

Public Case Detail

Cases Count: 76

Case Number : 198263

Data Entry Date : 18/06/2004

Gender : M

Hospitalisation :

Weight (kg) : 40

Onset Date : 08/06/2004

Age :

DOB : 20/03/1992

Outcome :

Causality : Causality possible

Not yet recovered

Information: Symptoms recurred when came off anti-diarrheals.
 Patient was started on 18mg 25/05/05, 40mg 01/06/04, 60mg 08/06/04, 40mg 11/06/04.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------|--------------------------|-----------------------|------------------|
| Diarrhoea | Required Visit to Doctor | Diarrhoea for 4 days. | Anti Diarrheals. |

Medicine details :

Atomoxetine Hydrochloride (Suspected) Reason : Behavior disorders of childhood
 60 Milligram Daily
Batch : Started : 08/06/2004 Stopped :

Public Case Detail

Cases Count: 76

Case Number : 198467

Data Entry Date : 24/06/2004

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/06/2004

Age :

DOB : 11/10/1979

Outcome :

Causality : Causality possible

Not yet recovered

Information: New drug, 1st report. Indication of ADHD from 6+ years of age.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|--------------------------|---|-------------------|
| Affect lability | Required Visit to Doctor | temperature dysregulation (feeling cold), hyperactivity, irritability & lability to point where experienced suicidal ideation | Medication ceased |
| Feeling cold | Required Visit to Doctor | temperature dysregulation (feeling cold), hyperactivity, irritability & lability to point where experienced suicidal ideation | Medication ceased |
| Irritability | Required Visit to Doctor | | |
| Psychomotor hyperactivity | Required Visit to Doctor | | |
| Suicidal ideation | Required Visit to Doctor | | |

Medicine details :

Atomoxetine Hydrochloride (Suspected)

Reason : Behavior disorders of childhood

Capsule

40 Milligram

1 time

Oral

Batch : unknown

Started : 18/06/2004

Stopped : 22/06/2004

Public Case Detail

Cases Count: 76

Case Number : 198545

Data Entry Date : 28/06/2004

Gender : M

Hospitalisation : Treated in Accident/Emergency Depart

Weight (kg) : 0

Onset Date : 02/06/2004

Age :

DOB : 12/10/1991

Outcome :

Causality : Causality possible

Not yet recovered

Information: Dosage had been increased from 18mg daily to 36mg daily and then to 40mg daily a few days prior to onset of events.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|-------------------------------|-----------|
| Tachycardia | | Tachycardia and palpitations. | |
| Palpitations | | | |

Medicine details :

Dexamphetamine Sulphate (Suspected)

Reason :

10 Milligram Daily

Batch :

Started :

L TERM

Stopped :

Continuing

Strattera (Suspected)

Reason : Behavior disorders of childhood

Capsule

40 Milligram Daily

Oral

Batch :

Started : 03/05/2004

Stopped :

Continuing

Public Case Detail

Cases Count: 76

Case Number : 199694

Data Entry Date : 05/08/2004

Gender : M

Hospitalisation :

Weight (kg) : 29.1

Onset Date : 14/07/2004

Age :

DOB : 12/09/1996

Outcome :

Causality : Causality possible

Not yet recovered

Information:

| Reaction : | | | |
|---------------------------|-----------------|--|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Gastrointestinal disorder | Severe | Patient experienced severe GIT upset (nausea, reflux, generally unwell). | |

| Medicine details : | | | |
|--|-----------------------------|---|---|
| Atomoxetine Hydrochloride (Suspected) | | Reason : Behavior disorders of childhood | |
| | 35 Milligram | Daily | |
| Batch : | Started : 21/06/2004 | Stopped : | 0 |

Public Case Detail

Cases Count: 76

Case Number : 199697

Data Entry Date : 05/08/2004

Gender : M

Hospitalisation :

Weight (kg) : 28

Onset Date : 24/07/2004

Age :

DOB : 24/03/1995

Outcome : 29/07/2004

Causality : Causality probable

Recovered

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|--------------------------|--|-----------|
| Gastrointestinal disorder | Required Visit to Doctor | Patient experienced GIT upset with nausea ++, severe headache. | |
| Headache | Required Visit to Doctor | | |
| Nausea | Required Visit to Doctor | | |

Medicine details :

| | | | |
|------------------------------|-----------------------------|---|------|
| Strattera (Suspected) | | Reason : Behavior disorders of childhood | |
| Capsule | 10 Milligram | Daily | Oral |
| Batch : | Started : 16/07/2004 | Stopped : 28/07/2004 | 0 |

Public Case Detail

Cases Count: 76

Case Number : 200332

Data Entry Date : 27/08/2004

Gender : M

Hospitalisation :

Weight (kg) : 72

Onset Date : 11/08/2004

Age :

DOB : 25/11/1985

Outcome :

Causality : Causality possible

Recovered

Information:

| Reaction : | | | |
|-----------------------|-----------------|---|-----------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Orchitis | | Patient suffered swollen, painful and tender testicles. | Dose decreased to 40mg/day. |

| Medicine details : | | | |
|------------------------------|------------------|------------------|------|
| Strattera (Suspected) | | Reason : | |
| Capsule | 80 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 203879

