Oral application | 10.0 Milligram | Reason: Daily | | Oral |
| ` . , | 10.0 Milligram 3tarted: 01/01/1992 | | 3topped: | Oral |
| Oral application | · · | | | |
| Oral application 3atch: | · · | Daily | Stopped: Congestive hea | |

Laboratory Investigations:

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

Additional Information:

Trimethoprim x 7 days 31jan-> 6 feb 1997. cephalexin 25m tds 6 mar->13 mar 97 exposure to quinine bisculate 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.

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 202 of 307



Date 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:
 Age:
 Onset Date:
 24/04/1997
 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

| ROCALTROL (Suspected) | | Reason: | Osteoporosis | |
|-----------------------|----------------------------|---------|--------------------------|--------|
| Capsule | 500.0 Microgram | Daily | Oral | |
| Зatch: | Started: 01/01/1995 | | Stopped: | CONTIN |
| LASIX (Suspected) | | Reason: | Congestive heart failure | |
| Tablet | 40.0 Milligram | Daily | Oral | |
| 3atch: | Started: 01/01/1995 | | Stopped: | |

Laboratory Investigations:

Additional Information:

Trimethoprim x 7 days 31jan-> 6 feb 1997. cephalexin 25m tds 6 mar->13 mar 97 exposure to quinine bisculate 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.

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 203 of 307



Date 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:
Onset Date: 31/12/1996
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

| Veaction Detai | - | - | |
|----------------|----------|--------------------|---|
| 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

3atch: Started: Stopped:

Laboratory Investigations:

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

Additional Information:

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

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 204 of 307



Date Range: 1 Jan 1989 To 31 Dec 2059 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-----------|
| Agitation | | | |
| Anxiety | | | |

Medicine Details:

| Medicine Details. | | | | | |
|----------------------|----------------|------------|--|--|--|
| MELLERIL (Suspected) | Reason: | | | | |
| Tablet | 75.0 Milligram | Daily Oral | | | |
| 3atch: | Started: | Stopped: | | | |
| SINEQUAN (Suspected) | | Reason: | | | |
| | 60.0 Milligram | Daily | | | |
| 3atch: | Started: | Stopped: | | | |

Laboratory Investigations:

| Date | Туре | 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.



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

| - | \sim | | eta | |
|---|--------|------|-----|--|
| | | | | |
| | | | | |

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 Detai

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

Medicine Details:

EFEXOR (Suspected) Reason:

75.0 Milligram Daily

3atch: 3tarted: 12/05/1997 **3topped:** 21/06/1997

DEPTRAN (Suspected) Reason: Depression

50.0 Milligram Daily

Batch: Started: Stopped:

Laboratory Investigations:

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

Additional Information:



Date 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------------|-----------|
| Hyperglycaemia | | Fluctuating blood sugar. | |

Medicine Details:

| OESTRADIOL (Suspected) | | Reason: | Menopausal s | ymptoms |
|--------------------------------|---------------------------------------|--------------------------|--------------|--------------|
| Implant | 0.0 | | | Subcutaneous |
| 3atch: | Started: 01/01/1994 | | Stopped: | |
| FLIXOTIDE (Suspected) | | Reason: | Asthma | |
| Inhalation | 4.0 Dose Unspe | cified Daily | | Inhalation |
| Зatch: | 3tarted: 01/04/1995 | | Stopped: | |
| | | | | |
| SANDOMIGRAN (Suspected) | | Reason: | Headache | |
| SANDOMIGRAN (Suspected) Tablet | 2.0 Dose Unspe | Reason: ecified Daily | Headache | Oral |
| | 2.0 Dose Unspe Started: 01/05/1996 | | Headache | Oral |
| Tablet | · | | | Oral |
| Tablet 3atch: | · | ecified Daily | | Oral |

Laboratory Investigations:

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

Additional Information:

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

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 207 of 307



Date 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 Detai

Medicine Details:

| MEGICINE DELANS. | | | | |
|-----------------------------------|----------------------------|--------------|--------------------------------|--|
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: | Otr mus rheum,fibrosit&myalgia | |
| Tablet | 50.0 Milligram | Daily | Oral | |
| 3atch: | Started: 01/04/1997 | | Stopped: | |
| SEREVENT (Suspected) | | Reason: | Asthma | |
| Inhalation | 4.0 Dose Unspe | cified Daily | Inhalation | |
| 3atch: | Started: 01/04/1995 | | Stopped: | |

Laboratory Investigations:

Additional Information:

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

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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

| Case Number: 1 Reported: (| 118846 | Sea | 1 | | | Gender: F | | |
|-------------------------------|-------------------------|---------------------|-------------------|--------|--------------------|------------------------------|--|--|
| | | • | | | | | | |
| spitalisation: | J 4 /01/1991 | | | | | Age: | | |
| Onset Date: | | | | | | DOB: | | |
| Outcome: | Linknown | | | | Ca | usality: Causality possible | | |
| | JIKIIOWII | | | | O. | desailty. Causality possible | | |
| action Detai Preferred | Torm | Seve | ority | Popor | Description | Treatment | | |
| onstipation | reiiii | Sevi | епц | Кери | Description | Heatment | | |
| | | | • | | | | | |
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| | | | | | | | | |
| | | | | | | | | |
| edicine Deta | ile | | | | | | | |
| INEQUAN (Suspec | | | | Reas | on: Otr&unsp forms | neuralg&neurit | | |
| Capsule | • | | 10.0 Mill | | | Oral | | |
| 3atch: | | 3ta | Started: Stopped: | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| boratory Inv | /estigatio | ns: Range | Date Tested | Result | | Details | | |

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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: Reported: ospitalisation: Onset Date: | 10/07/1997 | Seq: | 1 | | | Gender Weight Age DOB | t: o: 75Y |
| | Not yet reco | vered | | | | Causality | : Causality possible |
| eaction Detail | | Seve | ority | Papar | Description | | Treatment |
| Dyspepsia | tu reiiii | Seve | city | Repon | . Description | Cin | netidine, disapride given |
| | | | | | | wit | h little success. |
| Desophagitis | | | | | | | |
| ledicine Det | ails: | | | | | | |
| SINEQUAN (Susp | | | | Reaso | on: | | |
| Capsule | | | | | | | |
| | | | 50.0 Millio | | Daily | Oral | |
| 3atch: | | Sta | rted: | gram L TERM | Daily Stopped: | | |
| _aboratory In | nvestigatio Type | | | | | • | tails |



Date 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 Detai

| 100000000000000000000000000000000000000 | | - | |
|---|----------|---------------------|-----------|
| 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

3atch: Started: 01/04/1997 Stopped:

Laboratory Investigations:

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

Additional Information:

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



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

| Re | | | |
|----|--|--|--|
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| | | | |
| | | | |

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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--------------------|-----------|
| Urinary retention | | | |

Medicine Details:

| PETHIDINE HYDROCHLORIDE (Other drug |) | | | Reason: | Abdominal pain |
|-------------------------------------|----------|------|-----------|---------|----------------------------|
| | 10 | 0.00 | Milligram | As ne | ecessary |
| 3atch: | Started: | 18/ | /06/1997 | | Stopped: |
| AMLODIPINE (Other drug) | | | | Reason: | |
| | | 5.0 | Milligram | Daily | |
| 3atch: | Started: | | | L TERM | Stopped: |
| EPILIM (Other drug) | | | | Reason: | Other&unspecified epilepsy |
| | | 1.0 | Gram | Daily | |
| 3atch: | Started: | | | | Stopped: |
| | marteu. | | | | Mopped. |
| DUCENE (Other drug) | starteu. | | | Reason: | Abdominal pain |
| DUCENE (Other drug) | Janteu. | 2.0 | Milligram | | ••• |

Laboratory Investigations:

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

Additional Information:



Report Detail

Case Number: 120683

Reported: 10/09/1997

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: M

Weight:

| ospitalisation: | | | | | Age : 7 | 1 | |
|------------------------------------|-------------|-------------|---------|---------------|-----------------|----------------|--------|
| Onset Date: | | | | | DOB : 04 | 4/03/1926 | |
| Outcome: Unknown | | | | C | Causality: C | ausality possi | ible |
| action Detai | | | | | | | |
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| | | | | | | | |
| ledicine Details: | | | | 2 | | | |
| OMEPRAZOLE (Other drug) | | | Reason: | Other disease | es of esophagus | • | |
| | | Milligram | Daily | | | | |
| 3atch: | Started: | | | Stopped: | | | |
| DOXEPIN HYDROCHLORIDE (Suspected) | | | Reason: | Depression | | | |
| | | Milligram . | Daily | | | | |
| Batch: | Started: | L | _ TERM | Stopped: | 17/06/1997 | | |
| DOXEPIN HYDROCHLORIDE (Suspected) | | | Reason: | Depression | | | |
| | | Milligram | Daily | | 0.110.011.00= | | |
| 3atch: | Started: 18 | /06/1997 | | Stopped: | 24/06/1997 | | |
| | | | | | | | |
| | | | | | | | |
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| aboratory Investigations: | | | | | | | |
| azoratory invoctigationer | | | | | | | |
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| dditional Information: | | | | | | | |
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| ort Run 30/07/200 03:50PN Database | · nusime | | ADRS00 | 14 | | Page 213 | of 207 |



Date 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|--------------------|-----------|
| Erectile dysfunction | | | |

Medicine Details:

| Medicine Details. | | | | | |
|----------------------|----------|-----------|---------|--------|--|
| SINEQUAN (Suspected) | | | Reason: | | |
| Capsule | 50.0 | Milligram | Daily | Oral | |
| Зatch: | Started: | | 3t | opped: | |
| SINEQUAN (Suspected) | | | Reason: | | |
| Capsule | 100.0 | Milligram | Daily | Oral | |
| 3atch: | Started: | | \$t | opped: | |

Laboratory Investigations:

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

Additional Information:

Patient experienced reaction when dose of sinequan was increased from 50mg to 100mg.



Date 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 Gender: M Seq: 1 Reported: 15/10/1997 Weight: Hospitalisation: Age: A7

Onset Date: 31/12/1997 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

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

Medicine Details:

ZOCOR (Suspected) 0.0 Started: 3atch: Stopped:

Reason:

Othr&unspec metabolic diseases

DOXEPIN HYDROCHLORIDE (Suspected) Reason: Specific disorders of sleep

Capsule 10.0 Milligram Daily Oral L TERM 3atch: Started: Stopped:

Laboratory Investigations:

| Date | Туре | 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.



Date 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

| Vedelion Detai | _ | | |
|----------------|----------|---------------------|--|
| Preferred Term | Severity | Report Description | Treatment |
| Rash | | Eczematous eruption | |
| Pruritus | | | Ceased amlodipine & frusemide. given topical steroids, dexepin at night, |

Medicine Details:

| AMLODIPINE (Suspected) | | Reason: | Essential ben | ign hypertension | |
|-----------------------------------|---------------------|---------|---------------|------------------|--------|
| | 5.0 Milligram | Daily | | | |
| 3atch: | Started: 11/05/1997 | | Stopped: | 11/06/1997 | |
| FRUSEMIDE (Suspected) | | Reason: | Essential ben | ign hypertension | |
| Oral application | 40.0 Milligram | Daily | | Oral | |
| Заtch: | Started: 01/03/1996 | | Stopped: | 16/09/1997 | |
| POTASSIUM CHLORIDE (Suspected) | | Reason: | | | |
| Oral application | 1.2 Gram | Daily | | Oral | |
| Зatch: | 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 | Туре | 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.

