# Public Case Detail

**Cases Count: 50**

## Case Number : 231715

**Data Entry Date :** 09/08/2007

**Hospitalisation :**

**Onset Date :** 05/06/2007

**Outcome :**

Unknown

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 15/03/1963

**Causality :** Causality possible

**Information:** In 2006 the patient started paroxetine hydrochloride oral at 3 tablets daily.

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | | Patient experienced withdrawal symtoms when she had reduced the dose Aropax. Also experienced inability to sleep, nightmares, waking with "pricking or stabbing" sensation, cold sweats, nausea, "wonkiness" dizziness, irritation, fungus growing on her knee and obsessive thinking. | Aropax discontinued. Commenced Luvox and ceased. Commenced temazepam. |

## Medicine details :

**AROPAX (Suspected)** **Reason :**

Tablet 1 Dose Unspec As necessary Oral

**Batch :** **Started :** **Stopped :** 26/06/2007

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**LUVOX (Other drug)** **Reason :**

50 Milligram

**Batch :** **Started :** **Stopped :**

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**TEMAZEPAM (Other drug)** **Reason :**

10 Milligram

**Batch :** **Started :** **Stopped :**

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# Public Case Detail

**Cases Count: 50**

## Case Number : 232146

**Data Entry Date :** 17/08/2007

**Hospitalisation :** Required a visit to the doctor

**Onset Date :** 15/11/2005

**Outcome :**

Unknown

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :** 44Y

**DOB :**

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Weight increased | | Patient was over weight already but has gained 15kg on Aropax. | Drug not stopped. |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Depression

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** 15/11/2005 L TERM **Stopped :** Continuing.

# Public Case Detail

**Cases Count: 50**

## Case Number : 232697

**Data Entry Date :** 29/08/2007

**Hospitalisation :** Required a visit to the doctor

**Onset Date :** 15/07/2007

**Outcome :**

Not yet recovered

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 13/09/1984

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Therapeutic response unexpected | | Resumption of regular menstrual periods one month after starting Aropax. | Given a hormonal supplement to amenorrhoea. |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Depression

1 Dose Unspec Daily Oral

**Batch :** **Started :** 15/06/2007 **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 233272

**Data Entry Date :** 11/09/2007

**Hospitalisation :**

**Onset Date :** 19/08/2007

**Outcome :**

Unknown

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 18/07/1982

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | | Approximately 3 days after discontinuing Paroxetine hydrochloride, on 19 Aug 2007, the patient experienced nausea, tingling sensation, which the patient described as shock-like and light headedness. Drug withdrawal syndrome. | |

## Medicine details :

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :**

Tablet 1 Dose Unspec Daily Oral

**Batch :** **Started :** 15/01/2007 **Stopped :** 17/08/2007

# Public Case Detail

**Cases Count: 50**

## Case Number : 233307

**Data Entry Date :** 12/09/2007

**Hospitalisation :** Required a visit to the doctor

**Onset Date :** 30/06/2007

**Outcome :** Recovered

**Information:** CERT(RECHALL)

**Gender :** F

**Weight (kg) :** 80

**Age :**

**DOB :** 12/09/1962

**Causality :** Causality certain

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Restless legs syndrome | | Restless legs - severe. Stopped "like a switch" with cessation of Paroxetine. | Cessation of Paroxetine. |

## Medicine details :

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :** Depression

60 Milligram Daily

**Batch :** **Started :** **Stopped :** 0

# Public Case Detail

**Cases Count: 50**

## Case Number : 233331

**Data Entry Date :** 12/09/2007

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 06/09/1985

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | | Drug withdrawal syndrome. Vomiting, weight increased, headache, vertigo, diarrhoea, sensory disturbance, nausea, dependence. Patient was prescribed Aropax when she was 17 and was addicted within 1 month. She has gained over 30kg. She has been trying to get off the drug for 3 years. | |

## Medicine details :

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :**

Tablet 40 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 233902

**Data Entry Date :** 02/10/2007

**Hospitalisation :** Admitted to hospital

**Onset Date :** 28/11/2006

**Outcome :**

Recovered

**Information:**

**Gender :** M

**Weight (kg) :** 0

**Age :**

**DOB :** 18/12/1946

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pyrexia | Caused or prolonged inpatient hospitalisation | Patient developed fever, sweats, rigors, worsening anxiety and urinary retention. | Aropax ceased. |
| Anxiety | Caused or prolonged inpatient hospitalisation | | |
| Chills | Caused or prolonged inpatient hospitalisation | | |
| Hyperhidrosis | Caused or prolonged inpatient hospitalisation | | |
| Serotonin syndrome | Caused or prolonged inpatient hospitalisation | | |
| Urinary retention | Caused or prolonged inpatient hospitalisation | | |

## Medicine details :

**AROPAX (Suspected)** **Reason :**

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

**MIRTAZAPINE (Suspected)** **Reason :**

Tablet 60 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

**LEVODOPA (Other drug)** **Reason :**

Tablet 5 Dose Unspec Oral

**Batch :** **Started :** **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 234223

**Data Entry Date :** 10/10/2007

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :** 30Y

**DOB :**

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug withdrawal syndrome | | Patient experienced vomiting and dizziness with withdrawal of drug. | Drug withdrawn |

## Medicine details :

**AROPAX (Suspected)**

**Reason :**

**Batch :**

**Started :**

**Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 234626

**Data Entry Date :** 22/10/2007

**Hospitalisation :**

**Onset Date :** 15/01/2003

**Outcome :**

Not yet recovered

**Information:**

**Gender :** M

**Weight (kg) :** 100

**Age :**

**DOB :** 04/04/1967

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Dyskinesia | | Jerking of arms and legs (and head occasionally) in bed. | Attempted to reduce dose. |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Obsessive compulsive neurosis