Data Entry Date : 04/01/2005

Gender : M

Hospitalisation :

Weight (kg) : 71.9

Onset Date : 06/10/2004

Age :

DOB : 09/07/1993

Outcome :

Causality : Causality probable

Recovered

Information: Note - showed increased symptoms with increased dose. Symptoms stopped when drug stopped.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|----------|--|---------------------|
| Agitation | | The patient became agitated, emotionally labile and experienced thoughts of self harm. | Atomoxetine ceased. |
| Affect lability | | | |
| Self-injurious ideation | | | |

Medicine details :

Strattera (Suspected)

Reason :

Capsule

25 Milligram

Daily

Oral

Batch :

Started : 06/10/2004

Stopped : 22/10/2004

Public Case Detail

Cases Count: 76

Case Number : 204246

Data Entry Date : 14/01/2005

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 35

Onset Date : 15/07/2004

Age :

DOB : 03/05/1995

Outcome :
Recovered

Causality : Causality probable

Information:

| Reaction : | | | |
|-----------------------|--------------------------|---|---------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Abnormal behaviour | Required Visit to Doctor | With gradual increase in drug dose, developed abnormal behaviours including a "strange" facial expression with ?bilateral eyelid ptosis, and became very withdrawn emotionally. | Atomoxetine discontinued. |
| Emotional disorder | Required Visit to Doctor | | |
| Eyelid ptosis | Required Visit to Doctor | | |

| Medicine details : | | | |
|--|-----------------------------|---|------|
| Atomoxetine Hydrochloride (Suspected) | | Reason : Behavior disorders of childhood | |
| Capsule | 18 Milligram | Daily | Oral |
| Batch : | Started : 25/06/2004 | Stopped : 16/07/2004 | |

Public Case Detail

Cases Count: 76

Case Number : 205312

Gender : F

Data Entry Date : 16/02/2005

Weight (kg) : 0

Hospitalisation :

Age :

Onset Date : 15/01/2005

DOB : 06/04/1997

Outcome :

Causality : Causality possible

Recovered

Information: History includes explosive mood swings. One week later the patient recommenced the Atomoxetine without effect, the patient stil experienced mood swings.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-----------------------------|----------|--|---|
| Drug ineffective | | Six days after commencing Strattera the child was seeking attention and wanted the focus to be on her. She became very agitated whilst travelling in the family car, described as an explosive mood swing. She stated that she was going to open the door and put herself in front of the car. She tried to open the car door. The mother confirmed that the drug was not effective. | Strattera ceased, changed back to Dexamphetamine. |
| Agitation | | | |
| Attention-seeking behaviour | | | |
| Mood swings | | | |
| Suicide attempt | | | |

Medicine details :

| | | | |
|------------------------------|---|------------------|------|
| Strattera (Suspected) | Reason : Behavior disorders of childhood | | |
| Capsule | 10 Milligram | Daily | Oral |
| Batch : A051888 | Started : 15/12/2004 | Stopped : | 0 |

Public Case Detail

Cases Count: 76

Case Number : 207582

Data Entry Date : 03/05/2005

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 17

Onset Date : 13/04/2005

Age :

DOB : 21/12/1999

Outcome : 16/04/2005

Causality : Causality certain

Recovered

Information: Drug is cert/rechallenge. Similar response with earlier trial of use after 2 weeks of treatment with similar dose - 10mg/day - 04/03/05 to 18/03/05.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--|-------------------|
| Vomiting | | Patient experienced vomiting and headache. | Ceased Strattera. |
| Headache | | | |

Medicine details :

| | | | |
|------------------------------|-----------------------------|-----------------------------|------|
| Strattera (Suspected) | Reason : | | |
| Capsule | 10 Milligram | Daily | Oral |
| Batch : | Started : 29/03/2005 | Stopped : 13/04/2005 | |

Public Case Detail

Cases Count: 76

Case Number : 208106

Data Entry Date : 23/05/2005

Gender : M

Hospitalisation :

Weight (kg) : 51

Onset Date : 25/03/2005

Age :

DOB : 08/11/1991

Outcome :

Causality : Causality probable

Recovered

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------|-----------------------|--|------------------|
| Chest pain | Incapacity/disability | Chest pains, severe coughing, hostile and aggressive behaviour. Problems immediately disappeared with cessation of medication. | Cease Medication |
| Aggression | Incapacity/disability | | |
| Cough | Incapacity/disability | | |

Medicine details :

| | | | |
|------------------------------|-----------------------------|------------------|------------|
| Strattera (Suspected) | | Reason : | |
| Capsule | Milligram | Daily | Oral |
| Batch : | Started : 10/03/2005 | Stopped : | 12/05/2005 |

Public Case Detail

Cases Count: 76

Case Number : 208168

Data Entry Date : 25/05/2005

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 48

Onset Date :

Age :

DOB : 13/01/1991

Outcome :