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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 De | tail | | | | | | |
|-------------------------------------|----------------------------|------------------|--|--------------------------------------|---------------|-----------------------------|--|
| Report Iospitalisati Onset Da | ate: | Seq: 1 | | Gender: F Weight: Age: DOB: | | | |
| | me: Unknown | | | | Сац | isality: Causality possible | |
| eaction De | etaı ferred Term | Severity | | Renor | t Description | Treatment | |
| Nightmare | erred remi | Geventy | | Порог | Description | ricatilicit | |
| | | | | | | | |
| Medicine I | | | | 2000 | Depression | | |
| SINEQUAN (S | | ŗ | Reason: Depression 50.0 Milligram Daily Ora | | | ral | |
| 3atch: | | | Started: Stopped: | | | | |
| | y Investigati | | e Tested | Popult | | Dotailo | |
| Date | Туре | Range Date | e Lested | Result | | Details | |
| Additional | l Information | · | | | | | |
| eport Run 30/0 | 7/200 03:50PN | Database: pusime | | Α | DRS004 | Page 217 of 307 | |



Date 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:
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 | | | |
| 3atch: | Started: 01/01/1990 | Stopped: | | | |
| DEPTRAN (Interaction) | 5 | eason: | | | |
| | 25.0 Milligram | Daily | | | |
| Зatch: | Started: 01/01/1997 | Stopped: | | | |
| | _ | | | | |
| DIAZEPAM (Other drug) | ₹ | eason: | | | |
| DIAZEPAM (Other drug) | ۱.0 Dose Unspecifi | | | | |
| DIAZEPAM (Other drug) 3atch: | | | | | |
| , J | 1.0 Dose Unspecifi | ed Daily | | | |
| 3atch: | 1.0 Dose Unspecifi | ed Daily Stopped: eason: | | | |

Laboratory Investigations:

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

Additional Information:

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

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

| Report D | etail |
|----------|-------|
|----------|-------|

 Case Number:
 123742
 Seq: 1
 Gender: M

 Reported:
 30/12/1997
 Weight:

Hospitalisation: Age: 50Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Medicine Details:

| Medicine Details. | | | | | |
|------------------------------|----------------------|----------|--|--|--|
| PREPULSID FORTE (Other drug) | Reason: | | | | |
| | 2.0 Dose Unspecified | Daily | | | |
| 3atch: | Started: 01/01/1993 | Stopped: | | | |
| AROPAX (Other drug) | Reaso | n: | | | |
| | 1.0 Dose Unspecified | Daily | | | |
| 3atch: | 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.

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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: 123743 Seq: 1 Gender: M
Reported: 31/12/1997 Weight:
Hospitalisation: Age: 43Y

Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

| teaction Detai | action beta | | | | | | | |
|------------------|-------------|----------------------|----------------------|--|--|--|--|--|
| Preferred Term | Severity | Report Description | Treatment | | | | | |
| Cough | | Continuing dry cough | | | | | | |
| Gingival atrophy | | Shrinking gums | Deptran discontinued | | | | | |
| Toothache | | Tooth pain | | | | | | |
| Dysgeusia | | | | | | | | |

Medicine Details:

| BETALOC (Other drug) | | Reason: | Essential ben | ign hypertension |
|----------------------|----------------------------|---------|---------------|------------------|
| Tablet | 100.0 Milligram | Daily | | Oral |
| 3atch: | Started: 01/01/1997 | | Stopped: | |
| DEPTRAN (Suspected) | | Reason: | Depression | |
| | 0.0 | | | |
| 3atch: | Started: 01/12/1996 | | Stopped: | 28/12/1997 |
| DILANTIN (Suspected) | | Reason: | Other&unspec | cified epilepsy |
| Oral application | 500.0 Milligram | Daily | | Oral |
| 3atch: | Started: 01/01/1992 | | Stopped: | |

Laboratory Investigations:

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

Additional Information:

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

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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: 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|----------------------------------|-----------|
| Pollakiuria | | Increased frequency of urination | |

Medicine Details:

SINEQUAN (Suspected) Reason: Depression

Capsule 20.0 Milligram Daily Oral

3atch: 3tarted: 12/02/1998 **3topped:** CONTIN

Laboratory Investigations:

| Date | Туре | 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.

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 221 of 307



Date 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:
Onset Date:

DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

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

Medicine Details:

| SINEQUAN (Suspected) | | Reason: Anxiety n | eurosis |
|----------------------|----------|-------------------|---------|
| Tablet | 0.0 | Daily | Oral |
| 3atch: | Started: | Stoppe | ed: |

Laboratory Investigations:

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

Additional Information:

The patient also has hepatitis c



Date 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--|-----------|
| Weight increased | | Gained 1 stone during first 2 years of | |

Medicine Details:

SINEQUAN (Suspected)

Capsule

0.0

Oral

3atch:

3tarted: 01/01/1995

Stopped:

Laboratory Investigations:

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

Additional Information:

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



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

| eport Detail Case Number: 127727 | Seq: 1 | | | der: F |
|--|-----------------|-------------------------|----------------------|--------------------------|
| Reported: 25/05/19 | 998 | | Wei | |
| spitalisation: | | | | lge: |
| Onset Date: | rocovered | | | OB: |
| Outcome: Not yet a action Detai | recovered | | Causa | lity: Causality possible |
| Preferred Term | Severity | Report Des | scription | Treatment |
| ysgeusia | | Bitter persistant taste | | |
| | | | | |
| edicine Details: DEPTRAN (Interaction) | | Reason: | Depression | |
| Tablet | 50.0 | Milligram Daily | | |
| 3atch: | Started: | L TERM | Stopped: | |
| RENITEC (Interaction) | 0.5 | Reason: | Essential benign hyp | ertension |
| Tablet 3atch: | 2.5 Started: | Milligram Daily L TERM | Oral Stopped: | |
| | | | | |
| aboratory Investiga Date Type | Range Date Tes | sted Result | | Details |
| | | | | |
| | | | | |



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

| R۵ | no | rt | ח | eta | il |
|----|----|-------|------------------|-----|----|
| UE | νv | יו ני | \boldsymbol{L} | τιa | |

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 Detai

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

Medicine Details:

| DIAZEPAM (Other drug) | | Reason: |
|----------------------------------|-----------------|----------------|
| | 0.0 | |
| Зatch: | Started: | Stopped: |
| ENALAPRIL MALEATE (Other drug) | | Reason: |
| | 0.0 | |
| 3atch: | Started: | Stopped: |
| VERAPAMIL HYDROCHLORIDE (Other d | rua) | Reason: |
| • | 3/ | |
| ٠ | 240.0 Milligram | Daily |
| Satch: | • | Daily Stopped: |
| 3atch: OESTRADIOL (Other drug) | 240.0 Milligram | • |
| | 240.0 Milligram | Stopped: |

Laboratory Investigations:

| Date | Туре | 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.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Case Number: | | Seq: 1 | | | Gender: | F |
|-----------------|-------------------|------------------------------------|------------------------|---------------|----------------------|------------------------|
| - | 21/07/1998 | | | | Weight: | |
| ospitalisation: | | | | | Age: | 55Y |
| Onset Date: | | | | | DOB: | |
| | Not yet recovered | | | | Causality: | Causality certain |
| action Detai | | | | | | |
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| | | | | | | |
| edicine Det | ails: | | | | | |
| SINEQUAN (Suspe | ected) | | 30 | eason: | | |
| Capsule | | 10.0 | Milligram | Daily | Oral | |
| 3atch: | | Started: | | 3to | opped: | |
| | | | | | | |
| | | | | | | |
| aboratory In | vestigations: | | | | | |
| aboratory In | vestigations: | | | | | |
| aboratory In | vestigations: | | | | | |
| aboratory In | vestigations: | | | | | |
| aboratory In | vestigations: | | | | | |
| | | | | | | |
| dditional Inf | formation: | rawing from sin | equan once be | fore the date | e of onset is not ne | cessarily accurate but |
| dditional Inf | formation: | rawing from sin e during the mo | equan once be nth. | fore the date | e of onset is not ne | cessarily accurate but |
| dditional Inf | formation: | rawing from sin | equan once be nth. | fore the date | e of onset is not ne | cessarily accurate but |
| dditional Inf | formation: | rawing from sin e during the mo | equan once be inth. | fore the date | e of onset is not ne | cessarily accurate but |

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 226 of 307



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

| r: 130187 d: 14/08/1998 n: e: Not yet recovai red Term | - | rerity | Report | Wei | der: F ght: Age: OB: Ility: Causality possible Treatment |
|--|-----------------------|-----------------------------|---|--|---|
| etails: | Sev | erity | Report | t Description | Treatment |
| etails: | Jev | City | Теры | Description | redifficit |
| | | | | | |
| pootou, | | | Reaso | on: Depression | |
| | | 25.0 Milli | | Daily Oral | |
| | Sta | | | | |
| | | | | | |
| Туре | Range | Date Tested | Result | | Details |
| nformation: | | | | | |
| | Investigation Type | Investigations: Type Range | Investigations: Type Range Date Tested | Investigations: Type Range Date Tested Result | Investigations: Type Range Date Tested Result |



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

| Report Det | tail | | | | | | | |
|---|--------------------|----------------|-------------|--------|--------------------------------------|---------------|-----------------|--|
| Case Number: 130188 Reported: 14/08/1998 Hospitalisation: Onset Date: | | | 1 | | Gender: F Weight: Age: DOB: | | | |
| Outcome: Not yet recovered | | | | | Ca | usality: Caus | sality possible | |
| eaction De | etai erred Term | Seve | rity / | Donor | t Description | | Treatment | |
| nsomnia | erred remi | Seve | ity | Кери | t Description | | пеаннени | |
| | | | | | | | | |
| ledicine [SINEQUAN (S | | | | Reas | on: Depression | | | |
| Capsu | | | 50.0 Milli | | | Oral | | |
| 3atch: | | Start | | | Stopped: | | | |
| .aboratory | / Investigati | | Date Tested | Result | | Details | | |
| Buto | 1,450 | rango | Date 100tou | rtooun | | Dotallo | | |
| Additional | Information | 1: | | | | | | |
| port Run 30/0 | 7/200 03:50PN | Database: pusi | ime | A | DRS004 | Ī | Page 228 of 307 | |



Date 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 Detai

| 104011011 20141 | | | |
|--------------------------|----------|--|---|
| Preferred Term | Severity | Report Description | Treatment |
| Hypertonia | | Muscle spasms and cramps especially to | |
| Drug withdrawal syndrome | | | Changed therapy to tofranil after sudden deptran cessation with decreased symptoms. |
| Insomnia | | | |
| Myalgia | | | |

Medicine Details:

DEPTRAN (Suspected)

Oral application

3atch:

Reason: Depression

Oral

Daily

Oral

Storped: 10/06/1998

Laboratory Investigations:

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

Additional Information:

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



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

| eport Detail | | | | |
|---|----------------------------|----------|------------|---------------------------|
| Case Number: 130546 Reported: 25/08/1998 ospitalisation: | Seq: 1 | | Wei | der: F ght: Age: AD |
| Onset Date: 26/06/1998 | | | | OB: |
| Outcome: Recovered | | | | lity: Causality possible |
| eaction Detai | | | | |
| Preferred Term | Severity | Report D | escription | Treatment |
| Convulsion Orug withdrawal syndrome neons Fatigue | | | | |
| Feeding disorder neonatal Respiratory disorder | | | | |
| | | | | |
| | | Reason: | | |
| DOXEPIN HYDROCHLORIDE (Suspec | 0.0 | Reason: | Stopped: | |
| DOXEPIN HYDROCHLORIDE (Suspec | | Reason: | Stopped: | |
| DOXEPIN HYDROCHLORIDE (Suspec | 0.0 | | Stopped: | |
| DOXEPIN HYDROCHLORIDE (Suspec | 0.0 Started: | | Stopped: | |
| 3atch: PROTHIADEN (Suspected) 3atch: | 0.0 Started: 0.0 Started: | | | |
| DOXEPIN HYDROCHLORIDE (Suspected) PROTHIADEN (Suspected) 3atch: | 0.0 Started: 0.0 Started: | Reason: | | Details |

Additional Information:

Doxepin and prothiaden administered to the mother in pregnancy and pueperium. 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.