Tablet 60 Milligram Daily Oral

**Batch :** **Started :** 01/06/2002 **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 234951

**Data Entry Date :** 01/11/2007

**Hospitalisation :**

**Onset Date :** 15/01/2003

**Outcome :**

Unknown

**Information:**

**Gender :** M

**Weight (kg) :** 0

**Age :**

**DOB :** 04/04/1967

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Overdose | | Patient received paroxetine hydrochloride tablets for obsessive compulsive disorder. After increasing dose above 60mg per day, the patient experienced jerking of limbs and twitch. The patient's arms or legs will suddenly shoot out forcefully. The action involves the whole limb. The event particularly occurs when the patient is going to sleep. If the patient becomes drowsy during the day (eg, when a passenger in a car) it can happen then. | Dose was decreased and symptoms improved. |
| Muscle twitching | | | |
| Myoclonus | | | |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Obsessive compulsive neurosis

Tablet 80 Milligram Daily Oral

**Batch :** **Started :** 15/01/2003 **Stopped :**

---

**DIAZEPAM (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**Paracetamol-Codeine Phosphate (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**TRAMADOL HYDROCHLORIDE (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

# Public Case Detail

**Cases Count: 50**

## Case Number : 236146

**Data Entry Date :** 11/12/2007

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Recovered

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :** 52Y

**DOB :**

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Alcohol use | | 'Went mad' for 3 years. Craving alcohol. Became alcoholic. Weight increased 20 kg. Personality change. Went to supermarket every few hours. Sleeping all day. | Ceased medication. Lost 20kg, now swimming , diet and exercise. |
| Alcoholism | | | |
| Personality change | | | |
| Weight increased | | | |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Depression

**Batch :** **Started :** 01/01/2001 **Stopped :** 01/10/2004

---

**STILNOX (Suspected)** **Reason :** Specific disorders of sleep

Tablet Oral

**Batch :** **Started :** 01/01/2001 **Stopped :** 31/12/2004

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# Public Case Detail

**Cases Count: 50**

## Case Number : 237243

**Data Entry Date :** 23/01/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :** 99u

**DOB :**

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyperhidrosis | | Patient reported that she was initially moody, temperamental, bad tempered, sweating excessively and had a dry mouth. She described feelings of being angry, violent, emotional and that noise irritated her. Her self mutilation was worsening. | |
| Aggression | | | |
| Anger | | | |
| Dry mouth | | | |
| Hyperacusis | | | |
| Hyperhidrosis | | | |
| Intentional self-injury | | | |
| Mood altered | | | |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Depression

Tablet 60 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 237647

**Data Entry Date :** 05/02/2008

**Hospitalisation :** Admitted to hospital

**Onset Date :** 10/01/2008

**Outcome :** 16/01/2008
Recovered

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 10/10/1948

**Causality :** Causality possible

**Information:**

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Disorientation | Caused or prolonged inpatient hospitalisation | Disorientation, delirium, agitation, "feeling hot". | Stopped medication. |
| Agitation | Caused or prolonged inpatient hospitalisation | | |
| Delirium | Caused or prolonged inpatient hospitalisation | | |
| Feeling hot | Caused or prolonged inpatient hospitalisation | | |
| Serotonin syndrome | Caused or prolonged inpatient hospitalisation | | |

## Medicine details :

**OXYCONTIN (Suspected)** **Reason :** Pain

160 Milligram Daily

**Batch :** **Started :** 15/01/2007 L TERM **Stopped :** 11/01/2008 0

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**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :** Depression

Tablet 40 Milligram Daily Oral

**Batch :** **Started :** L TERM **Stopped :** 11/01/2008 0

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**PENICILLIN NOS (Suspected)** **Reason :** Acute tonsillitis

1000 Milligram Daily

**Batch :** **Started :** 08/01/2008 **Stopped :** 11/01/2008 0

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**AMITRIPTYLINE HYDROCHLORIDE (Other drug)** **Reason :** Specific disorders of sleep

50 Milligram Daily

**Batch :** **Started :** L TERM **Stopped :** 0

---

**ENDONE (Other drug)** **Reason :** Pain

**Batch :** **Started :** 15/10/2005 L TERM **Stopped :** 15/01/2007

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# Public Case Detail

**Cases Count: 50**

## Case Number : 237768

**Data Entry Date :** 08/02/2008

**Hospitalisation :**

**Onset Date :** 16/01/2008

**Outcome :**

Unknown

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :** 65Y

**DOB :**

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cerebrovascular accident | Caused or prolonged inpatient hospitalisation | On 16 Jan 2008 patient was hospitalised after suffering a stroke. | |

## Medicine details :

**ATACAND (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

**LIPITOR (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

**NEXIUM (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

**PREMARIN (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 238125

**Data Entry Date :** 20/02/2008

**Hospitalisation :** Admitted to hospital

**Onset Date :**

**Outcome :**

Recovered

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :** 78Y

**DOB :**

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Serotonin syndrome | Caused or prolonged inpatient hospitalisation | Patient started on Paroxetine 20mg - took first dose in evening (and a herbal relaxant tablet she had been using previously with no ill effects) Presented to Emergency Department next day with shaking and feeling very unwell - doctor observed marked clonus and rigidity - diagnosed seretonergic reaction to paroxetine | stop paroxetine - regular observations - admit for 3 days |
| Clonus | Caused or prolonged inpatient hospitalisation | | |
| Tremor | Caused or prolonged inpatient hospitalisation | | |

## Medicine details :

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :**

Tablet 20 Milligram 1 time Oral

**Batch :** AD554 **Started :** 13/02/2008 **Stopped :** 14/02/2008 0

# Public Case Detail

**Cases Count: 50**

## Case Number : 238776

**Data Entry Date :** 11/03/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Recovered

**Information:**

**Gender :** F

**Weight (kg) :** 60

**Age :**

**DOB :** 12/04/1972

**Causality :** Causality probable

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Night sweats | | Night sweats. | Aropax ceased. |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Anxiety neurosis

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** 24/07/2003 **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 238936