Causality : Causality possible

Unknown

Information:

| Reaction : | | | |
|-----------------------|-----------------|--|-------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Dizziness | | Patient experienced dizziness, knee pains and swelling of knee, dyspepsia. | Stopped Stratera. |
| Arthralgia | | | |
| Dyspepsia | | | |
| Joint swelling | | | |

| Medicine details : | | | |
|------------------------------|-----------------------------|---|------|
| Strattera (Suspected) | | Reason : Behavior disorders of childhood | |
| Capsule | 40 Milligram | Daily | Oral |
| Batch : | Started : 15/08/2004 | Stopped : 13/05/2005 | |

Public Case Detail

Cases Count: 76

Case Number : 209854

Gender : M

Data Entry Date : 15/07/2005

Weight (kg) : 59

Hospitalisation : Required a visit to the doctor

Age :

Onset Date : 04/03/2005

DOB : 12/01/1990

Outcome : 20/03/2005

Causality : Causality possible

Recovered

Information: The patient's medical history included learning difficulty, and frontal lobe epilepsy (1999). The patient's last serious seizure occurred on ?? dec 2003

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|--|---------------------|
| Convulsion | | Patient experienced loss of seizure control. | Ceased Atomoxetine. |
| Condition aggravated | | convulsions aggravated. | |

Medicine details :

Carbamazepine (Interaction)

Reason : Other&unspecified epilepsy

Tablet 400 Milligram Daily Oral

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

Lamotrigine (Interaction)

Reason : Other&unspecified epilepsy

Tablet 55 Milligram Daily Oral

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

Sodium Valproate (Interaction)

Reason : Other&unspecified epilepsy

1.2 Gram Daily Oral

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

Strattera (Interaction)

Reason :

25 Milligram Daily

Batch : **Started :** 24/01/2005 S TERM **Stopped :** 0

Case Number : 209855

Data Entry Date : 15/07/2005

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/05/2005

Age :

Outcome : 05/05/2005

DOB : 13/12/1994

Recovered

Causality : Causality possible

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--|--------------------------------------|
| Convulsion | | Deterioration in control of seizures. The patient experienced a deterioration in seizure control, from one fit to five fits daily. These were partial seizures and also possibly absence seizures. | Dose of Atomoxetine reduced to 25mg. |

Medicine details :

| | | | |
|--|-----------------------------|-----------------|--------------------|
| Carbamazepine (Interaction) | | Reason : | |
| Tablet | 840 Milligram | Daily | Oral |
| Batch : | Started : | L TERM | Stopped : |
| Risperidone (Interaction) | | Reason : | |
| Tablet | 4 Milligram | Daily | Oral |
| Batch : | Started : 14/04/2004 | L TERM | Stopped : |
| Sodium Valproate (Interaction) | | Reason : | |
| Tablet | 800 Milligram | Daily | Oral |
| Batch : | Started : 15/02/2005 | S TERM | Stopped : |
| Strattera (Interaction) | | Reason : | |
| | 40 Milligram | Daily | |
| Batch : | Started : 15/05/2005 | S TERM | Stopped : 0 |
| Fluoxetine Hydrochloride (Other drug) | | Reason : | |
| | 20 Milligram | Daily | Oral |
| Batch : | Started : 15/03/2005 | S TERM | Stopped : |
| Melatonin (Other drug) | | Reason : | |
| | 3 Milligram | Daily | Oral |
| Batch : | Started : 15/01/2005 | S TERM | Stopped : |

Public Case Detail

Cases Count: 76

Case Number : 210050

Data Entry Date : 21/07/2005

Gender : F

Hospitalisation :

Weight (kg) : 159

Onset Date : 15/03/2005

Age :

DOB : 04/04/1986

Outcome :

Causality : Causality possible

Recovered

Information: The patients medical history included mixed seizure disorder (general tonic clonic and absence seizures, simple or shildhood) from october 1995. The patient had previous long term good seizure control since february 2001

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|---|------------------------------------|
| Convulsion | | Patient experienced recurrence of absence seizures. | Increased Lamotrigine to 150mg bd. |

Medicine details :

| | | | |
|---------------------------------------|-----------------------------|-----------------|------------------------------|
| Lamotrigine (Interaction) | | Reason : | |
| Tablet | 200 Milligram | Daily | Oral |
| Batch : | Started : 15/10/1995 | L TERM | Stopped : |
| Sodium Valproate (Interaction) | | Reason : | |
| Tablet | 1 Gram | Daily | Oral |
| Batch : | Started : 15/10/1995 | L TERM | Stopped : |
| Strattera (Interaction) | | Reason : | |
| | 60 Milligram | Daily | |
| Batch : | Started : 18/08/2004 | S TERM | Stopped : Continuing. |

Public Case Detail

Cases Count: 76

Case Number : 211490

Data Entry Date : 07/09/2005

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 36

Onset Date :

Age :

DOB : 16/03/1996

Outcome :

Causality : Causality certain

Recovered

Information: Suspected drug positive rechallenge.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|---|-----------|
| Aggression | | Patient experienced aggression and was totally irrational for 3 days, became violent, totally out of character. | |
| Thinking abnormal | | | |