Date 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 Detai

| todotion botal | 8 | <u>-</u> | |
|----------------------|----------|--------------------|-----------|
| Preferred Term | Severity | Report Description | Treatment |
| Personality disorder | | Personality change | |
| Flushing | | | |
| Headache | | | |
| Hyperhidrosis | | | |
| Insomnia | | | |
| Muscle twitching | | | |

Medicine Details:

SINEQUAN (Suspected)

Capsule

Reason: Othr and unspecified urticaria

Daily

Oral

3atch: Started: 10/08/1998 Stopped: CONTIN

Laboratory Investigations:

| Date | Туре | 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.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

| Case Number: 130880 Reported: 07/09/1998 Iospitalisation: | ported: 07/09/1998 sation: | | | Gender: F Weight: Age: DOB: | | | |
|---|-------------------------------|-------------|--------|--------------------------------------|----------------------------|--|--|
| Onset Date: Outcome: Unknown | | | | Cau | sality: Causality possible | | |
| eaction Detai | | | | Cau | sality. Causality possible | | |
| Preferred Term | Seve | erity | Report | Description | Treatment | | |
| Tachycardia | | | • | · | | | |
| | | | | | | | |
| Medicine Details: SINEQUAN (Suspected) | | | Reaso | n: | | | |
| Capsule | | 0.0 | | O | ral | | |
| 3atch: | 3taı | rted: | L TERM | Stopped: | | | |
| _aboratory Investigatio | o ns: Range | Date Tested | Result | | Details | | |
| 71. | 3 | | | | | | |
| Additional Information: | | | | | | | |
| port Run 30/07/200 03:50PN | Database: pus | sime | AE | DRS004 | Page 232 of 307 | | |



Date 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 Detai

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

Medicine Details:

| Medicine Details. | | | | | |
|-----------------------------------|---------------------|-------------|---------|------------|--------|
| CAPADEX (Other drug) | | Reason: | | | |
| | 0.0 | As necessa | ary | | |
| Зatch: | Started: | 3 | topped: | | |
| OXAZEPAM (Other drug) | | Reason: | | | |
| | 15.0 Milligram | Daily | | | |
| Зatch: | Started: | 3 | topped: | | CONTIN |
| DOXEPIN HYDROCHLORIDE (Suspected) | | Reason: Dep | ression | | |
| | 100.0 Milligram | Daily | | | |
| 3atch: | Started: 01/07/1998 | 3 | topped: | 06/08/1998 | |

Laboratory Investigations:

| Date | Туре | 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.

Report Run 30/07/200 03:50PN Database: pusime ADRS004 Page 233 of 307



Date 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: 11/09/19 | • | | Weight: 70.00 |
| ospitalisation: | | | Age: 84Y |
| Onset Date: | | | DOB: |
| Outcome: Recove | ered | C | ausality: Causality probable |
| eaction Detai | | | , ,, |
| Preferred Term | Severity | Report Description | Treatment |
| Constipation | | | Ceased doxepin and started citalopram |
| | | | |
| Medicine Details: DOXEPIN HYDROCHLORIDE | F (Suspected) | Reason: Depression | |
| DOXEL IN THE DROOMEONIDE | | filligram Daily | |
| 3atch: | Started: | Stopped: | 16/06/1998 |
| | | | |
| aboratory Investiga | ations: | | |
| _aboratory Investiga Date Type | ations: Range Date Teste | d Result | Details |
| Laboratory Investiga Date Type | 1 | d Result | Details |



Date 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 Detai

| i todotioni Botai | | | |
|--------------------|----------|--------------------|--|
| 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) | र | eason: | |
|----------------------|----------------------|-----------------|--|
| | 10.0 Milligram | Daily | |
| 3atch: | Started: 01/01/1988 | Stopped: | |
| | | | |
| TENORMIN (Suspected) | ₹ | eason: | |
| TENORMIN (Suspected) | र। 50.0 Milligram | eason: Daily | |

Laboratory Investigations:

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

Additional Information:

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



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

Case Number:133235Seq:1Gender:MReported:18/11/1998Weight:Hospitalisation:Admitted to hospitalAge:83Y

Onset Date: 25/10/1998 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--------------------|---------------------------|
| Orthostatic hypotension | | | Ceased deptran and endep. |

Medicine Details:

| COLOXYL (Other drug) | | Reason: | Constipation | |
|----------------------|----------|----------------|-------------------------------|--|
| | 50.0 | Milligram As r | ecessary | |
| 3atch: | Started: | L TERM | Stopped: | |
| CAPADEX (Other drug) | | Reason: | Pain | |
| | 0.0 | As r | ecessary | |
| 3atch: | Started: | | Stopped: | |
| QUINSUL (Other drug) | | Reason: | Pain in limb | |
| | 300.0 | Milligram Dail | y | |
| 3atch: | Started: | L TERM | Stopped: | |
| ASPIRIN (Other drug) | | Reason: | Chron isch heart dis no hyper | |
| | 100.0 | Milligram Dail | у | |
| 3atch: | Started: | L TERM | Stopped: | |

Laboratory Investigations:

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

Additional Information:



Report Detail

Case Number: 133235

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: M

| | 18/11/1998 | | | | Weight: | |
|---|----------------------|----------|-----------|---------|-----------|--------------------|
| | Admitted to hospital | | | | Age: | 83Y |
| Onset Date: Outcome: | | | | | DOB: | Coupolity possible |
| Reaction Detai | | | | | Causanty: | Causality possible |
| Reaction Detai | | | | | | |
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| | | | | | | |
| Medicine Deta | aile: | | | | | |
| AMFAMOX (Other | | | | Reason: | | |
| | | 80.0 | Milligram | Daily | | |
| 3atch: | | Started: | · · | , | Stopped: | |
| ENDEP (Suspected | i) | | | Reason: | | |
| | | 0.0 | | | | |
| | | | | | | |
| 3atch: | | Started: | | | Stopped: | |
| 3atch: DEPTRAN (Suspec | eted) | Started: | | Reason: | Stopped: | |
| DEPTRAN (Suspec | eted) | 50.0 | Milligram | Reason: | | |
| | eted) | | Milligram | | Stopped: | |
| DEPTRAN (Suspec | eted) | 50.0 | Milligram | | | |
| DEPTRAN (Suspec | eted) | 50.0 | Milligram | | | |
| DEPTRAN (Suspec | eted) | 50.0 | Milligram | | | |
| DEPTRAN (Suspec | | 50.0 | Milligram | | | |
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| DEPTRAN (Suspec | | 50.0 | Milligram | | | |
| DEPTRAN (Suspec | | 50.0 | Milligram | | | |
| DEPTRAN (Suspec | vestigations: | 50.0 | Milligram | | | |
| DEPTRAN (Suspection) 3atch: Laboratory Interpretation | vestigations: | 50.0 | Milligram | | | |
| DEPTRAN (Suspection) 3atch: Laboratory Interpretation | vestigations: | 50.0 | Milligram | | | |
| DEPTRAN (Suspection) 3atch: Laboratory Interpretation | vestigations: | 50.0 | Milligram | | | |
| DEPTRAN (Suspection) 3atch: Laboratory Interpretation | vestigations: | 50.0 | Milligram | | | |

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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

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|---|----|---|---|----|---|-----|---|
| | v | • | _ | | _ | CLU | |

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 Detai

| | | - | |
|----------------|----------|---|-----------------------|
| 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

 3atch:
 3tarted:
 11/12/1998
 3topped:
 13/12/1998

Laboratory Investigations:

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

Additional Information:



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

| Case Number: 135756 | Seq: 1 | | | Sender: ⊦ | | |
|---------------------------|------------------|-------------------------------|-------------|-------------------------|--|--|
| Reported: 02/02/1999 | | Weight: | | | | |
| spitalisation: | | | Age: 77 | | | |
| Onset Date: | | | _ | DOB : 02/03/1921 | | |
| Outcome: Recovered | | Causality: Causality possible | | | | |
| action Detai | Carra vitra | Dananti | Danasiation | Topoderopat | | |
| Preferred Term | Severity | кероп і | Description | Treatment | | |
| yponatraemia | | | | Deptran ceased. | | |
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| | | | | | | |
| edicine Details: | | | | | | |
| DEPTRAN (Suspected) | | Reason | 1: | | | |
| D-4-h | 0.0 | | Managada | | | |
| 3atch: | Started: | | Stopped: | | | |
| | | | | | | |
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| aboratory Investigation | | | | | | |
| Date Type | Range Date Tes | ted Result | | Details | | |
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| dditional Information: | | | | | | |
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| ort Run 30/07/200 03:50PN | Database: pusime | ADI | RS004 | Page 239 of 307 | | |
| | | | | | | |



Date 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|----------------------|-----------------------|
| Erectile dysfunction | | Erectile dysfunction | Sinequan discontinued |

Medicine Details:

SINEQUAN (Suspected)

Capsule

50.0 Milligram

Daily

Oral

Started:

Stopped:

Laboratory Investigations:

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

Additional Information:

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

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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: 137056 Gender: M Seq: 1 Reported: 08/03/1999 Weight:

Hospitalisation: Age: 74Y

Onset Date: 31/12/1996 DOB: Causality: Causality possible

Outcome: Not yet recovered

Reaction Detail

| todotion Botal | | E | |
|------------------|----------|---|------------------------|
| 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

3atch: 3tarted: 01/01/1980 Stopped: 31/01/1996

Laboratory Investigations:

| Date | Туре | 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.

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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:
 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-------------------|
| Depression | | Depressed | Deptran (doxepin) |

Medicine Details:

| NICORETTE PATCH (Suspected) | | Reason: | Smoker | | |
|-----------------------------|---------------------|---------|------------|-------------|--------|
| Cream | 15.0 Milligram | Daily | | Transdermal | |
| 3atch: | Started: 08/03/1999 | | Stopped: | | CONTIN |
| DEPTRAN (Suspected) | | Reason: | Depression | | |
| Tablet | 0.0 | Daily | | Oral | |
| 3atch: | Started: | | Stopped: | | CONTIN |

Laboratory Investigations:

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

Additional Information:

History of chronic depression



Date 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 Detai

| | | ā. | a |
|----------------|----------|----------------------|---------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Pruritus | | Itchy skin eruption. | Ceased lipex,sinequan and |
| Rash | | | ' |

Medicine Details:

| LASIX (Suspected) | | Reason: | |
|----------------------|---------------------|---------------------|--------------------|
| | 0.0 | | |
| 3atch: | Started: | Stopped: | |
| LIPEX (Suspected) | | Reason: Othr&unspec | metabolic diseases |
| Tablet | 20.0 Milligram | Daily | Oral |
| 3atch: | Started: 01/01/1993 | Stopped: | 28/03/1999 |
| SINEQUAN (Suspected) | | Reason: | |
| Capsule | 25.0 Milligram | Daily | Oral |
| 3atch: | Started: | Stopped: | |

Laboratory Investigations:

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

Additional Information:

Recommenced 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.

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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

| _ | | 4 | | 4 | - 1 |
|---------------------|--------|----|----|-----|-----|
| $oldsymbol{\omega}$ | nn | r. | | eta | |
| RH | | | ., | -14 | |
| | \sim | | _ | - | |

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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|----------------|
| Cough | | Dry cough | Deptran ceased |

Medicine Details:

DEPTRAN (Suspected) Reason:

0.0

Batch: Started: Stopped:

Laboratory Investigations:

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

Additional Information:

Dry cough with deptran but stops when drug ceased.



Date 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 Detai

| 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

3atch: 3tarted: 17/12/1998 3topped: 24/02/1999

Laboratory Investigations:

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

Additional Information:

See original report for other drug details - ms contin, antenex, pulmicort nebules, ventolin nebules & ceclor susp.