**Data Entry Date :** 13/03/2008

**Hospitalisation :**

**Onset Date :** 27/12/2007

**Outcome :**

Unknown

**Information:**

**Gender :** M

**Weight (kg) :** 0

**Age :**

**DOB :** 25/09/1958

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Diabetes mellitus | | Treatment was discontinued on 27 Dec 2007 due to the onset of diabetes, lack of efficacy, patient's objection to regular blood tests and weight gain. On unspecified dates the patient experienced panic attacks, paranoid ideation with ego dystonic (almost delusion) ideation in spite of treatment with Clozapine and Aropax (paroxetine hydrochloride) and Valproate. | Clozaril treatment was discontinued. |
| Delusion | | | |
| Drug ineffective | | | |
| Panic attack | | | |
| Paranoia | | | |
| Weight increased | | | |

## Medicine details :

**AROPAX (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**CLOZARIL (Suspected)** **Reason :**

Tablet Oral

**Batch :** **Started :** 27/06/1994 **Stopped :** 27/12/2007

---

**VALPRO (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

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# Public Case Detail

**Cases Count: 50**

## Case Number : 239079

**Data Entry Date :** 18/03/2008

**Hospitalisation :** Required a specialist consultation

**Onset Date :** 03/07/2007

**Outcome :**

Recovered

**Information:**

**Gender :** F

**Weight (kg) :** 72

**Age :**

**DOB :** 31/03/1983

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Contusion | | Easy bruising. | |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Anxiety neurosis

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** 17/03/2007 **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 239087

**Data Entry Date :** 18/03/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Recovered

**Gender :** F

**Weight (kg) :** 0

**Age :** 40Y

**DOB :**

**Causality :** Causality possible

**Information:** The fetus developed neural deficits, (cerebellar hypoplasia).

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Abortion induced | | The patient became pregnant while receiving paroxetine hydrochloride at 20mg. At an unknown time after starting paroxetine hydrochloride, the patient experienced elective abortion, as three and a half months into the pregnancy, the pregnancy was terminated due to neural deficits (failure to develop the cerebellum). | |
| Drug exposure during pregnancy | | | |

## Medicine details :

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :**

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 239090

**Data Entry Date :** 18/03/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Death

**Gender :** U

**Weight (kg) :** 0

**Age :** 99U

**DOB :**

**Causality :** Causality possible

**Information:** Three and a half months into the pregnancy, the pregnancy was terminated.

Follow-up up information received 11 June 2008:
Mother's history
The patient's mother has previously had 1 spontaneous abortion and 1 therapeutic abortion.
The patient's mother smokes 10 cigarettes per day.

Father's history:
The patient's father smokes 15-20 cigarettes per day and 1-2 standard drinks per day.
No familial defects/chromosomal/genetic within family of origin or his two biological children.

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Nervous system disorder | Congenital anomaly / birth defect | Female patient (LH age 40) has been taking Aropax for 6-8 years. The patient then fell pregnant whilst on Aropax 20mg daily. Three and a half months into the pregnancy, the pregnancy was terminated due to neural deficits (failure to develop the cerebellum). | |
| Cerebellar hypoplasia | Congenital anomaly / birth defect | | |
| Congenital neurological disorder | Congenital anomaly / birth defect | | |
| Drug exposure during pregnancy | Congenital anomaly / birth defect | | |

## Medicine details :

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :**

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 240655

**Data Entry Date :** 06/05/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :** 43Y

**DOB :**

**Causality :** Causality unclear

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pleural effusion | | Pleural effusion, ascites, weight decreased and galactorrhoea. | |
| Ascites | | | |
| Galactorrhoea | | | |
| Weight decreased | | | |

## Medicine details :

**AROPAX (Suspected)** **Reason :**

Tablet 40 Milligram Daily Oral

**Batch :** **Started :** L TERM **Stopped :** 0

**ORAL CONTRACEPTIVE NOS (Other drug)** **Reason :** Contraception

Oral

**Batch :** **Started :** **Stopped :**

## Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|
| Other data | | | | Cancer 28/04/08 antigen 125 increased. |

# Public Case Detail

**Cases Count: 50**

## Case Number : 241627

**Data Entry Date :** 05/06/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :** 01/04/2007
Death

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 08/06/1951

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug level increased | Death | Uncertain onset date. Patient died of multiple drug toxicity. Had beeen taking morphine, codeine and flunitrazepam at same dose for over ten years. Had been taking paroxetine two tabs daily for three years. Obtained OTC promethazine and died shortly after commencing it. Containers containing medication do NOT suggest deliberate overdose. Morphine, codeine and flunitrazepam all within therapeutic ranges and as expected for dose. Paroxetine and promethazine both present at about 8 times the upper limit of the therapeutic range. Suspected metabolic interaction between paroxetine and promethazine affecting clearance rates. Note patient had cholecystectomy, total colectomy and previous history of non-viral non-alcoholic hepatitis of uncertain aetiology. LFTs normal immediately prior to time of death. | N/A - found deceased by spouse |
| Drug interaction | Death | | |

## Medicine details :

**PAROXETINE HYDROCHLORIDE (Interaction)** **Reason :** Depression

Tablet 40 Milligram Daily Oral

**Batch :** **Started :** **Stopped :** 0

# Medicine details :

**PROMETHAZINE HYDROCHLORIDE (Interaction)** **Reason :**

Tablet 25 Milligram Daily Oral

**Batch :** **Started :** **Stopped :** 0

---

**CODEINE (Other drug)** **Reason :**

Tablet 60 Milligram 4 times Oral

**Batch :** **Started :** **Stopped :**

---

**FLUNITRAZEPAM (Other drug)** **Reason :**

Tablet 3 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

---

**FRUSEMIDE (Other drug)** **Reason :**

Tablet 40 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

---

**MORPHINE HYDROCHLORIDE (Other drug)** **Reason :**

Tablet 60 Milligram 4 times Oral

**Batch :** **Started :** **Stopped :**

---

**PANTOPRAZOLE (Other drug)** **Reason :**

Tablet 40 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

---

**PROPRANOLOL HYDROCHLORIDE (Other drug)** **Reason :**

Tablet 10 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

---

# Public Case Detail

**Cases Count: 50**

## Case Number : 241636

**Data Entry Date :** 05/06/2008

**Hospitalisation :**

**Onset Date :** 05/06/2008

**Outcome :**

Unknown

**Information:**

**Gender :** M

**Weight (kg) :** 0

**Age :**

**DOB :** 10/01/1950

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Swollen tongue | Caused or prolonged inpatient hospitalisation | Developed swelling of the tongue and lips overnight | ceased captopril, advised further caution with karvezide. |
| Lip swelling | Caused or prolonged inpatient hospitalisation | | |