Medicine details :

Strattera (Suspected)

Reason : Behavior disorders of childhood

Capsule

25 Milligram

Daily

Oral

Batch :

Started : 27/04/2005

Stopped : 25/08/2005

0

Public Case Detail

Cases Count: 76

Case Number : 211934

Data Entry Date : 23/09/2005

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date :

Age :

Outcome : 15/08/2005

DOB : 30/07/1993

Recovered

Causality : Causality probable

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------------|----------|--|--------------------|
| Decreased appetite | | Patient experienced anorexia, weight loss, fidgeting, compulsive behaviour eg. ripping fingers and toe nails out, cutting and picking clothing and anger outburst. | Strattera stopped. |
| Aggression | | | |
| Obsessive-compulsive disorder | | | |
| Restlessness | | | |
| Weight decreased | | | |

Medicine details :

| | | | |
|------------------------------|-----------------------------|-----------------------------|------|
| Strattera (Suspected) | Reason : | | |
| Capsule | 60 Milligram | Daily | Oral |
| Batch : | Started : 15/12/2004 | Stopped : 15/08/2005 | |

Public Case Detail

Cases Count: 76

Case Number : 212597

Data Entry Date : 17/10/2005

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/02/2005

Age : 11Y

Outcome :

DOB :

Recovered

Causality : Causality probable

Information: Journal of paediatrics and child health. Paxton GA, Cranswick NE. Acute suicidality after commencing atomoxetine. Volume 44 2008; pg 596-598

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--|-----------|
| Suicidal ideation | | Patient threatened to kill himself, cycling of his mood and agitation and crying. Handwriting changed and threw a cricket stump javelin style at a school teacher. | |
| Affect lability | | | |
| Agitation | | | |
| Crying | | | |
| Dysgraphia | | | |
| Mood swings | | | |

Medicine details :

Strattera (Suspected)

Reason : Behavior disorders of childhood

Capsule

25 Milligram

Daily

Oral

Batch :

Started : 15/02/2005

Stopped : 15/05/2005

Public Case Detail

Cases Count: 76

Case Number : 212705

Data Entry Date : 19/10/2005

Gender : M

Hospitalisation :

Weight (kg) : 25

Onset Date : 30/05/2004

Age : 8Y

DOB :

Outcome :

Causality : Causality possible

Not yet recovered

Information: History: High protein, low carbohydrate diet.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------|---|-----------|
| Depressed mood | | Patient experienced sadness and hit his head against a wall (purposely). He has had thoughts of suicide- stating that he wants to kill himself. | |
| Self injurious behaviour | | | |
| Suicidal ideation | | | |

Medicine details :

Strattera (Suspected)

Reason : Behavior disorders of childhood

Capsule

20 Milligram

Daily

Oral

Batch :

Started : 27/05/2004

Stopped :

Continuing

Public Case Detail

Cases Count: 76

Case Number : 213520

Data Entry Date : 17/11/2005

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 03/11/2005

Age : 20Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|---|--|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Syncopa | Caused or prolonged inpatient hospitalisation | | |
| Fall | Caused or prolonged inpatient hospitalisation | Approximately one year after commencing Atomoxetine treatment the patient woke up and fainted. | |

| Medicine details : | | | |
|------------------------------|------------------|------------------|------|
| Strattera (Suspected) | Reason : | | |
| Capsule | 80 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 220443

Data Entry Date : 31/07/2006

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 30/09/2005

Age :

DOB : 03/11/1999

Outcome :

Causality : Causality possible

Recovered

Information:

| Reaction : | | | |
|-----------------------|-----------------|---|------------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Coagulopathy | | Patient experienced coagulopathy characterised by loose bowel motions with blood in stools, epistaxis (2 in a month) and easy bruising. | Ceased Strattera and Epilim. |

| Medicine details : | | | |
|------------------------------|---|-----------------------------|------|
| Epilim (Suspected) | Reason : | | |
| Batch : | Started : 29/07/2005 | Stopped : 19/10/2005 | 0 |
| Strattera (Suspected) | Reason : Behavior disorders of childhood | | |
| Capsule | 10 Milligram | Daily | Oral |
| Batch : | Started : 09/09/2005 | Stopped : 09/10/2005 | 0 |

| Laboratory Investigations : | | | | |
|---------------------------------------|---------------|-------------|--------|---------|
| Type | Range | Date Tested | Result | Details |
| Prothrombin time | 10-14 seconds | 10/10/2005 | 18 | |
| Prothrombin time | 10-14 seconds | 28/10/2005 | 12 | |
| Activated partial thromboplastin time | 24-40 seconds | 10/10/2005 | 19 | |
| Activated partial thromboplastin time | 24-40 seconds | 28/10/2005 | 30 | |
| Fibrinogen | 2.00-6.00 g/L | 10/10/2005 | 1.81 | |
| Fibrinogen | 2.00-6.00 g/L | 28/10/2005 | 3.55 | |

Public Case Detail

Cases Count: 76

Case Number : 220681

Gender : M

Data Entry Date : 09/08/2006

Weight (kg) : 25

Hospitalisation : Required a visit to the doctor

Age :