Date 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 Detai

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

Medicine Details:

| SINGULAIR (Suspected) | | Reason: | |
|-----------------------|----------|----------|--|
| | 0.0 | | |
| 3atch: | Started: | Stopped: | |
| | | | |

SINEQUAN (Suspected) Reason:

10.0 Milligram Daily

3atch: 3tarted: 11/06/1999 3topped:

Laboratory Investigations:

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

Additional Information:

See original report for other drugs: atrovent, ventolin, flixotide, largactil, lasix, oxis prednisone, prepulsid and other drugs.



Date 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------|-----------------------------|--|
| Confusional state | | | High salt diet and fluids, iv normal saline and kcl. paroxetine ceased and other medications |
| Vomiting Hypokalaemia | | Poor oral intake / vomiting | |
| Hyponatraemia | | | |

Medicine Details:

| MODURETIC (Suspected) | Reason: | | | | | |
|----------------------------|----------|------------|-------------|----------|------------|--|
| | 1.0 | Dose Unspe | cified Dail | у | | |
| 3atch: | Started: | | | Stopped: | 23/12/1998 | |
| PAROXETINE HYDROCHLORIDE (| | Reason: | Depression | | | |
| | 20.0 | Milligram | Dail | у | | |
| 3atch: | Started: | | | Stopped: | 23/12/1998 | |
| SINEQUAN (Suspected) | | | Reason: | | | |
| Capsule | 10.0 | Milligram | Dail | y | Oral | |
| 3atch: | Started: | | | Stopped: | 23/12/1998 | |

Laboratory Investigations:

| Date | Туре | 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.

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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: 143867 Seq: 1 Gender: M

Reported: 20/09/1999 Weight:

Hospitalisation: Age: 70Y
Onset Date: 31/12/1999
DOB:

Onset Date: 31/12/1999

Outcome: Unknown

DOB:

Causality: Causality possible

Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-------------------------|
| Tinnitus | | | No action taken as yet. |

Medicine Details:

SINEQUAN (Suspected) Reason:

Capsule 25.0 Milligram Daily Oral

3atch: Started: 01/01/1989 Stopped:

Laboratory Investigations:

| Date | Туре | 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.

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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:
 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 Detai

| todotion botai | dotion botta | | | | | | | | |
|----------------|--------------|--------------------|-----------|--|--|--|--|--|--|
| Preferred Term | Severity | Report Description | Treatment | | | | | | |
| Fatigue | | | | | | | | | |
| Hyperhidrosis | | | | | | | | | |
| Tremor | | | | | | | | | |

Medicine Details:

DEPTRAN (Suspected) Reason: Pain

10.0 Milligram Daily

3atch: 3tarted: 17/09/1999 3topped: 18/09/1999

Laboratory Investigations:

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

Additional Information:

See original report for details of other drug - paracetamol/codeine.



Date 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 Detai

| todotion Botal | action botal | | | | | | | | |
|----------------|--------------|--------------------|-----------------------|--|--|--|--|--|--|
| 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 |
| 3atch: | 3tarted: 01/08/1999 | Stopped: | 28/09/1999 |
| HYPERICUM-ST JOHN'S WORT (Interac | tion) | Reason: Nervousness | |
| Oral application | 2.0 Gram | Daily | Oral |
| Oral application | 2.0 014111 | Daily | Orai |

Laboratory Investigations:

| Date | Туре | 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.



Date 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

| todotion Botal | | _ | <u> - </u> |
|------------------|----------|--|--|
| 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

3atch: 3tarted: 01/07/1999 3topped:

SINEQUAN (Interaction) Reason:

50.0 Milligram Daily

3atch: 3tarted: 01/01/1995 3topped: 01/11/1999

Laboratory Investigations:

| Date | Туре | 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.

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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: 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|------------------|----------|--------------------|-----------------------------|
| Drug ineffective | | | Plans to discontine doxepin |

Medicine Details:

| ZOLOFT (Interaction) | | | Reason: | Depression |
|-------------------------------------|----------|-----------|---------|--------------------------------|
| | 50.0 | Milligram | Daily | |
| 3atch: | Started: | | | Stopped: |
| DOXEPIN HYDROCHLORIDE (Interaction) | | | Reason: | Otr&unsp vertebrogen pain synd |
| | 10.0 | Milliarom | Doily | |

10.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

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

Additional Information:

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



Date 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 Detai

| odotion Botal | | | | | | | | |
|-------------------|----------|--------------------|--|--|--|--|--|--|
| Preferred Term | Severity | Report Description | Treatment | | | | | |
| Agitation | | | | | | | | |
| Confusional state | | | Therapy with sinequan and inderal ceased, add risperdal. | | | | | |
| Nightmare | | | | | | | | |

Medicine Details:

| INDERAL (Other drug) | | Reason: Essential benign hypertension | |
|----------------------|----------------|---------------------------------------|--|
| | 80.0 Milligram | Daily | |
| 3atch: | Started: | Stopped: | |
| | | | |
| SINEQUAN (Suspected) | | Reason: | |
| SINEQUAN (Suspected) | 25.0 Milligram | Reason: Daily | |

Laboratory Investigations:

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

Additional Information:

Patient also taking monopril, iscover, triprim.



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

| Report Do | etail |
|-----------|-------|
|-----------|-------|

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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|------------------|
| Hyponatraemia | | | Sinequan ceased. |

Medicine Details:

SINEQUAN (Suspected) Reason:

0.0

Batch: Started: Stopped:

Laboratory Investigations:

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

Additional Information:

Patient actually felt better while on sinequan.



Case Number: 152692

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: F

| Reported: 16/05/2000 | | Weight: | | | | | |
|--|------------------------------|--------------------|-------------------------------|--|--|--|--|
| ospitalisation: | | | Age: 55Y DOB: | | | | |
| Onset Date: | | | | | | | |
| Outcome: Not yet recov | erea | | Causality: Causality possible | | | | |
| Preferred Term | Severity | Report Description | Treatment | | | | |
| epatic function abnormal | | <u> </u> | | | | | |
| yperuricaemia | | | | | | | |
| yponatraemia | | | Sinequan ceased. | | | | |
| alaise | | | S. roquan osassa. | | | | |
| | | | | | | | |
| ledicine Details: SINEQUAN (Suspected) | | Reason: | | | | | |
| | 0.0 | | | | | | |
| 3atch: | Started: | Stopped | i: | | | | |
| | | | | | | | |
| aboratory Investigation Date Type | NS: Range Date Tested | Result | Details | | | | |
| Туре Туре | Nange Date resteu | Result | Details | | | | |
| Additional Information: | | | | | | | |
| ort Run 30/07/200 03:51PN [| Database: pusime | ADRS004 | Page 255 of 307 | | | | |



Date 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 Detai

| touotion Dotai | | | | | | | | | | |
|-----------------------------------|----------|--------------------|---|--|--|--|--|--|--|--|
| Preferred Term | Severity | Report Description | Treatment | | | | | | | |
| Anaemia | | | | | | | | | | |
| Confusional state | | | Patient admitted to hospital, all therapy ceased. | | | | | | | |
| Hepatic function abnormal | | | | | | | | | | |
| Pyrexia | | | | | | | | | | |
| Red blood cell sedimentation rate | | | | | | | | | | |

Medicine Details:

| SINEMET (Other drug) | | Reason: | | |
|----------------------------|------------|---------|----------|------------|
| | 0.0 | | | |
| 3atch: | Started: | | Stopped: | CONTIN |
| RIVOTRIL (Other drug) | | Reason: | | |
| | 0.0 | | | |
| 3atch: | Started: | | Stopped: | |
| ARICEPT (Suspected) | | Reason: | | |
| | 0.0 | | | |
| 3atch: | Started: | | Stopped: | 25/08/2000 |
| SELEGILINE HYDROCHLORIDE (| Suspected) | Reason: | | |
| | 0.0 | | | |
| 3atch: | Started: | | Stopped: | |

Laboratory Investigations:

| Date | Туре | 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.



Case Number: 157333

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

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 Detai **Medicine Details: CABASER** (Suspected) Reason: 0.0 Started: 3atch: Stopped: **DOXEPIN HYDROCHLORIDE (Suspected)** Reason: 0.0 Started: Stopped: 3atch: **LEVODOPA** (Suspected) Reason: 0.0 Started: 3atch: Stopped: **PROTHIADEN** (Suspected) Reason: 0.0 3atch: Started: Stopped: **Laboratory Investigations:** Date Tested Result Details Date Type Range 30/08/2000 359 GGT = SGGT = 12 - 43 SAP = ALP 285

Additional Information:

SAP = ALP

Patient also taking doxepin, levodopa, benzodiazepine.

20 - 110

20 - 110

28/08/2000

30/08/2000

265



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

| Report Detail | | | | | | | |
|---|---------------------------------|-----------|---------------------------------|---------------|-----------------|----------------------------|--------------------|
| Case Number: Reported: Hospitalisation: | 157333 04/09/2000 | Seq: 1 | | | | Gender: Weight: Age: | |
| Onset Date: | 25/08/2000 | | | | | | 03/01/1927 |
| | Recovered | | | | С | | Causality possible |
| Reaction Detai | | | | | | • | 71 |
| Medicine Deta COMTAN (Suspec Tablet 3atch: | | | 200.0 Milligram : 17/07/2000 | Reason: Daily | Paralysis agita | ans Oral 25/08/2000 | |
| Laboratory In | vestigations: | | | | | | |
| Additional Int Patient also taking | formation: doxepin, levodopa | benzodiaz | epine. | | | | |

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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: 160686 Seq: 1 Gender: F

Reported: 09/01/2001 Weight: Hospitalisation: Age:

Onset Date: 30/07/2000 DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

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

Medicine Details:

SINEQUAN (Suspected) Reason:

Capsule 25.0 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

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

Additional Information:

Patient increased dose of sinequin from 25mg to 50mg daily, then experienced symptoms.



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

| Report D | etai |
|----------|------|
|----------|------|

Case Number:160811Seq:1Gender:MReported:19/01/2001Weight:60.00Hospitalisation:Admitted to hospitalAge:66Y

Onset Date: 17/01/2001 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|-------------------------------|
| Hypotension | | Bp 90/50 | Patient hospitalised. deptran |
| Face oedema | | | |

Medicine Details:

| ZYBAN SR (Interaction) | | Reason: | |
|------------------------|-----------------|-----------------------|------|
| Tablet | 300.0 Milligram | Daily | Oral |
| 3atch: | Started: | Stopped: | |
| DEPTRAN (Interaction) | | Reason: Anxiety neuro | sis |
| (, | | , | |
| | 30.0 Milligram | Daily | |

Laboratory Investigations:

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



Date 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 Detai

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

Medicine Details:

DEPTRAN (Suspected) Reason: Depression

20.0 Milligram Daily

3atch: 3tarted: 06/12/2000 3topped:

TOPAMAX (Suspected) Reason:

50.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

| Date | Туре | 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 suppreessor cells and mature t3 lymphocytes.