## Medicine details :

**GenRx Captopril (Suspected)** **Reason :**

Tablet 50 Milligram Daily Oral

**Batch :** **Started :** L TERM **Stopped :** 0

**GenRx Paroxetine (Suspected)** **Reason :**

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** S TERM **Stopped :** 0

**KARVEZIDE 300/12.5 (Suspected)** **Reason :**

Tablet 1 Dose Unspec Daily Ophthalmic

**Batch :** **Started :** L TERM **Stopped :** 0

# Public Case Detail

**Cases Count: 50**

## Case Number : 241920

**Data Entry Date :** 16/06/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** F

**Weight (kg) :** 0

**Age :** 25Y

**DOB :**

**Causality :** Causality possible

**Information:** Suspected interaction: Concurrent use of paroxetine and atomoxetine may result in an increase in atomoxetine steady-state plasma concentrations.

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Suicidal ideation | | Suicidal ideation, nausea and gastroesophageal reflux. | Reduced dose of Atomoxetine |
| Gastrooesophageal reflux disease | | | |
| Nausea | | | |

## Medicine details :

**PAROXETINE HYDROCHLORIDE (Interaction)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**Strattera (Interaction)** **Reason :** Behavior disorders of childhod

60 Milligram Daily

**Batch :** **Started :** **Stopped :**

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# Public Case Detail

**Cases Count: 50**

## Case Number : 242020

**Data Entry Date :** 18/06/2008

**Hospitalisation :**

**Onset Date :** 24/05/2008

**Outcome :** 28/05/2008
Recovered

**Gender :** F

**Weight (kg) :** 4

**Age :**

**DOB :** 24/05/2008

**Causality :** Causality possible

**Information:** Maternal medication use during pregnancy.

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Agitation neonatal | Life threatening | | |
| Apnoea | Life threatening | | |
| Drug withdrawal syndrome neonatal | Life threatening | | |
| Myoclonus | Life threatening | | |
| Neonatal respiratory distress syndrome | Life threatening | | |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Anxiety neurosis

Tablet 40 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 242175

**Data Entry Date :** 23/06/2008

**Hospitalisation :**

**Onset Date :** 09/05/2008

**Outcome :**

Not yet recovered

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :** 89Y

**DOB :**

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Inappropriate antidiuretic hormone secretion | | Drug induced SIADH. Presented with nausea, lethargy, and anorexia following 4 days of paroxetine. | Citalopram witheld. Ceased paroxetine. Fluid restriction |
| Anorexia | | | |
| Lethargy | | | |
| Nausea | | | |

## Medicine details :

**CITALOPRAM HYDROBROMIDE (Suspected)** **Reason :**

20 Milligram Daily

**Batch :** **Started :** **Stopped :** 02/05/2008

---

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**ALENDRONATE SODIUM (Other drug)** **Reason :**

70 Milligram Weekly

**Batch :** **Started :** **Stopped :**

---

**COLOXYL (Other drug)** **Reason :**

1 Dose Unspec As necessary

**Batch :** **Started :** **Stopped :**

---

**IRBESARTAN (Other drug)** **Reason :**

300 Milligram Daily

**Batch :** **Started :** **Stopped :**

---

**OMEPRAZOLE (Other drug)** **Reason :**

20 Milligram Daily

**Batch :** **Started :** **Stopped :**

---

**OXAZEPAM (Other drug)** **Reason :**

7.5 Milligram Daily

**Batch :** **Started :** **Stopped :** 02/05/2008

---

## Medicine details :

**PARACETAMOL (Other drug)** **Reason :**

2 Dose Unspec As necessary

**Batch :** **Started :** **Stopped :**

---

**TIMOLOL MALEATE (Other drug)** **Reason :**

0.5 Percent Daily

**Batch :** **Started :** **Stopped :**

---

## Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|
| Sodium | | 12/03/2007 | 120 | |
| Sodium | | 13/03/2007 | 122 | |
| Sodium | | 14/03/2007 | 128 | |
| Sodium | | 23/03/2007 | 129 | |
| Sodium | | 08/05/2008 | 127 | |

# Public Case Detail

**Cases Count: 50**

## Case Number : 242480

**Data Entry Date :** 01/07/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Death

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :** 48Y

**DOB :**

**Causality :** Causality unclear

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Death | Death | On unknown date, three years ago, the patient started paroxetine at 40mg. At an unknown time, the patient subsequently took Phenergan 25mg and died. It was unknown if the patient took all these medications all at the one time. The reporter stated that he patient did not overdose on Aropax or Phenergan. At the time of reporting, the event was fatal. | |

## Medicine details :

**AROPAX (Suspected)** **Reason :**

Tablet 40 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

---

**CODEINE (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**FLUNITRAZEPAM (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**MORPHINE SULPHATE (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**PHENERGAN (Suspected)** **Reason :**

25 Milligram Daily

**Batch :** **Started :** **Stopped :**

---

# Public Case Detail

**Cases Count: 50**

## Case Number : 242513

**Data Entry Date :** 01/07/2008

**Hospitalisation :**

**Onset Date :** 01/01/2005

**Outcome :**

Recovered

**Information:**

**Gender :** F

**Weight (kg) :** 16

**Age :**

**DOB :** 19/08/2005

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Cardiac septal defect | Congenital anomaly / birth defect | Cardiac Ventriculo septal defect .mother on Paroxetine(aropax) throughout pregnancy dose 20mg/day No other birth defects | cardiac monitoring |

## Medicine details :

**AROPAX (Suspected)** **Reason :**

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 242586

**Data Entry Date :** 01/07/2008

**Hospitalisation :** Required a visit to the doctor

**Onset Date :** 06/03/2008

**Outcome :** 01/04/2008
Recovered

**Gender :** F

**Weight (kg) :** 85

**Age :**

**DOB :** 06/01/1957

**Causality :** Causality probable

**Information:**

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Therapeutic response unexpected with drug substitution | | She got severe gastric irritatble diarrhoea. | Changed back to Aropax |

## Medicine details :

**Extine (Suspected)** **Reason :** Depression

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** 06/03/2008 **Stopped :** 01/04/2008

# Public Case Detail

**Cases Count: 50**

## Case Number : 243530

**Data Entry Date :** 05/08/2008

**Hospitalisation :**

**Onset Date :** 15/10/2007

**Outcome :**

Not yet recovered

**Gender :** F

**Weight (kg) :** 0

**Age :** 43Y

**DOB :**

**Causality :** Causality unclear

**Information:** The physician reported that they do not believe the galactorrhoea was caused by either of the patient's medications.