Onset Date : 17/07/2006

DOB : 21/10/1998

Outcome :
Not yet recovered

Causality : Causality possible

Information:

| Reaction : | | | |
|-------------------------|-----------------|---|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Depressed mood | | Depressed sensitive and tearful mood, anxiety-excessive worry and tightness in throat soon after increasing Atomoxetine dose from 18mg/day to 25mg/day. | |
| Anxiety | | | |
| Tearfulness | | | |
| Therapy regimen changed | | | |
| Throat tightness | | | |

| Medicine details : | | | |
|--|-----------------------------|---|--|
| Atomoxetine Hydrochloride (Suspected) | | Reason : Behavior disorders of childhood | |
| | 25 Milligram | Daily | |
| Batch : | Started : 15/07/2006 | Stopped : | |
| Cephalexin (Other drug) | | Reason : Othr diseases of urinary tract | |
| Batch : | Started : 15/05/2006 | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 220852

Gender : M

Data Entry Date : 17/08/2006

Weight (kg) : 34.5

Hospitalisation : Required a visit to the doctor

Age :

Onset Date :

DOB : 02/08/1998

Outcome :

Causality : Causality possible

Recovered

Information: Growth of 7 cm in 3 months since stopping drug.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|---|-----------|
| Growth retardation | | Started on atomoxetine in early 2004 and did not grow for 18 months | |

Medicine details :

| | |
|--|---|
| Atomoxetine Hydrochloride (Suspected) | Reason : |
| Capsule | Oral |
| Batch : | Started : |
| | Stopped : |
| Catapres (Suspected) | Reason : Behavior disorders of childhood |
| Batch : | Started : |
| | Stopped : |

Public Case Detail

Cases Count: 76

Case Number : 221550

Data Entry Date : 12/09/2006

Gender : M

Hospitalisation :

Weight (kg) : 85

Onset Date : 26/08/2006

Age :

DOB : 09/07/1973

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|---|--|
| Headache | | <p>Patient commenced Strattera (atomoxetine hydrochloride) 10 mg on 23/08/06 in the morning, and noted onset almost immediately of the following symptoms: headache, subjective increase in body temperature, nausea, anorexia. Persisted with Strattera 10 mg mane for the next three days (i.e. 24/8, 25/8 and 26/8). Noted a worsening of side effects when consumed alcohol (consumed 40 grams on 23/8 at least 8 hours after first dose; consumed 10 grams on 25/8, again at least 8 hours after dosing). Took Cialis 20 mg on the evening of 26/8/06 at least 12 hours after dose of Strattera and noted the following symptoms commencing afterwards: irritability of mood, restlessness, insomnia, nausea and subjective increase in temperature. These symptoms persisted at a clinically significant (subjective distress) level for 24 hours, resolved completely at 48 hours after taking the Cialis.</p> | <p>Patient ceased Strattera following development of adverse reaction that occurred when he took Cialis.</p> |
| Decreased appetite | | | |
| Drug interaction | | | |
| Feeling hot | | | |
| Nausea | | | |

| Medicine details : | | | | |
|--------------------------------|-----------------------------|-----------------------------|-----------------|---|
| Cialis (Interaction) | | | Reason : | |
| Tablet | 20 Milligram | As necessary | Oral | |
| Batch : | Started : 26/08/2006 | Stopped : | | 0 |
| <hr/> | | | | |
| Strattera (Interaction) | | | Reason : | |
| | 10 Milligram | Daily | Oral | |
| Batch : | Started : 23/08/2006 | Stopped : 26/08/2006 | | 0 |

| Laboratory Investigations : | | | | |
|------------------------------------|-------|-------------|--------|---------|
| Type | Range | Date Tested | Result | Details |
| Other data | | | | |

Public Case Detail

Cases Count: 76

Case Number : 221914

Data Entry Date : 26/09/2006

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/06/2006

Age : 9Y

Outcome :

DOB :

Recovered

Causality : Causality probable

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------|---|-------------------------|
| Blood pressure increased | | Significant increase in blood pressure. | Strattera discontinued. |

Medicine details :

| | | | |
|------------------------------|------------------|---|------|
| Strattera (Suspected) | | Reason : Behavior disorders of childhood | |
| Capsule | 40 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : 15/08/2006 | |

Public Case Detail

Cases Count: 76

Case Number : 222837

Gender : F

Data Entry Date : 01/11/2006

Weight (kg) : 36

Hospitalisation :

Age :

Onset Date : 20/06/2006

DOB : 21/01/1991

Outcome :

Causality : Causality possible

Not yet recovered

Information:

| Reaction : | | | |
|-----------------------|---|---|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Pancreatitis | Caused or prolonged inpatient hospitalisation | Acute pancreatitis with subsequent persistent pancreatitis. | |
| Abnormal behaviour | Caused or prolonged inpatient hospitalisation | Marked deterioration in behaviour | |

| Medicine details : | | | |
|------------------------------|-----------------------------|------------------|--|
| Strattera (Suspected) | | Reason : | |
| | 40 Milligram | Daily | |
| Batch : | Started : 12/05/2006 | Stopped : | |

| Laboratory Investigations : | | | | |
|------------------------------------|--------------|--------------------|---------------|--------------------------------------|
| Type | Range | Date Tested | Result | Details |
| Amylase | | | | Peak amylase of 1012 U/L (114 - 286) |