Date 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 Detai

| | - | | |
|-------------------|----------|--------------------|-------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Confusional state | | | Bupropion ceased. |
| Convulsion | | | |
| Delirium | | | |

Medicine Details:

| ZYBAN SR (Interaction) | | | Reason: | Smoker | |
|-------------------------------------|-------------|-----------|----------------|---------------|------------|
| Tablet | 150.0 | Milligram | Daily | | Oral |
| 3atch: | Started: 28 | 3/02/2001 | | Stopped: | 23/03/2001 |
| FLUOXETINE HYDROCHLORIDE (Interacti | on) | | Reason: | Depression | |
| | 20.0 | Milligram | Daily | | |
| 3atch: | Started: | | L TERM | Stopped: | |
| DOXEPIN HYDROCHLORIDE (Interaction) | | | Reason: | Anxiety neuro | sis |
| Oral application | 100.0 | Milligram | Daily | | Oral |
| 3atch: | Started: | | | Stopped: | |
| ORUDIS SR (Other drug) | | | Reason: | Unspecified a | rthritis |
| Oral application | 1.0 | Dose Uns | pecified Daily | | Oral |
| 3atch: | Started: | | | Stopped: | |

Laboratory Investigations:

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



Case Number: 163781

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

| Reported: 18/04/2001 | | | | | Weight: | |
|---|----------|------|-----------|----------|--------------------------|--------------------|
| ospitalisation: | | | | | Age: | 49 |
| Onset Date: 04/03/2001 | | | | | DOB: | 02/07/1951 |
| Outcome: Recovered | | | | | Causality: | Causality probable |
| action Detai | | | | | | |
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| | | | | | | |
| Medicine Details: | | | | | | |
| SULFASALAZINE (Other drug) | | | | Reason: | Regional enteritis | |
| (0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0. | | 1.5 | Gram | Daily | | |
| 3atch: | Started: | 1.0 | | L TERM | Stopped: | |
| PANTOPRAZOLE (Other drug) | 71411041 | | | Reason: | Other diseases of esopha | nus |
| Oral application | 5 | 30 O | Milligram | Daily | Oral | juo |
| 3atch: | Started: | 50.0 | | L TERM | Stopped: | |
| Jaicii. | Jianteu. | | | LILIXIVI | лорреи. | |
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| aboratory Investigations: | | | | | | |
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| Additional Information: | | | | | | |
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| dditional Information: | | | | | | |
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| Additional Information: | | | | | | |



Date 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|-----------------|----------|--------------------|---|
| Cervix disorder | | | Pt booked in for day surgery to have cervical lesion excised. |

Medicine Details:

| NORIMIN-1 (Suspected) | Reaso | on: | Contraception | |
|-----------------------|----------------------|-------|---------------|--------|
| Tablet | 1.0 Dose Unspecified | Daily | Oral | |
| 3atch: | Started: 01/09/2000 | | Stopped: | CONTIN |
| DEPTRAN (Suspected) | Reaso | on: | | |
| Tablet | 25.0 Milligram | Daily | Oral | |
| | | | | |

Laboratory Investigations:

| Date | Туре | 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.



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

DOB:

Report Detail

Case Number: 166631 Seq: 1 Gender: F

Reported: 19/07/2001 Weight: 50.00 Hospitalisation: Age: 88Y

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Onset Date: 03/04/2001

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------------------|-----------|
| Alopecia | | Scalp, eyelashes amd eyebrows. | |

Medicine Details:

SINEQUAN (Suspected) Reason:

Capsule 25.0 Milligram Daily Oral

3atch: 3tarted: 01/03/2001 **3topped:**

Laboratory Investigations:

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

Additional Information:

Patient is allergic to - aldomet, bactrim and tetoxoid.



Date 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 Detai

| todotion Dotai | | _ | |
|------------------|----------|---|---------------|
| 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 | }topped: | 18/05/2001 |
| DEPTRAN (Interaction) | | Reason: | Depression | |
| | 150.0 | Milligram Daily | ′ | |
| 3atch: | Started: | L TERM | Stopped: | CONTIN |
| PANADEINE FORTE (Other drug) | | Reason: | Pain | |
| | 8.0 | Dose Unspecified Daily | ′ | |
| 3atch: | Started: | L TERM | }topped: | CONTIN |
| DIAZEPAM (Other drug) | | Reason: | Anxiety neuro | sis |
| | 10.0 | Milligram Daily | 1 | |
| 3atch: | Started: | L TERM | Stopped: | CONTIN |

Laboratory Investigations:

| Date | Туре | 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.

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| Case Number: 7 Reported: 7 ospitalisation: Onset Date: | | Seq: | 1 | | | Gender: Weight: Age: DOB: | |
|--|--------------------------------|---------------------|----------------|--------|----------------|------------------------------------|--------------------|
| Outcome: 1 | Not yet recov | ered | | | C | Causality: | Causality possible |
| eaction Detai Preferred | Term | Seve | erity | Repor | Description | | Treatment |
| Agitation Somnolence | | 3011 | 3.1.9 | T TOPO | Вессириен | | Trod.mont |
| | | | | | | | |
| Medicine Deta SINEQUAN (Suspec | | | | Reas | on: Depression | | |
| Tablet | | | 25.0 Milli | igram | Daily | Oral | |
| 3atch: | | 3ta | rted: 18/08/20 | 001 | Stopped: | | CONTIN |
| Laboratory Inv | restigatior ^{Type} | 1S: Range | Date Tested | Result | | Deta | ils |
| | ormation: | | | | | | |



Date 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 Detai

| Caction Betai | | | |
|------------------|----------|--------------------------|--|
| Preferred Term | Severity | Report Description | Treatment |
| Gait disturbance | | Gait disorder and falls. | |
| Hyponatraemia | | | Doxepin, diclofenac and tramadol ceased. changed pain relief to ms contin 5mg bd. reduced diamicron dose to 40mg bd. |
| Vertigo | | | |

Medicine Details:

| SENEGA AND AMMONIA (Other drug) | | | ₹eason: | | |
|---------------------------------|-----------------------|----------------------|---------------|---------------|--------|
| Oral Liquid | 30.0 | Millilitre | Daily | Oral | |
| 3atch: | Started: | | | Stopped: | |
| PARACETAMOL (Other drug) | | | ₹eason: | | |
| Tablet | 6.0 | Gram | Daily | Oral | |
| 3atch: | Started: | | | Stopped: | CONTIN |
| ASPIRIN (Other drug) | | | ₹eason: | | |
| | | | | | |
| Tablet | 150.0 | Milligram | Daily | Oral | |
| Tablet 3atch: | 150.0 Started: | Milligram | Daily | Oral Stopped: | CONTIN |
| | | Milligram | Daily Reason: | | CONTIN |
| 3atch: | | Milligram Milligram | • | | CONTIN |

Laboratory Investigations:

| Date | Туре | Range | Date Tested | Result | Details |
|------|--------|-------|-------------|--------|------------------------|
| | Sodium | | 20/03/2002 | 124 | On admission na - 124. |
| | Sodium | | 31/03/2002 | 135 | On admission na - 124. |



| Case Number: | | | | | |
|--|------------------------------------|---|------------------------------|--------------|--------------------|
| | | Seq: 1 | | Gender: | M |
| _ | 07/05/2002 | | | Weight: | 077/ |
| ospitalisation: Onset Date: | 20/03/2002 | | | Age: DOB: | 8/ Y |
| | | 1 | | _ | Caucality passible |
| eaction Detai | Not yet recovered | ı | | Causanty. | Causality possible |
| action Detai | | | | | |
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| Medicine Det | aile: | | | | |
| GLICLAZIDE (Other | | | Reason: | | |
| Tablet | | 160.0 Millig | ram Daily | Oral | |
| 3atch: | | Started: | | Stopped: | CONTIN |
| DOXEPIN HYDRO | CHLORIDE (Suspecte | d) | Reason: | | |
| | | 10.0 Millig | ram Daily | Oral | |
| Capsule | | 10.0 Milling | . , | | |
| Capsule 3atch: | | Started: | , | Stopped: | |
| | DIUM (Suspected) | _ | Reason: | | |
| 3atch: | DIUM (Suspected) | _ | Reason: | | |
| 3atch: DICLOFENAC SOI | DIUM (Suspected) | Started: | Reason: | Stopped: | |
| 3atch: DICLOFENAC SOI Tablet 3atch: | DIUM (Suspected) ROCHLORIDE (Suspe | \$tarted: 50.0 Millig \$tarted: 16/03/200 | Reason: | Stopped: | |
| 3atch: DICLOFENAC SOI Tablet 3atch: | | \$tarted: 50.0 Millig \$tarted: 16/03/200 | Reason: ram Daily 02 Reason: | Stopped: | |



| ail | | | |
|-----------------|---|---|--|
| | Seq: 1 | | Gender: F |
| | • | | Weight: |
| | ospital | | Age: |
| | | | DOB: |
| ne: Unknown | | | Causality: Causality possible |
| | - | | <u> </u> |
| | Severity | Report Description | Treatment |
| ia | | | Patient was hospitalised. |
| | | | |
| | | Reason: Depression | |
| | | Stonned: | |
| | | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | |
| | | | |
| √ Investigation | s: | | |
| v Investigation | S: Range Date Tested | Result | Details |
| | er: 176296 ed: 14/06/2002 on: Admitted to hote: ne: Unknown etai erred Term iia Details: uspected) | ped: 14/06/2002 pn: Admitted to hospital te: ne: Unknown ptai erred Term Severity nia Details: uspected) | ed: 14/06/2002 on: Admitted to hospital te: ne: Unknown etai erred Term Severity Report Description nia Details: uspected) Reason: Depression 0.0 |



Date 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** Age: 66

Hospitalisation:

Onset Date: 28/07/2002 **DOB:** 12/08/1935

Outcome: Recovered Causality: Causality possible

Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--------------------|--|
| Headache | | | Reduced doxepin to 125mg at night. date of recovery: 29/7/02 |
| Dizziness | | | |

Medicine Details:

| BACLOFEN (Other drug) | | Reason: | |
|-------------------------|---------------------|----------|--|
| | 50.0 Milligram | Daily | |
| 3atch: | Started: | Stopped: | |
| ASPIRIN (Other drug) | | Reason: | |
| | 150.0 Milligram | Daily | |
| 3atch: | Started: | Stopped: | |
| LIPITOR (Other drug) | | Reason: | |
| | 40.0 Milligram | Daily | |
| 3atch: | Started: | Stopped: | |
| NICORANDIL (Other drug) | | Reason: | |
| | 10.0 Milligram | Daily | |
| 3atch: | Started: 24/07/2002 | Stopped: | |

Laboratory Investigations:

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

Additional Information:

Headaches at night after doxepin increased to 150mg from 125mg.



Date 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 Reported: 01/08/2002 Hospitalisation: Onset Date: 28/07/2002 Outcome: Recovered Reaction Detai | Seq: 1 | Gender: M Weight: 80.00 Age: 66 DOB: 12/08/1935 Causality: Causality possible |
| | | |
| | | |
| Medicine Details: | | |
| DEPTRAN (Suspected) | 05.0 14:11: | Reason: Depression |
| 3atch: | 25.0 Milligram Started: 23/07/2002 | Daily Stopped: |
| | | |
| Laboratory Investigation | is: | |
| Additional Information: Headaches at night after doxepin | increased to 150mg from 125m | ng. |

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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: 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 Detai

| 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 |
| 3atch: | Started: | L TERM | Stopped: | |
| OROXINE (Other drug) | | Reason: | Myxedema | |
| Oral application | 100.0 | Microgram Daily | 1 | Oral |
| 3atch: | Started: | L TERM | Stopped: | |
| DEPTRAN (Suspected) | | Reason: | Depression | |
| Capsule | 25.0 | Milligram Daily | / | Oral |
| 3atch: | Started: 01/ | 03/2002 | Stopped: | 01/08/2002 |

Laboratory Investigations:

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



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

| Report L | etail |
|----------|-------|
|----------|-------|

 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 Detai

| 10404011 2044 | | | |
|-------------------------|----------|--------------------|--|
| Preferred Term | Severity | Report Description | Treatment |
| Orthostatic hypotension | | | Ceased doxepin, methyldopa, and verapamil. |

Medicine Details:

| WARFARIN SODIUM (Other drug) | | | ₹eason: | | |
|------------------------------------|-----------------|-------------------|------------------|---------------|--------|
| Tablet | 0.0 | | | Oral | |
| 3atch: | Started: | | | Stopped: | CONTIN |
| PREDNISONE (Other drug) | | | Reason: | | |
| Tablet | 15.0 | Milligram | Daily | Oral | |
| 3atch: | Started: | | | Stopped: | CONTIN |
| | | | | | |
| POTASSIUM NOS (Other drug) | | | Reason: | | |
| POTASSIUM NOS (Other drug) Tablet | 1.2 | Gram | Reason: Daily | Oral | |
| ` ' | 1.2 Started: | Gram | | Oral Stopped: | CONTIN |
| Tablet | | Gram | | | CONTIN |
| Tablet 3atch: | Started: | Gram Milligram | Daily | | CONTIN |

Laboratory Investigations:

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



Case Number: 178854

Reported: 11/09/2002

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

Weight:

| n: Otr&nos disord of heart rhythm |
|-----------------------------------|
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| |
| |
| |
| Daily Oral |
| Stopped: 29/07/2002 |
| n: Essential benign hypertension |
| Daily Oral |
| Stopped: 29/07/2002 |
| n: Depression |
| Daily Oral |
| Stopped: 29/07/2002 |
| D n: |



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

Report Detail

Case Number:178902Seq:1Gender:MReported:07/08/2002Weight:0.00Hospitalisation:Admitted to hospitalAge:24

Onset Date: DOB: 23/09/1977

Outcome: Unknown Causality: Causality possible

Reaction Detai

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------------------|----------------------|---|---|
| Therapeutic response decreased | 11 1 ! | syndrome, paranoia, psychosis and schizonhrenia | 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 dyas and then was committed to the mental health unit. |
| Hallucination Palpitations Paranoia | Life Life Life | | |

Medicine Details:

| ZOLOFT (Suspected) | | Reason: | Depression |
|---------------------|----------|----------------|------------|
| | 25.0 Mi | illigram Daily | , Oral |
| 3atch: | Started: | | Stopped: |
| DEPTRAN (Suspected) | | Reason: | |
| | 75.0 Mi | illigram Daily | , Oral |
| 3atch: | Started: | | Stopped: |
| ZOLOFT (Suspected) | | Reason: | |
| | 400.0 Mi | illigram Daily | 1 |
| 3atch: | Started: | | Stopped: |

Laboratory Investigations:

| Date | Туре | 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.