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Galactorrhoea | | In Oct 2007, 1 month after stopping Logynon ED, the patient developed bilateral galactorrhoea, then a worsening abdominal distention (ascites). Her physicians noted that her CA125 levels were raised. On 21 Apr 2008 the level was 71 (normal <35). However, it was not possible to diagnose any obvious malignancies. By the end of Mar 2008, the patient had also developed right sided pleural effusion. | Approx 6 litre of fluid was drained from her abdomen. |
| Mesothelioma | | | |
| Peritonitis | | | |
| Pleural effusion | | | |

## Medicine details :

**LOGYNON ED (Suspected)** **Reason :** Contraception

Tablet 1 Dose Unspec Daily Oral

**Batch :** **Started :** L TERM **Stopped :** 15/09/2007

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :** Depression

1 Dose Unspec Daily

**Batch :** **Started :** **Stopped :**

## Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|
| Calcium | <35 | 21/04/2008 | 71 | |

# Public Case Detail

**Cases Count: 50**

## Case Number : 243664

**Data Entry Date :** 11/08/2008

**Hospitalisation :** Required a visit to the doctor

**Onset Date :**

**Outcome :** Not yet recovered

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 16/10/1975

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Pain in extremity | | Recent onset of pain in feet and toes - bilateral. Some swelling of feet and ankles. PH back pain and FH of gout, but this does not look like gout. | |
| Arthralgia | | | |
| Arthritis | | | |

## Medicine details :

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :**

Tablet Oral

**Batch :** **Started :** **Stopped :**

---

**SODIUM VALPROATE (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**DUROMINE (Other drug)** **Reason :**

Capsule Oral

**Batch :** **Started :** **Stopped :** 0

---

**PANADEINE (Other drug)** **Reason :**

Oral

**Batch :** **Started :** **Stopped :**

---

# Public Case Detail

**Cases Count: 50**

## Case Number : 243834

**Data Entry Date :** 14/08/2008

**Hospitalisation :** Admitted to hospital

**Onset Date :**

**Outcome :**

Recovered

**Gender :** M

**Weight (kg) :** 0

**Age :** 53Y

**DOB :**

**Causality :** Causality unclear

**Information:** Interaction recorded in PI.
243834 is a duplicate of 245152.

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sinus bradycardia | Caused or prolonged inpatient hospitalisation | Bradycardia, drug interaction, hypotension, ACS, VT. | |
| Acute coronary syndrome | Caused or prolonged inpatient hospitalisation | | |
| Hypotension | Caused or prolonged inpatient hospitalisation | | |
| Ventricular tachycardia | Caused or prolonged inpatient hospitalisation | | |

## Medicine details :

**BUPROPION HYDROCHLORIDE (Interaction)** **Reason :** Smoker

Tablet 150 Milligram 2 times Oral

**Batch :** **Started :** 14/07/2008 **Stopped :** 04/08/2008 0

**METOPROLOL TARTRATE (Interaction)** **Reason :** Essential benign hypertension

Tablet 50 Milligram 2 times Oral

**Batch :** **Started :** **Stopped :** 0

**PAROXETINE NOS (Interaction)** **Reason :** Depression

20 Milligram 1 time Oral

**Batch :** **Started :** **Stopped :** 0

# Public Case Detail

**Cases Count: 50**

## Case Number : 243993

**Data Entry Date :** 21/08/2008

**Hospitalisation :**

**Onset Date :** 02/04/2008

**Outcome :**

Death, maybe drug

**Information:**

**Gender :** M

**Weight (kg) :** 127

**Age :** 45Y

**DOB :**

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Death | Death | Aropax in combination with alcohol, on coroners report as cause of death. | death |

## Medicine details :

**ALCOHOL (Suspected)** **Reason :**

Oral Liquid Oral

**Batch :** **Started :** **Stopped :** 0

**AROPAX (Suspected)** **Reason :** Depression

20 Milligram Daily Oral

**Batch :** **Started :** 06/03/2008 **Stopped :** 0

# Public Case Detail

**Cases Count: 50**

## Case Number : 244198

**Data Entry Date :** 28/08/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Recovered

**Gender :** M

**Weight (kg) :** 0

**Age :** 53Y

**DOB :**

**Causality :** Causality unclear

**Information:** Landau J and Ajani A. Bupropion and bradycardia. MJA 2008; 189(3):180
244198 is a duplicate of 245152.

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Sinus bradycardia | Caused or prolonged inpatient hospitalisation | Patient experienced sinus bradycardia, acute coronary syndrome, angina pectoris, hyptension, ventricular tachycardia. | Multiple doses of IV atropine, adrenaline, tow coronary stents were inserted into stenosed right coronary artery. |
| Acute coronary syndrome | Caused or prolonged inpatient hospitalisation | | |
| Angina pectoris | Caused or prolonged inpatient hospitalisation | | |
| Hypotension | Caused or prolonged inpatient hospitalisation | | |
| Ventricular tachycardia | Caused or prolonged inpatient hospitalisation | | |

## Medicine details :

**METOPROLOL TARTRATE (Interaction)** **Reason :**

Tablet 100 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

**PAROXETINE HYDROCHLORIDE (Interaction)** **Reason :**

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

**Zyban (Interaction)** **Reason :** Smoker

Tablet 300 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

## Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|
| Blood pressure | | | | 85/60mmHg |
| Heart Rate | | | | 170 beats/min, 45beats/min. |
| Troponin | | | | 1.2microg/L |

# Public Case Detail

**Cases Count: 50**

## Case Number : 245152

**Data Entry Date :** 03/10/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Recovered

**Gender :** M

**Weight (kg) :** 0

**Age :** 53Y

**DOB :**

**Causality :** Causality possible

**Information:** Bradycardia continued until hospital discharge, one month after discharge he was in sinus rhythm (60 beats/min) and was clinically well.