Public Case Detail

Cases Count: 76

Case Number : 223047

Data Entry Date : 13/11/2006

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 27/06/1984

Unknown

Causality : Causality possible

Information: Other relevant history suicide attempt.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|--------------------|----------|--|-----------|
| Suicidal ideation | | Suicidal ideation, homicidal ideation. | |
| Homicidal ideation | | | |

Medicine details :

Strattera (Suspected) Reason : Behavior disorders of childhood
10 Milligram

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

Zyprexa (Suspected) Reason : Unspecifid affective psychosis
5 Milligram Daily

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

Lithium Carbonate (Other drug) Reason :

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

Public Case Detail

Cases Count: 76

Case Number : 223348

Data Entry Date : 20/11/2006

Gender : M

Hospitalisation :

Weight (kg) : 41.5

Onset Date : 15/07/2006

Age :

DOB : 28/05/1996

Outcome :

Causality : Causality probable

Not yet recovered

Information:

| Reaction : | | | |
|-----------------------|-----------------|--|--|
| Preferred Term | Severity | Report Description | Treatment |
| Suicidal ideation | | Patient experienced nausea, then became acutely depressed, aggressive and had suicidal thoughts. | Treated with a small dose of Prozac. Strattera discontinued. |
| Aggression | | | |
| Depression | | | |
| Nausea | | | |

| Medicine details : | | | |
|------------------------------|-----------------------------|-----------------------------|------|
| Strattera (Suspected) | Reason : | | |
| Capsule | 1 Milligram | Daily | Oral |
| Batch : | Started : 02/03/2006 | Stopped : 06/07/2006 | 0 |

Public Case Detail

Cases Count: 76

Case Number : 223349

Gender : F

Data Entry Date : 20/11/2006

Weight (kg) : 0

Hospitalisation :

Age :

Onset Date :

DOB : 14/08/1999

Outcome :

Causality : Causality possible

Not yet recovered

Information: Patient's parents realised that the atomoxetine actually expired on 31/10/2005, this expired medication was commenced on approximately 18/09/2006, at around the same time several of the events started. She was on the expired medication for 15-20 days. The patient's laboratory results and corrective treatments were not reported. The out-of-date atomoxetine was discontinued and since then most of her symptoms have improved although she is still not back to her normal self.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------------|----------|--|---|
| Abdominal pain | | The patient experienced abdominal pain, nausea and severe right sided headache - dominating frontal and facial regions causing her to wake up at night, shooting pains throughout limbs, white spots in visual field, waking at night, regression in academic progress and difficulty recognising words. Also had faecal and urinary incontinence. | Patient symptoms have improved and she is taking in date atomoxetine. |
| Abnormal behaviour | | | |
| Dizziness | | | |
| Drug ineffective | | | |
| Educational problem | | | |
| Faecal incontinence | | | |
| Headache | | | |
| Insomnia | | | |
| Intracranial pressure increased | | | |
| Motor dysfunction | | | |
| Nausea | | | |
| Pain | | | |
| Strabismus | | | |
| Urinary incontinence | | | |
| Visual acuity tests abnormal | | | |
| Visual impairment | | | |
| Vomiting | | | |

Medicine details :

Strattera (Suspected)

Reason : Behavior disorders of childhood

Capsule

40 Milligram

Daily

Oral

Batch :

Started : 18/09/2006

Stopped :

0

Serenace (Other drug)

Reason :

Batch :

Started :

Stopped :

Public Case Detail

Cases Count: 76

Case Number : 223950

Data Entry Date : 08/12/2006

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 9Y

Outcome :

DOB :

Recovered

Causality : Causality probable

Information: On Strattera for about six months from the age of 9 after unsuccessful treatment with dexamphetamine for supposed "ADHD".

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------|---|--|
| Self injurious behaviour | | Self-harm, slams his head against walls, has extreme mood swings, violent outbursts. Always angry, depressed or sad and said he wanted to kill himself. | Stopped Strattera and changed diet: Failsafe diet. |
| Aggression | | | |
| Anger | | | |
| Depression | | | |
| Mood swings | | | |
| Suicidal ideation | | | |

Medicine details :

Strattera (Suspected)

Reason : Behavior disorders of childhood

Batch :

Started :

Stopped :

Public Case Detail

Cases Count: 76

Case Number : 226118

Gender : M

Data Entry Date : 26/02/2007

Weight (kg) : 26

Hospitalisation :

Age : 7Y

Onset Date : 28/01/2007

DOB :

Outcome :

Causality : Causality probable

Recovered

Information: The patient's dose of atomoxetine was increased from 10mg to 25mg daily. The cardiologist report was not available.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|------------------------------|----------|---|-------------------------------|
| Supraventricular tachycardia | | Patient experienced severe chest pain, what appeared to have been supraventricular tachycardia 2 weeks after a dose increase. | Atomoxetine was discontinued. |
| Chest pain | | The episode lasted 15 minutes | Carotid massage |