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

Report Detail

Case Number:178902Seq:1Gender:MReported:07/08/2002Weight:0.00Hospitalisation:Admitted to hospitalAge:24

Onset Date: DOB: 23/09/1977

Outcome: Unknown Causality: Causality possible

Reaction Detai

| todotion botal | _ | | |
|---------------------------|----------|--------------------|-----------|
| 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 |
| 3atch: | Started: | | | Stopped: | |
| ZOLOFT (Suspected) | | | Reason: | | |
| | 400.0 | Milligram | Daily | | |
| 3atch: | 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.

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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

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| Re | \sim | _ | u Lu | ш |

 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 Detai

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

Medicine Details:

| ASPIRIN (Other drug) | | | Reason: | Other coagula | tion defects |
|---------------------------------|--------------|--------------|---------|----------------|--------------|
| Tablet | 150.0 |) Milligram | Daily | | Oral |
| Зatch: | Started: | | | Stopped: | 09/08/2002 |
| MEDROXYPROGESTERONE ACETATE | (Other drug) | | Reason: | Menopausal s | ymptoms |
| Tablet | 10.0 |) Milligram | Daily | | Oral |
| Зatch: | Started: | | | Stopped: | 06/08/2002 |
| OESTROGENS CONJUGATED (Other dr | ug) | | Reason: | Menopausal s | ymptoms |
| Tablet | 0.3 | 3 Milligram | Daily | | Oral |
| | | • | 2 4 | | Olui |
| 3atch: | Started: | J | 24, | Stopped: | 06/08/2002 |
| 3atch: AMIZIDE (Suspected) | Started: | | Reason: | - '' | |
| | Started: |) Dose Unspe | Reason: | Essential beni | 06/08/2002 |

Laboratory Investigations:

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



Case Number: 179177

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Gender: F

| Reported: Hospitalisation: Onset Date: | | | | | | Weight: Age: DOB: | 77Y | |
|--|---------------------|-----------|-------------------|--------|-----------------|-------------------------|----------------|--------|
| | Not yet recovered | | | | С | ausality: | Causality poss | ible |
| eaction Detai | | | | | | | | |
| Medicine Deta | | | 7000 | | Facastial basis | | 1 | |
| Tablet | /DROCHLORIDE (Suspe | | Reas Milligram | Daily | Essential beni | gn nyperτens Oral | ion | |
| Batch: | | Started: | wiiiigram | Dally | Stopped: | 08/08/2002 | | |
| | HLORIDE (Suspected) | Juitou. | Reas | on: | Depression | 00/00/2002 | | |
| Oral applica | | 2.0 | Dose Unspecified | | 2 op. 000.0 | Oral | | |
| 3atch: | | Started: | | , | Stopped: | 02/08/2002 | | |
| -aboratory Inv | vestigations: | | | | | | | |
| Additional Info | ormation: | | | | | | | |
| port Run 30/07/200 | 03:51PN Database | e: pusime | , | ADRS00 |)4 | | Page 279 | of 307 |



Date 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 Detai

| todolion Botal | | | |
|--------------------------|----------|--------------------|--|
| Preferred Term | Severity | Report Description | Treatment |
| Coma | | | Patient was given iv valium. sinequin and valium were ceased, valium was |
| Drug withdrawal syndrome | | | |
| Grand mal convulsion | | | |

Medicine Details:

| SINEQUAN (Suspected) | | Reason: | Depression | |
|----------------------|----------|---------|--------------|--|
| | 0.0 | | | |
| 3atch: | Started: | | Stopped: | |
| VALIUM (Suspected) | | Reason: | Pain in limb | |
| | 0.0 | | | |
| 3atch: | Started: | | Stopped: | |

Laboratory Investigations:

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

Additional Information:

The onset date is not necessarily accurate but indicates onset sometime in the month.



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

Report Detail

Case Number:181203Seq: 1Gender: FReported:08/01/2003Weight: 0.00Hospitalisation:Admitted to hospitalAge: 78

Onset Date: 20/11/2002 **DOB**: 21/10/1924

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

| todotion Botai | | | = |
|----------------------|----------|--|------------------------------|
| 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 rheuma | toid arthritis |
|--------------------------|----------|-----------|---------|--------------|----------------|
| Tablet | 25.0 | Milligram | Week | dy | Oral |
| 3atch: | Started: | L | TERM | Stopped: | 18/11/2002 |
| LASIX (Suspected) | | | Reason: | Edema and di | ropsy |
| | 80.0 | Milligram | Daily | | |
| 3atch: | Started: | | | Stopped: | 20/11/2002 |
| SLOW-K (Suspected) | | | Reason: | | |
| Tablet | 600.0 | Milligram | Daily | | Oral |
| 3atch: | Started: | | | Stopped: | 20/11/2002 |
| ZANTAC (Suspected) | | | Reason: | | |
| Tablet | 300.0 | Milligram | Daily | | Oral |
| 3atch: | Started: | | | Stopped: | 20/11/2002 |

Laboratory Investigations:

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

| Reported: 08/01/2003 Hospitalisation: Admitted to hospi Onset Date: 20/11/2002 Outcome: Not yet recovered Reaction Detai | | | | C | | 0.00 |
|--|----------|------------|---------|------------|--------------------|------|
| Medicine Details: | | | 200000 | | | |
| ASPIRIN (Suspected) | 400.0 | N 4:11: | Reason: | | 01 | |
| Oral application | | Milligram | Daily | Managar | Oral | |
| BERTRAN (Supported) | Started: | | 2000 | Stopped: | 21/11/2002 | |
| DEPTRAN (Suspected) | 05.0 | Millianses | Reason: | Depression | Orol | |
| Oral application 3atch : | Started: | Milligram | Daily | Stopped: | Oral 21/11/2002 | |
| Laboratory Investigations: | | | | | | |
| Additional Information: | | | | | | |



Date 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|---|--------------------|--|
| Hypokalaemia | Caused or prolonged inpatient hospitalisation | | 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) | | | र | eason: | Depression | | |
|-----------------------------------|----------|-----|----------------|-----------|---------------|------------------|--------|
| Capsule | 15 | 0.0 | Milligram | Daily | | Oral | |
| Зatch: | Started: | | | | Stopped: | | |
| FELODIPINE (Suspected) | | | 3 | eason: | Depression | | |
| Tablet | 10 | 0.0 | Milligram | Daily | | Oral | |
| Зatch: | Started: | | | | Stopped: | | Contin |
| KARVEZIDE 300/12.5 (Suspected) | | | 3 | eason: | Essential ben | ign hypertension | |
| Tablet | | 1.0 | Dose Unspecifi | ied Daily | | Oral | |
| Зatch: | Started: | | | | Stopped: | | contin |
| NATRILIX SR (Suspected) | | | 5 | eason: | Essential ben | ign hypertension | |
| Tablet | | 1.5 | Milligram | Daily | | Oral | |
| 3atch: | Started: | | | | Stopped: | 28/02/2003 | |

Laboratory Investigations:

| Date | Туре | Range | Date Tested | Result | Details |
|------------|------------|-------|-------------|--------|---------|
| 23/06/2003 | Creatinine | | 24/02/2003 | 0.25 | |
| 23/06/2003 | Potassium | | 24/02/2003 | 3.2 | |



Date 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 Detai

| reaction Dotal | | | |
|----------------|----------|---------------------------------|--|
| 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 |
| 3atch: | Started: 26/05/2002 | Stopped: | 13/05/2003 |
| DOXEPIN HYDROCHLORIDE (Interaction) | | Reason: | |
| Capsule | 25.0 Milligram | Daily | Oral |
| 3atch: | Started: 16/11/2002 | Stopped: | 13/05/2003 |
| AMIZIDE (Interaction) | | Reason: | |
| Tablet | 1.0 Dose Unspeci | ified Daily | Oral |
| 3atch: | Started: 16/10/2001 | Stopped: | 13/05/2003 |
| ASPIRIN (Interaction) | | Reason: | |
| Tablet | 150.0 Milligram | Daily | Oral |
| | | | 15/05/2003 |

Laboratory Investigations:

| | | | | | |
|------------|-------------|-------|-------------|--------|---------|
| Date | Туре | Range | Date Tested | Result | Details |
| 11/07/2003 | Other data | | | | |

Additional Information:

Patient was also taking paracetamol, Timolol, Metoclopramide, Diazepam, Thiamine.

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| Daniel Data!! | | | | | |
|-----------------------------------|--|--|--|---------------------------|--|
| Report Detail Case Number: 194681 | Seq: 1 | | Gon | der: F | |
| Reported: 16/02/2004 | - | | | ght: 62.00 | |
| ospitalisation: | | | | Age: 66Y | |
| Onset Date: | | | | OB: | |
| Outcome: Recovered | | | | ality: Causality possible | |
| eaction Detai | | | | , , , | |
| Preferred Term | Severity | Repor | t Description | Treatment | |
| Convulsion | Required Visit to Doctor | Seizures, agitation sensory disturban | n, flushing, confusion, ces 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) | | Reas | , | | |
| Tablet | | Milligram | Daily | | |
| TRAMAL (Suspected) | Started: | 3000 | Stopped: | | |
| Tablet | 600.0 | Reas | | | |
| 3atch: | 600.0 Milligram Daily Started: Stopped: | | | | |
| SINEQUAN (Suspected) | ytartoa. | Reas | | | |
| | 75.0 | Milligram | Daily | | |
| 3atch: | Started: | J | Stopped: | | |
| _aboratory Investigatio | ons: | | | | |
| Date Type | Range Date Te | sted Result | | Details | |
| | | | | | |
| | | | | | |
| | | | | | |
| Additional Information | : | | | | |
| | | | | | |