Report Source Liferature
Journal: Reactions
Authorr: Landau J, Ajani AE
Tettle: Bupropion/metoprolol/paroxetine interaction-bradycardia: a case report
Volume:1215 Year:2008 Pages:10
Journal:Medical Journal of Australia
Author: LandauJ Ajani AE
Title: Buproppn and bradycardia
Volume:189 Year 2008: Pages:180.
MJA. Volume 189 Number 3* 4 August 2008.

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Acute coronary syndrome | Caused or prolonged inpatient hospitalisation | Patient experienced sinus bradycardia (45 beats/min), hypotension (blood pressure 85/60) was found to have a serum troponin 1 concentation of 1.2ug/L., he was admitted to hospital with an acute coronary syndrome. | Given multiple doses of IV atrophine and adrenalin. two days after admission, two coronary stents were successfullly deployed in a critically stenosed right coronary artery. |
| Angina pectoris | Caused or prolonged inpatient hospitalisation | | |
| Hypotension | Caused or prolonged inpatient hospitalisation | | |
| Sinus bradycardia | Caused or prolonged inpatient hospitalisation | | |

## Medicine details :

**BUPROPION HYDROCHLORIDE (Interaction)** **Reason :** Smoker

300 Milligram Daily

**Batch :** **Started :** **Stopped :** 0

**METOPROLOL TARTRATE (Interaction)** **Reason :** Essential benign hypertension

100 Milligram Daily

**Batch :** **Started :** **Stopped :**

**PAROXETINE HYDROCHLORIDE (Interaction)** **Reason :** Depression

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

## Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|
| Blood pressure | | | | Blood pressure decreased low 85/60 mmHg. |
| Heart Rate | | | | Heart rate decreased 45-50 beats/min. heart rate decreased 60 beats/min. |
| Troponin | | | | Troponin 1 1.2 ug/L. |

# Public Case Detail

**Cases Count: 50**

## Case Number : 245361

**Data Entry Date :** 13/10/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Information:**

**Gender :** F

**Weight (kg) :** 80

**Age :**

**DOB :** 07/05/1955

**Causality :** Causality unclear

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Mood swings | | Mood shift | Ceased green tea. |

## Medicine details :

**AROPAX (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**Green Tea (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**AMIODARONE HYDROCHLORIDE (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**ASPIRIN (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

# Public Case Detail

**Cases Count: 50**

## Case Number : 246245

**Data Entry Date :** 13/11/2008

**Hospitalisation :**

**Onset Date :** 18/08/2008

**Outcome :**

Not yet recovered

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 20/06/1966

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myalgia | | Severe myalgia, arthritis and markedly raised LFT's. | |
| Arthralgia | | | |
| Hepatic function abnormal | | | |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Depression

Tablet 1 Dose Unspec Daily Oral

**Batch :** **Started :** 25/01/2008 **Stopped :** 05/11/2008

# Public Case Detail

**Cases Count: 50**

## Case Number : 246688

**Data Entry Date :** 28/11/2008

**Hospitalisation :** Admitted to hospital

**Onset Date :**

**Outcome :**

Recovered

**Gender :** M

**Weight (kg) :** 0

**Age :** 53Y

**DOB :**

**Causality :** Causality possible

**Information:** 3 cases of interaction with bupropion, metoprolol and paroxetine reported on ADRAC database.
The most likely precipitant of the patient's bradycardia was his acute coronary syndrome, although bupropion may have contributed. The case highlights the potential for significant drug interactions when new drug therapies are initiatied. Bupropion and metoprolol (and other drugs metabolised by the cytochrome P450 2D6 isoenzyme pathway) should be co-administered with caution.
Citation:
Bupropion and bradycardia
Jacqueline Landau and Andrew E Ajani
Medical Journal of Australia
4 August 2008
Volume 189 Number 3
Duplicate of 245152

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Myocardial infarction | Caused or prolonged inpatient hospitalisation | A 53 year old man attended by paramedics for typical ischaemic chest pain. He had sinus bradycardia (45bpm) and hypotension (BP 85/60 mmHg). He reported his medications at the time of admission as including metoprolol 50mg twice daily for hypertension and paroxetine 20mg daily for depression. The parient was given multiple doses of intravenous atropine (total 1.2mg) and adrenalin (total 2mg). After an adrenalin infustion was begun he developed ventricular tachycardia (170 bpm) but his cardiac rhythm spontaneously returned to sinus bradycardia. Two days after admission two coronary stents were succussfully deployed in a critically stenosed right coronary artery. Bradycardia persisted (45-50 bpm). The following day it was discovered that 3 weeks previously the patient's general practitioner had prescribed bupropion 150mg twice daily to assist with smoking cessation, which he had been taking up until the day of admission. Bradycardia continued until hospital discharge. | |
| Angina pectoris | Caused or prolonged inpatient hospitalisation | | |
| Bradycardia | Caused or prolonged inpatient hospitalisation | | |
| Hypotension | Caused or prolonged inpatient hospitalisation | | |