Medicine details :

| | |
|---------------------------------|---|
| Strattera (Suspected) | Reason : Behavior disorders of childhood |
| 25 Milligram Daily Oral | |
| Batch : | Started : 15/01/2007 Stopped : 28/01/2007 |
| Strattera (Other drug) | Reason : Behavior disorders of childhood |
| Capsule 10 Milligram Daily Oral | |
| Batch : | Started : 01/07/2006 Stopped : 14/01/2007 0 |

Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|------------|-------|-------------|--------|--------------------------------------|
| Other data | | | | Heart rate was 160 beats per minute. |

Public Case Detail

Cases Count: 76

Case Number : 226323

Data Entry Date : 05/03/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/07/2006

Age : 9Y

Outcome :

DOB :

Recovered

Causality : Causality probable

Information:

| Reaction : | | | |
|-----------------------|---|--|--|
| Preferred Term | Severity | Report Description | Treatment |
| Hepatitis | Caused or prolonged inpatient hospitalisation | Patient had a history of vomiting, an ultrasound revealed an inflamed liver. | Intravenous hydration. Stratters ceased. |
| Vomiting | Caused or prolonged inpatient hospitalisation | | |

| Medicine details : | | | |
|------------------------------|---|-----------------------------|------|
| Strattera (Suspected) | Reason : Behavior disorders of childhood | | |
| Capsule | 35 Milligram | Daily | Oral |
| Batch : | Started : 15/06/2006 | Stopped : 15/07/2006 | |

| Laboratory Investigations : | | | | |
|------------------------------------|-------|-------------|--------|---|
| Type | Range | Date Tested | Result | Details |
| Ultrasound | | | | Jul 2006 Revealed an inflamed liver. Ultrasound also revealed: the portal triads of the liver had an echogenic appearance and there was tenderness overlying the liver. The sonographic features are non-specific, however, echogenic portal triads were sometimes seen in acute hepatitis. One month later in Aug 2006, an ultrasound was performed and the result was normal. |

Public Case Detail

Cases Count: 76

Case Number : 227168

Data Entry Date : 30/03/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 25/02/2007

Age : 48Y

DOB :

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--|---------------------------|
| Suicidal ideation | | Patient experienced thoughts of death and thoughts of wanting to die, nervousness, tingling in her arms and legs and numbness in her face and hands. | Atomoxetine discontinued. |
| Hypoaesthesia | | | |
| Nervousness | | | |
| Paraesthesia | | | |

Medicine details :

| | | | |
|------------------------------|---|-----------------------------|------|
| Strattera (Suspected) | Reason : Behavior disorders of childhood | | |
| Tablet | 100 Milligram | Daily | Oral |
| Batch : | Started : 15/01/2007 | Stopped : 01/03/2007 | |

Public Case Detail

Cases Count: 76

Case Number : 227440

Data Entry Date : 10/04/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|--|---------------------------|
| Abnormal behaviour | | After 6 days patient had violent reactions, which included bizarre behaviour, hostility, fantasy, suicide talks, anxiety attacks, distorted face and regressive behaviour. | Persisting with Strattera |
| Anxiety | | | |
| Facial spasm | | | |
| Hostility | | | |
| Paramnesia | | | |
| Regressive behaviour | | | |
| Suicidal ideation | | | |

Medicine details :

| | |
|------------------------------|--|
| Strattera (Suspected) | Reason : Other atyp forms schizophrenia |
| Batch : | Started : |
| | Stopped : |

Public Case Detail

Cases Count: 76

Case Number : 229120

Data Entry Date : 30/05/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 11Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|--|--------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Suicidal ideation | | The patient took Strattera for the treatment of ADHD to complement Ritalin, under the influence of which he became suicidal and depressed. | Ceased medication. |
| Depression | | | |
| Drug ineffective | | | |

| Medicine details : | | | |
|------------------------------|------------------|---|--|
| Ritalin (Suspected) | | Reason : Behavior disorders of childhood | |
| Batch : | Started : | Stopped : | |
| Strattera (Suspected) | | Reason : Behavior disorders of childhood | |
| Capsule | | Oral | |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 230590

Data Entry Date : 04/07/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 13Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

| Reaction : | | | |
|-------------------------|-----------------|--|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Psychotic disorder | | Patient developed psychosis, voices in his head. | |
| Hallucination, auditory | | | |

| Medicine details : | |
|------------------------------|---|
| Strattera (Suspected) | Reason : Behavior disorders of childhood |
| Batch : | Started : |
| | Stopped : |

Public Case Detail

Cases Count: 76

Case Number : 236301

Data Entry Date : 14/12/2007

Gender : M

Hospitalisation :

Weight (kg) : 31

Onset Date :

Age :

DOB : 27/07/1995

Outcome :