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

| 201905 | Seq: | 1 | | Gend | der: F | | | |
|--|---------------------------------------|---|--|--|--|--|--|--|
| 21/10/200 | 14 | | | Weig | ght: 68.00 | | | |
| | | | | A | .ge : 38 | | | |
| | | | | DO | OB : 07/04/1966 | | | |
| Not yet re | covered | | | Causal | l ity: Causality possible | | | |
| ıi | | | | | | | | |
| ed Term | Seve | erity | Report | Description | Treatment | | | |
| | | comp arm tinnit cold' | plained of stra and wrist, hea us, tingling in , anxiety, bag | nge sensation in the left daches, nausea, shakes feet, spasms, 'hot and | | | | |
| | | | | | | | | |
| | | | | | | | | |
| ; | | | | | | | | |
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| | | | | | | | | |
| | | | | | | | | |
| Medicine Details: | | | | | | | | |
| DOXEPIN HYDROCHLORIDE (Suspected) Reason: Depression | | | | | | | | |
| | | 25.0 Milli | igram | Daily Oral | | | | |
| | 3taı | rted: 24/09/2 | 004 | Stopped: | | | | |
| | | Data Tastad | Pacult | | Details | | | |
| туре | Range | Date Tested | Result | | Details | | | |
| Additional Information: | | | | | | | | |
| | : : : : : : : : : : : : : : : : : : : | tails: CCHLORIDE (Suspected) nvestigations: Type Range | : 21/10/2004 : : Not yet recovered ii ed Term Severity As d com arm tinnit cold' cons CHLORIDE (Suspected) 25.0 Mill Started: 24/09/2 | : 21/10/2004 : Not yet recovered il ed Term Severity Report As dosage increas complained of stra arm and wrist, hea tinnitus, tingling in cold', anxiety, bags constipation. Constipation Started: 24/09/2004 **Type Range Date Tested Result* | tails: Type Range Date Tested Result Severity Report Description 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. Severity Report Description 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. Severity Report Description 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. Severity Report Description Severity Report Description Severity Report Description Severity Report Description Severity Report Description Severity Report Description 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. Severity Report Description 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 constitute of the seven tingling in feet, spasms, 'hot and cold', anxiety, bags under the eyes and constitute of the seven tingling in feet, spasms, 'hot and cold', anxiety, bags under the eyes and constitute of the seven tingling in feet, spasms, 'hot and 'ho | | | |



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

| Reported: 21/10/2004 Hospitalisation: Onset Date: | Seq: 1 | Wei A D | der: F ght: 68.00 Age: 38 OB: 07/04/1966 |
|---|---------------------|---------------------------------------|---|
| Outcome: Not yet recovered Reaction Detai | d | Causa | lity: Causality possible |
| Preferred Term | Severity | Report Description | Treatment |
| Tremor | | · · · · · · · · · · · · · · · · · · · | |
| | | | |
| Medicine Details: | | | |
| DOXEPIN HYDROCHLORIDE (Suspected | | Reason: Depression | |
| Capsule | 25.0 Milligram | | |
| 3atch: | 3tarted: 24/09/2004 | Stopped: | |
| Laboratory Investigations: | | | |
| Additional Information: | | | |
| eport Run 30/07/200 03:51PN Datab | pase: pusime | ADRS004 | Page 287 of 307 |



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

DOB: 16/01/1953

Report Detail

Case Number: 203503 Seq: 1 Gender: F
Reported: 13/12/2004 Weight: 0.00

Hospitalisation: Admitted to hospital **Age**: 51

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Onset Date: 21/11/2004

| 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 | | |
| Зatch: | Started: 20/10/2004 | Stopped: | 22/11/2004 | | |
| SINEQUAN (Interaction) | | Reason: | | | |
| | 250.0 Milligram | Daily | Oral | | |
| 3atch: | Started: 20/10/2004 | Stopped: | 22/11/2004 | | |
| MOGADON (Other drug) | | Reason: Specific disor | ders of sleep | | |
| | 20.0 Milligram | | Oral | | |
| 3atch: | Started: 15/03/2004 | Stopped: | 22/11/2004 | | |
| TEMAZE (Other drug) | | Reason: Specific disor | ders of sleep | | |
| | 20.0 Milligram | | Oral | | |
| Зatch: | Started: 15/11/2004 | Stopped: | 22/11/2004 | | |

Laboratory Investigations:

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

| Case Number: 203503 | Seq: 1 | Ge | ender: F | | |
|---------------------------------------|---|-------------------------------|-----------------|--|--|
| Reported: 13/12/2004 | | 'eight: 0.00 | | | |
| Hospitalisation: Admitted to he | ospital | Age: 51 | | | |
| Onset Date: 21/11/2004 | | DOB : 16/01/1953 | | | |
| Outcome: Not yet recove | ered | Causality: Causality possible | | | |
| Reaction Detai | 1 2 1 | | | | |
| Preferred Term | Severity | Report Description | Treatment | | |
| Dyskinesia | Caused or prolonged inpatient hospitalisation | | | | |
| Syncope | Caused or prolonged inpatient hospitalisation | | | | |
| Tremor | Caused or prolonged inpatient hospitalisation | | | | |
| Manufacture Datation | 1 | | | | |
| Medicine Details: ORDINE (Other drug) | | Reason: Headache | | | |
| ORDINE (Other drug) | 200.0 Milligram | | al | | |
| 3atch: | Started: 20/10/2004 | | /11/2004 | | |
| Laboratory Investigation | ıs: | | | | |
| Additional Information: | | | | | |
| Paport Run 30/07/200 03:51PN F |)atabasa: nusimo | ADB\$004 | Domo 200 of 207 | | |

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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

| Repor | t 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 Detai

| teaction betai | | <u> </u> | |
|---------------------------------|---------------------------|--|-------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| | | Severe headaches,nausea, prostration, mental obtundation | Cessation of medication |
| Depressed level of consciousnes | Incapacity/dis ability | | |
| | Incapacity/dis ability | | |
| Prostration | Incapacity/dis ability | | |

Medicine Details:

| DOXEPIN HYDROCHLORIDE (Suspected) | 5 | leason: | | |
|-----------------------------------|---------------------|----------|------------|---|
| Tablet | 10.0 Milligram | Daily | Oral | |
| 3atch: | Started: 17/05/2005 | Stopped: | 20/05/2005 | 0 |

Laboratory Investigations:

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



Date 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 Detai

| todotion botal | | | |
|------------------|----------|---|-----------|
| Preferred Term | Severity | Report Description | Treatment |
| Medication error | | Medication error - doctor had prescribed 10mg, depression worsen and muscle | |
| Depression | | | |
| Myalgia | | | |

Medicine Details:

| METOPROLOL TARTRATE (Other drug) | | Reason: |
|----------------------------------|---------------------|----------|
| | 100.0 Milligram | |
| 3atch: | 3tarted: 10/05/2005 | Stopped: |
| LIPITOR (Other drug) | | Reason: |
| | 10.0 Milligram | |
| 3atch: | 3tarted: 10/05/2005 | Stopped: |
| NIFEDIPINE (Other drug) | | Reason: |
| | 60.0 Milligram | |
| 3atch: | Started: | Stopped: |
| ASPIRIN (Other drug) | | Reason: |
| | 100.0 Milligram | |
| 3atch: | Started: | Stopped: |

Laboratory Investigations:

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

Additional Information:

Unknown if Cialis was taken.



Date 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 |
| ospitalisation: | | | | | Age: | 58Y |
| Onset Date: | 10/05/2005 | | | | DOB: | |
| Outcome: | Not yet recovere | ed | | | Causality: | Causality possible |
| eaction Detai | | | | | - | |
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| ledicine Det | ails: | | | | | |
| SINEQUAN (Suspe | | | Reason: | Depression | | |
| Capsule | | 10.0 Milligran | n Daily | | Oral | |
| 3atch: | | Started: | | Stopped: | 10/05/2005 | 5 0 |
| LASIX (Suspected |) | | Reason: | | | |
| | | 20.0 Milligran | n Daily | | | |
| 3atch: | | 3tarted: 10/05/2005 | | Stopped: | | |
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| aboratory in | vestigations: | | | | | |
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| Additional In | ormation: | | | | | |
| Additional Inf Jnknown if Cialis v | | | | | | |
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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:
 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 Detai

| Cachon Betai | | | |
|---------------------|----------|---|-----------|
| 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: | | |
|------------------------|------------------|--------------------|--------------|--|
| Заtch: | Started: | }topped | : 27/01/2001 | |
| DOXEPIN HYDROCHLORIDE | (Suspected) | Reason: | | |
| | | | | |
| 3atch: | Started: | }topped | : 27/01/2001 | |
| | | | | |
| CYANOCOBALAMIN (Suspec | ted) | Reason: | | |
| CYANOCOBALAMIN (Suspec | ted) | Reason: | | |
| CYANOCOBALAMIN (Suspec | ted) Started: | ₹eason: }topped | : 27/01/2001 | |
| | Started: | | | |
| 3atch: | Started: | Stopped | | |

Laboratory Investigations:

| Date | Туре | 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+ ccrr: 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:

Report Run 30/07/200 03:51PN Database: pusime ADRS004 Page 293 of 307



Date 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 Detai

Medicine Details:

| RANITIDINE (Suspected) | | Reason: | | | |
|------------------------|----------|-----------|-------|---------|--|
| Tablet | 150.0 | Milligram | Daily | Oral | |
| 3atch: | Started: | | 3 | topped: | |

Laboratory Investigations:

| Date | Туре | 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 | рН | | 27/01/2001 | 7.30 | |



Date 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|----------|--|-----------------------------|
| Musculoskeletal stiffness | | Patient experienced stiffness, agitation, sweating, clonus ++ increased tone, serotonin syndrome or NMS. | Ceased all medication, ICU. |
| Agitation | | | |
| Clonus | | | |
| Hyperhidrosis | | | |
| Hypertonia | | | |
| Serotonin syndrome | | | |

Medicine Details:

| | | Reason: | Manic-depress | sion psycho,man | nic |
|--------------|--------------------------------|--------------------------------|---|--|---|
| Started: 18/ | /08/2005 | | Stopped: | 08/09/2005 | |
| | | Reason: | | | |
| Started: | | | Stopped: | 08/09/2005 | |
| ected) | | Reason: | | | |
| Started: | | | Stopped: | 08/09/2005 | |
| | | Reason: | | | |
| Started: | | | Stopped: | 08/09/2005 | 0 |
| | Started: ected) Started: | Started: ected) Started: | Started: 18/08/2005 Reason: Started: ected) Reason: Started: Reason: | Started: 18/08/2005 Stopped: Reason: Started: Stopped: ected) Reason: Started: Stopped: Reason: | Started: 18/08/2005 Reason: 3topped: 08/09/2005 Started: 3topped: 08/09/2005 Started: 3topped: 08/09/2005 Reason: 3topped: 08/09/2005 |

Laboratory Investigations:

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



Case Number: 212062

Reported: 28/09/2005

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Gender: F

Weight: 70.00

| Onset Date: 01/09/2005 | | Age: 56 DOB: 29/01/1949 | | | | | |
|-----------------------------------|----------------------------|---------------------------------------|---------------|----------------|----------|--------|--|
| Outcome: Not yet recovered | | Causality: Causality possible | | | | | |
| action Detai | | | | | | | |
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| | | | | | | | |
| edicine Details: | | | | | | | |
| SISPERIDONE (Suspected) | | Reason: | Otr spec symp | o psychopathol | nec | | |
| Batch: | Started: 28/08/2009 | 5 | Stopped: | 08/09/2005 | | | |
| ITHIUM CARBONATE (Suspected) | Flation 20,00,200 | Reason: | | sion psycho,ma | anic | | |
| Tablet | 1.0 Gram | Daily | · | Oral | | | |
| 3atch: | 3tarted: 18/08/2009 | | Stopped: | 08/09/2005 | 0 | | |
| | | | | | - | | |
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| . h t | | | | | | | |
| aboratory Investigations: | | | | | | | |
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| dditional Information: | | | | | | | |
| dulional information. | | | | | | | |
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| ort Run 30/07/200 03:51PN Databas | se: pusime | ADRS00 | 4 | | Page 296 | of 307 | |