## Medicine details :

**BUPROPION HYDROCHLORIDE (Interaction)** **Reason :** Smoker

300 Milligram Daily

**Batch :** **Started :** **Stopped :**

---

**METOPROLOL TARTRATE (Interaction)** **Reason :** Essential benign hypertension

100 Milligram Daily

**Batch :** **Started :** **Stopped :**

---

## Medicine details :

**PAROXETINE HYDROCHLORIDE (Interaction)** **Reason :** Depression

20 Milligram Daily

**Batch :** **Started :** **Stopped :**

---

**ATROPINE (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

# Public Case Detail

**Cases Count: 50**

## Case Number : 247186

**Data Entry Date :** 16/12/2008

**Hospitalisation :** Required a visit to the doctor

**Onset Date :** 15/02/2008

**Outcome :** 18/11/2008
Recovered

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 23/01/1983

**Causality :** Causality probable

**Information:**

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Enuresis | | Nocturnal enuresis. New onset after > 9 years on constant dose of aropax gradually increased to being every night, soaking bed in spite of continence pads. | Withdrawal of Aropax. |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Obsessive compulsive neurosis

40 Milligram Daily

**Batch :** **Started :** **Stopped :**

---

**LEVLEN ED (Other drug)** **Reason :** Contraception

1 Dose Unspec Daily

**Batch :** **Started :** **Stopped :**

---

# Public Case Detail

**Cases Count: 50**

## Case Number : 247258

**Data Entry Date :** 18/12/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Recovered

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :** 38Y

**DOB :**

**Causality :** Causality unclear

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Intentional overdose | Caused or prolonged inpatient hospitalisation | intentional overdose of paroxetine, alcohol, temazepam and diphenhydramine | |

## Medicine details :

**DIPHENHYDRAMINE HYDROCHLORIDE (Suspected)** **Reason :**

Tablet 400 Milligram 1 time Oral

**Batch :** **Started :** **Stopped :**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :**

Tablet 1800 Milligram 1 time Oral

**Batch :** **Started :** **Stopped :**

**TEMAZE (Suspected)** **Reason :**

Capsule 280 Milligram 1 time Oral

**Batch :** **Started :** **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 247461

**Data Entry Date :** 05/01/2009

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :** 99u

**DOB :**

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Aggression | | Weight gain of 48kg, feeling aggressive and angry, nausea, vomiting, feeling spaced out, tremor of whole body, thinking irrationally, "zaps" in head and tingling over body. | Weaning off Aropax |
| Anger | | | |
| Feeling abnormal | | | |
| Nausea | | | |
| Paraesthesia | | | |
| Sensory disturbance | | | |
| Thinking abnormal | | | |
| Tremor | | | |
| Vomiting | | | |
| Weight decreased | | | |
| Weight increased | | | |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Anxiety neurosis

Tablet Daily Oral

**Batch :** **Started :** **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 247664

**Data Entry Date :** 13/01/2009

**Hospitalisation :**

**Onset Date :** 07/10/2008

**Outcome :**

Unknown

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 21/02/1933

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | Caused or prolonged inpatient hospitalisation | Hyponatraemia, hypokalaemia and dizziness and fatigue. | Rehydration |
| Dizziness | Caused or prolonged inpatient hospitalisation | | |
| Fatigue | Caused or prolonged inpatient hospitalisation | | |
| Hypokalaemia | Caused or prolonged inpatient hospitalisation | | |

## Medicine details :

**KARVEZIDE 300/12.5 (Suspected)** **Reason :**

Tablet Oral

**Batch :** **Started :** **Stopped :**

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :**

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

## Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|
| Sodium | 135 - 145 | 06/10/2008 | 119 | |
| Sodium | 135 - 145 | 07/10/2008 | 131 | |
| Potassium | 3.5 - 5.0 | 06/10/2008 | 3.4 | |
| Potassium | 3.5 - 5.0 | 07/10/2008 | 3.6 | |

# Public Case Detail

**Cases Count: 50**

## Case Number : 248260

**Data Entry Date :** 04/02/2009

**Hospitalisation :**

**Onset Date :** 04/09/2008

**Outcome :**

Recovered

**Information:**

**Gender :** M

**Weight (kg) :** 0

**Age :** 85Y

**DOB :**

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Hyponatraemia | | Hyponatraemia | Fluid, rest, ceased Paroxetine, Coversyl Plus and Kaluril. |

## Medicine details :

**COVERSYL PLUS (Suspected)** **Reason :**

Tablet 1 Dose Unspec Daily Oral

**Batch :** **Started :** **Stopped :**

---

**KALURIL (Suspected)** **Reason :**

Tablet 5 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

---

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :** Depression

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** **Stopped :** 06/09/2008

---

**CODEINE (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**MIXTARD 30/70 (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :** 0

---

**PARACETAMOL (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**PROCHLORPERAZINE MALEATE (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

**SIMVASTATIN (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

---

## Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|
| Sodium | | 04/09/2008 | 120 | |
| Sodium | | 04/09/2008 | 119 | |

## Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|---|---|---|---|---|
| Sodium | | 10/09/2008 | 134 | |

# Public Case Detail

**Cases Count: 50**

## Case Number : 248341

**Data Entry Date :** 06/02/2009

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** F

**Weight (kg) :** 0

**Age :** 99u

**DOB :**

**Causality :** Causality probable

**Information:** The drug withdrawal symtoms are well known to occur after abrupt paroxetine cessation. There is no evidence to suggest it is linked to ectopic pregnancy.

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Drug exposure during pregnancy | | Approximately 2 years after starting paroxetine hydrochloride, the patient experienced drug exposure during pregnancy. It was reported that after she "stopped the Aropax she experienced dizziness for about 2 to 3 days". The patient also experienced drug withdrawal effects, palpitations, chest heaviness and anxiety. | Treatment with Aropax was discontinued. |
| Anxiety | | | |
| Chest discomfort | | | |
| Dizziness | | | |
| Palpitations | | | |
| Withdrawal syndrome | | | |

## Medicine details :

**AROPAX (Suspected)** **Reason :**

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 248399

**Data Entry Date :** 09/02/2009

**Hospitalisation :** Required a visit to the doctor

**Onset Date :** 12/09/2008

**Outcome :**

Recovered

**Information:**

**Gender :** F

**Weight (kg) :** 86

**Age :**

**DOB :** 23/12/1939

**Causality :** Causality probable

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Neuroleptic malignant syndrome | | On day that first dose was taken, developed a severe adverse reaction suggestive of neuroleptic malignant syndrome - nausea, sweating, feeling cold, disorientated, weakness and ataxia. | |
| Asthenia | | | |
| Ataxia | | | |
| Disorientation | | | |
| Feeling cold | | | |
| Hyperhidrosis | | | |
| Nausea | | | |