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

| Report De | tail | | | | |
|-------------------------------------|---------------------|--|------------------|--|------------------------------------|
| Report Hospitalisati Onset Da | ate: 29/12/2004 | Seq: 1 | | We | ight: 0.00 Age: 85 OOB: 30/11/1919 |
| | me: Recovered | | | Causa | ality: Causality possible |
| Reaction Depot | erred Term | Severity | Penort | Description | Treatment |
| | | <u> </u> | • | • | |
| Hyponatraen | lla | | suspected SIADH | enced hyponatraemia, and confusion. | Hydrene ceased, fluid |
| Confusional | state | Caused or prolonged inpatient hospitalisation | | | |
| Inappropriate | e antidiuretic horr | mon Caused or prolonged inpatient hospitalisation | | | |
| Medicine I | | | 2000 | | |
| Table | ONE (Suspected) | 5.0 | Reason Milligram | on: Daily Oral | |
| 3atch | | Started: | wiiiigram | Stopped: | |
| DEPTRAN (Si | | Juli tou. | Reaso | | |
| | .opco.cu, | 10.0 | Milligram | Daily Oral | |
| 3atch | : | Started: | J | Stopped: | |
| HYDRENE 25 | /50 (Suspected) | | Reaso | on: Essential benign hy | pertension |
| | | 0.5 | Milligram | Daily | |
| 3atch | ! | Started: | L TERM | }topped: | |
| Laborator Date | y Investigatio | ons: Range Date Tes | sted Result | | Details |
| | 71 | 3 13 15 | | | |
| Additional | Information: | : | | | |



Date 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 Detai

| Caction Detai | | | i - |
|---------------------------------|----------|--|--|
| Preferred Term | Severity | Report Description | Treatment |
| Serotonin syndrome | | Patient developed severe serotonergic features, including confusion, nausea, fever, clonus, hyperreflexia, hypertonia, shivering and tachycardia, serotonin sydrome, 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 (Interacti | on) | | Reason: | | | | |
|--|----------------------|-----------|------------------|----------|------|---|--|
| Tablet | 80.0 | Milligram | Daily | | Oral | | |
| Заtch: | Started: | | | Stopped: | | 0 | |
| FLUVOXAMINE MALEATE (Interaction) | | | Reason: | | | | |
| Tablet | 200.0 | Milligram | Daily | | Oral | | |
| Зatch: | Started: | | | Stopped: | | | |
| | | | | | | | |
| DOXEPIN HYDROCHLORIDE (Interaction) | | | Reason: | | | | |
| DOXEPIN HYDROCHLORIDE (Interaction) Capsule | 50.0 | Milligram | Reason: Daily | | Oral | | |
| , | 50.0 Started: | Milligram | | }topped: | Oral | | |
| Capsule | | Milligram | | Stopped: | Oral | | |
| Capsule 3atch: | | Milligram | Daily | Stopped: | Oral | | |

Laboratory Investigations:

| Date | Туре | 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.

Report Run 30/07/200 03:51PN Database: pusime ADRS004 Page 298 of 307



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

| Case Number: 215247 Reported: 24/01/2006 Hospitalisation: Onset Date: Outcome: Unknown Reaction Detai | Seq: 1 | Weig Ag DC | ler: F lht: 0.00 ge: 70Y DB: lity: Causality possible |
|---|----------|--------------------|---|
| Preferred Term | Severity | Report Description | Treatment |
| Coordination abnormal Hyperreflexia Hypertonia Mydriasis Nausea Pyrexia Restlessness Tachycardia Medicine Details: | Coverny | | Trodunciik |
| RALOXIFENE (Other drug) | | Reason: | |
| 3atch: | Started: | Stopped: | |
| CALCIUM CARBONATE (Other drug) | | Reason: | |
| 3atch: | Started: | Stopped: | |
| Dilzem CD (Other drug) | | Reason: | |
| 3atch: | Started: | Stopped: | |
| SIMVASTATIN (Other drug) | | Reason: | |
| 3atch: | Started: | Stopped: | |
| Laboratory Investigations | : - | | |

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.



Date 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------------|----------|---|---|
| Neuroleptic malignant syndrome | H C | instability, pyschotic features, diaphoresis, marked rigidity, disorientation and visual hallucinations, whilst taking oxycodone. | Oxycodone, doxepin hydrochloride, selegeline and dexmethasone 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 | | | | |
| Заtch: | Started: | L | TERM | Stopped: | | | |
| OXYCODONE HYDROCHLORIDE (Suspect | ted) | | Reason: | | | | |
| | 40.0 | Milligram | Daily | | Oral | | |
| Зatch: | Started: | | | Stopped: | | 0 | |
| DOXEPIN HYDROCHLORIDE (Suspected) | | | Reason: | Depression | | | |
| | 100.0 | Milligram | Daily | | Oral | | |
| Зatch: | Started: | | | Stopped: | | 0 | |
| SELEGILINE HYDROCHLORIDE (Suspecte | ed) | | Reason: | Paralysis agita | ins | | |
| Tablet | 10.0 | Milligram | Daily | | Oral | | |
| Зatch: | Started: | | | Stopped: | | 0 | |

Laboratory Investigations:

| Date | Туре | 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 109/L |

Additional Information:

J.Clin. Neurosci. 2006; 13(7):857-859.

Report Run 30/07/200 03:51PN Database: pusime ADRS004 Page 300 of 307



Date 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: | М | | |
| Reported: 08/11/2006 | - | | | Weight: 0.00 | | | | |
| Hospitalisation: | | | | | Age: | | | |
| Onset Date: | | | | | DOB: | | | |
| Outcome: Recovered | | | | (| | Causality possible | | |
| Reaction Detai | | | | · | zausanty. | Causanty possible | | |
| Preferred Term | Severity | | Report Desc | crintion | | Treatment | | |
| | | | Report Desi | Сприоп | | Пеаннени | | |
| Agitation | Life | | | | | | | |
| Autonomic nervous system imbal | Alexander Alexandra | | | | | | | |
| Blood creatine phosphokinase in | the contract of the contract of | | | | | | | |
| 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 | | | |
| Зatch: | Started: | | | Stopped: | | 0 | | |
| | | | | | | | | |
| Laboratory Investigations | : | | | | | | | |
| Additional Information: J.Clin. Neurosci. 2006; 13(7):857-85 | 9. | | | | | | | |



Date 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 Detai

| touction betai | | | |
|--------------------------|----------|--------------------|-----------|
| 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 | | | | |
| Зatch: | Started: | L | . TERM | Stopped: | | | |
| OXYCODONE HYDROCHLORIDE (Su | spected) | | Reason: | | | | |
| | 40.0 | Milligram | Daily | | Oral | | |
| Зatch: | Started: | | | Stopped: | | 0 | |
| DOXEPIN HYDROCHLORIDE (Suspec | cted) | | Reason: | Depression | | | |
| | 100.0 | Milligram | Daily | | Oral | | |
| 3atch: | Started: | | | Stopped: | | 0 | |
| SELEGILINE HYDROCHLORIDE (Sus | pected) | | Reason: | Paralysis agita | ins | | |
| Tablet | 10.0 | Milligram | Daily | | Oral | | |
| 3atch: | 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

| | 222959 08/11/2006 | Seq: 1 | | | | Gender: Weight: | 0.00 | |
|---|--|-------------|-------------|---------|-------------|--------------------|-----------------|--------|
| Hospitalisation: | | | | | | Age: | 58Y | |
| Onset Date: | | | | | | DOB: | | |
| | Recovered | | | | | Causality: | Causality possi | ible |
| Reaction Detai | | | | | | | | |
| | | | | | | | | |
| Medicine Deta | | | | Reason: | Cervicalgia | | | |
| Tablet | · · · [- · · · · · / | 4.0 |) Milligram | Daily | | Oral | | |
| 3atch: | | Started: | 3 - | , | Stopped: | | 0 | |
| Laboratory In | vestigations: | | | | | | | |
| Additional Inf J.Clin. Neurosci. 20 | Formation: 006; 13(7):857-859. | | | | | | | |
| 2000rt Pun 30/07/200 |) 03:51DN Datak | aso: pusimo | | ADDSOC | 14 | | Dama 202 | of 207 |

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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: 224326 Reported: 28/12/2006 ospitalisation: Onset Date: | Seq: 1 | | Wei <i>A</i> | der: F ght: 0.00 Age: 99U OB: |
| Outcome: Unknown | | | | lity: Causality possible |
| action Detai | | + | | |
| Preferred Term | Severity | İ | Description | Treatment |
| aucoma | | glaucoma | | |
| | | | | |
| | | | | |
| ledicine Details: | | 2000 | e. Chasifia disardara of | alaan |
| SINEQUAN (Suspected) | | Reaso | Specific disorders of Oral | sieep |
| 3atch: | Started: | L TERM | Stopped: | |
| aboratory Investigatior | | | | |
| Date Type | Range Date To | ested Result | | Details |
| dditional Information: | | | | |
| | | | | |
| ort Run 30/07/200 03:51PN [| Database: pusime | AD | RS004 | Page 304 of 307 |



Date 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 Detai

| Preferred Term | Severity | Report Description | Treatment |
|----------------|---|--------------------|---|
| | Caused or prolonged inpatient hospitalisation | | Admitted to hospital for management. Tramadol |
| | Caused or prolonged inpatient hospitalisation | | |

Medicine Details:

| TRAMAL SR (Interaction) | | | Reason: | Otr&unsp vertel | brogen pain synd | |
|-------------------------------------|----------|-----------|---------|-----------------|------------------|--|
| Tablet | 100.0 | Milligram | Daily | | Oral | |
| Зatch: | Started: | | | Stopped: | 0 | |
| DOXEPIN HYDROCHLORIDE (Interaction) | | | Reason: | Pain | | |
| Capsule | 25.0 | Milligram | Daily | | Oral | |
| Зatch: | Started: | | | Stopped: | 0 | |
| Sensipar (Interaction) | | | Reason: | Hyperparathyro | idism | |
| Tablet | 30.0 | Milligram | Daily | | Oral | |
| Зatch: | Started: | | | Stopped: | 0 | |
| LITHIUM CARBONATE (Other drug) | | | Reason: | | | |
| | | | | | | |
| Зatch: | Started: | | | Stopped: | | |

Laboratory Investigations:

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

Additional Information:

Tramad ceased and symptoms resolved. When tramadol recommenced for back pain, symptoms returned.

Report Run 30/07/200 03:51PN Database: pusime ADRS004 Page 305 of 307



Date 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 Reported: 10/01/2007 Iospitalisation: Onset Date: 12/09/2006 Outcome: Recovered | Seq: 1 | | | 0.00 |
| eaction Detai | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| Medicine Details: THYROXINE SODIUM (Other drug) | | Reason: | | |
| (0 | | | | |
| 3atch: | Started: | | Stopped: | |
| QUININE SULPHATE (Other drug) | | Reason: | | |
| 3atch: | Started: | | Stopped: | |
| NITRAZEPAM (Other drug) | | Reason: | | |
| Зatch: | Started: | | Stopped: | |
| ALUMINIUM HYDROXIDE (Other dru | g) | Reason: | | |
| 3atch: | Started: | | Stopped: | |
| _aboratory Investigations | | | | |
| -uboratory invoctigations | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| Additional Information: | | | | |
| ramad ceased and symptoms reso | olved. When tramadol | recommenced for ba | ck pain, symptoms retu | urned. |
| | | | | |
| | | | | |

Report Run 30/07/200 03:51PN Database: pusime ADRS004 Page 306 of 307



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

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 Detai

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

Medicine Details:

| Micalcinic Details. | | | |
|-----------------------|---------------------|------------------------|------------|
| DIAZEPAM (Other drug) | | Reason: | |
| 3atch: | Started: | Stopped: | 0 |
| DEPTRAN (Suspected) | | Reason: Anxiety neuros | sis |
| Tablet | 50.0 Milligram | Daily | Oral |
| 3atch: | 3tarted: 16/01/2007 | Stopped: | 02/02/2007 |

Laboratory Investigations:

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