## Medicine details :

**PAXTINE (Suspected)** **Reason :** Anxiety neurosis

20 Milligram 1 time

**Batch :** **Started :** 12/09/2008 **Stopped :** 12/09/2008

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**ALDACTONE (Other drug)** **Reason :**

Milligram each/every

**Batch :** **Started :** **Stopped :**

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**Anagraine (Other drug)** **Reason :**

Dose Unspec As necessary

**Batch :** **Started :** **Stopped :**

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**BRICANYL TURBUHALER (Other drug)** **Reason :**

Dose Unspec As necessary

**Batch :** **Started :** **Stopped :**

---

**CELEBREX (Other drug)** **Reason :**

Milligram As necessary

**Batch :** **Started :** **Stopped :**

---

**CENTRUM TABLETS (Other drug)** **Reason :**

Dose Unspec Daily

**Batch :** **Started :** **Stopped :**

---

# Medicine details :

**MERSYNDOL (Other drug)** **Reason :**

Dose Unspec As necessary

**Batch :** **Started :** **Stopped :**

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**MYLANTA (Other drug)** **Reason :**

Milligram As necessary

**Batch :** **Started :** **Stopped :**

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**PANADEINE (Other drug)** **Reason :**

Dose Unspec As necessary

**Batch :** **Started :** **Stopped :**

---

**PARIET (Other drug)** **Reason :**

Milligram Daily

**Batch :** **Started :** **Stopped :**

---

**PULMICORT TURBUHALER (Other drug)** **Reason :**

Dose Unspec Daily

**Batch :** **Started :** **Stopped :**

---

**SPIRIVA (Other drug)** **Reason :**

Microgram Daily

**Batch :** **Started :** **Stopped :**

---

**TRITACE (Other drug)** **Reason :**

Milligram Daily

**Batch :** **Started :** **Stopped :**

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# Public Case Detail

**Cases Count: 50**

## Case Number : 248481

**Data Entry Date :** 11/02/2009

**Hospitalisation :** Required a visit to the doctor

**Onset Date :**

**Outcome :** 11/08/2009
Recovered

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 03/04/1976

**Causality :** Causality possible

**Information:**

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Metrorrhagia | | Patient said that after starting Aropax she had intermittent bleeding and spotting which often started after having taken 1-2 weeks of the active pill of Levlen. | |
| Vaginal haemorrhage | | | |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Anxiety neurosis

Tablet 10 Milligram Daily Oral

**Batch :** **Started :** 15/04/2008 **Stopped :** 15/10/2008

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**LEVLEN ED (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

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# Public Case Detail

**Cases Count: 50**

## Case Number : 248673

**Data Entry Date :** 17/02/2009

**Hospitalisation :** Required a visit to the doctor

**Onset Date :**

**Outcome :** Not yet recovered

**Information:**

**Gender :** F

**Weight (kg) :** 56

**Age :**

**DOB :** 20/11/1985

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Somnambulism | | Sleepwalking | Monitoring |

## Medicine details :

**AROPAX (Suspected)** **Reason :** Depression

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** 27/10/2008 **Stopped :**

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**ALPRAZOLAM (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

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**MAXOLON (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

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**SOMAC (Other drug)** **Reason :**

**Batch :** **Started :** **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 248729

**Data Entry Date :** 18/02/2009

**Hospitalisation :**

**Onset Date :** 12/12/2008

**Outcome :**

Unknown

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 12/01/1968

**Causality :** Causality possible

**Information:** The next day the patient took a quarter of a tablet (5 mg) and still felt she was in a stupor.

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Stupor | | Patient experienced stupor and could not work. | Paroxetine ceased |
| Impaired work ability | | | |

## Medicine details :

**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :**

Tablet 10 Milligram Daily Oral

**Batch :** **Started :** 12/12/2008 **Stopped :** 14/12/2008

# Public Case Detail

**Cases Count: 50**

## Case Number : 249992

**Data Entry Date :** 07/04/2009

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Information:**

**Gender :** M

**Weight (kg) :** 0

**Age :**

**DOB :** 19/09/1983

**Causality :** Causality possible

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Asthenia | | | |
| Blood potassium increased | | | |
| Chest pain | | | |
| Dehydration | | | |
| Disturbance in attention | | | |
| Headache | | | |
| Hepatic function abnormal | | | |
| Insomnia | | | |
| Mood altered | | | |
| Nausea | | | |
| Rash pruritic | | | |
| Rectal haemorrhage | | | |
| Tremor | | | |
| Weight increased | | | |

## Medicine details :

**AROPAX (Suspected)** **Reason :**

Tablet 20 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

# Public Case Detail

**Cases Count: 50**

## Case Number : 250185

**Data Entry Date :** 15/04/2009

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Death

**Information:**

**Gender :** F

**Weight (kg) :** 0

**Age :** 78Y

**DOB :**

**Causality :** Causality unclear

## Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---|---|---|---|
| Fall | Death | pharmacist report that patient was dispensed aripiorazole 10mg and died soon afterwards. On polypharmacy including benzodiazepines and paroxetine. Fell from a first floor window . died a few days alter. reporter unsure whether fall was suicide, and also unsure if the patient took the medication. | |
| Death | Death | | |

## Medicine details :

**Abilify (Suspected)** **Reason :**

Tablet 10 Milligram Daily Oral

**Batch :** **Started :** **Stopped :**

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**Benzodiazepine NOS (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

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**PAROXETINE HYDROCHLORIDE (Suspected)** **Reason :**

**Batch :** **Started :** **Stopped :**

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Selection Parameters : Date Range: 01/08/2007 To 31/12/2059 GM medicines Only Medicine Names: AROPAX, PAROXETINE HYDROCHLORIDE, PAROXETINE NOS, PAXTINE, Oxetine, GenRx Paroxetine, Extine