Causality : Causality possible

Recovered

Information:

| Reaction : | | | |
|-----------------------|-----------------|---------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Rash | | truncal rash | |
| Balanitis | | | |
| Periorbital oedema | | | |

| Medicine details : | | | |
|--|-----------------------------|---|------|
| Atomoxetine Hydrochloride (Suspected) | | Reason : Behavior disorders of childhood | |
| Capsule | 40 Milligram | Daily | Oral |
| Batch : | Started : 19/11/2007 | Stopped : | 0 |

Case Number : 236378

Data Entry Date : 17/12/2007

Gender : U

Hospitalisation :

Weight (kg) : 23

Onset Date : 01/12/2007

Age :

DOB : 04/02/2000

Outcome :

Causality : Causality possible

Not yet recovered

Information: Background:ADHD and aspergers syndrome.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|---|--|-----------|
| Suicidal ideation | Caused or prolonged inpatient hospitalisation | Suicidal ideation and mood changes (self-harming behaviour, withdrawn in himself) ? secondary to increase of Strattera. Strattera has been increased from 25mg daily to 40mg daily, 3/7 later poor sleep, increased aggression, no eye contact, anxiety then threats to self with knife, picking his skin, pinching self and others, poking self with knife (drawing blood). | |
| Aggression | Caused or prolonged inpatient hospitalisation | | |
| Anxiety | Caused or prolonged inpatient hospitalisation | | |
| Mood altered | Caused or prolonged inpatient hospitalisation | | |
| Self injurious behaviour | Caused or prolonged inpatient hospitalisation | | |
| Sleep disorder | Caused or prolonged inpatient hospitalisation | | |
| Social avoidant behaviour | Caused or prolonged inpatient hospitalisation | | |

Medicine details :

| | | | | |
|-------------------------------|------------------|---|------------------|---|
| Strattera (Suspected) | | Reason : Behavior disorders of childhood | | |
| Capsule | 40 Milligram | Daily | Oral | |
| Batch : | Started : | S TERM | Stopped : | 0 |
| Strattera (Other drug) | | Reason : Behavior disorders of childhood | | |
| Capsule | 25 Milligram | Daily | Oral | |
| Batch : | Started : | S TERM | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 236629

Data Entry Date : 24/12/2007

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 21.9

Onset Date : 02/11/2007

Age :

DOB : 02/11/1997

Outcome : 22/11/2007

Causality : Causality probable

Recovered

Information:

| Reaction : | | | |
|-----------------------|-----------------|--------------------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Tic | | Increase in pre-existing motor tics. | |

| Medicine details : | | | |
|--|-----------------------------|---|--|
| Atomoxetine Hydrochloride (Suspected) | | Reason : Behavior disorders of childhood | |
| | 15 Milligram | Daily | |
| Batch : | Started : 01/11/2007 | Stopped : 21/11/2007 | |

Public Case Detail

Cases Count: 76

Case Number : 236802

Data Entry Date : 09/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/11/2007

Age : 6Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|---|---|---|
| Preferred Term | Severity | Report Description | Treatment |
| Hypertension | Caused or prolonged inpatient hospitalisation | The patient recieved atomoxetine hydrochloride for the treatmentof attention deficit-hyperactivity disorder, beginning in Nov 2007. 2 weeks after starting the atomoxetine, the patient experienced hypertension, epigastric pain and headache. | Ranitidine. Nifedipine. Discontinued atomoxetine. |
| Abdominal pain upper | Caused or prolonged inpatient hospitalisation | | |
| Headache | Caused or prolonged inpatient hospitalisation | | |

| Medicine details : | | | |
|------------------------------|---|------------------|------|
| Strattera (Suspected) | Reason : Behavior disorders of childhood | | |
| Capsule | 10 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 236996

Data Entry Date : 16/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/11/2007

Age : 12Y

Outcome :

DOB :

Recovered

Causality : Causality probable

Information: Positive dechallenge no rechallenge.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|---|------------------------|
| Suicidal ideation | | The patient received atomoxetine hcl (Strattera). 10mg frequency and route of administration not reported, for the treatment of attention deficit disorder, beginning on an unspecified date in Nov 2007, six weeks before the date of report. On an unspecified date in Nov 2007, soon after starting medication, the patient experienced very strong suicidal ideation, was crying and talking about dead bodies and about hanging himself. | Discontinued Strattera |

Medicine details :

| | | | |
|------------------------------|-----------------------------|---|------|
| Strattera (Suspected) | | Reason : Behavior disorders of childhood | |
| Capsule | 10 Milligram | Daily | Oral |
| Batch : | Started : 15/11/2007 | Stopped : 15/11/2007 | 0 |
| Ritalin (Other drug) | | Reason : | |
| Batch : | Started : | Stopped : | |

Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|------------|-------|-------------|--------|---|
| Other data | | | | Patient's laboratory results were not provided. |

Public Case Detail

Cases Count: 76

Case Number : 237070

Data Entry Date : 18/01/2008

Gender : M

Hospitalisation : Required a specialist consultation

Weight (kg) : 52

Onset Date : 18/11/2007

Age : 11Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information: Medical history of attention deficit disorder, attention hyperactivity disorder at five and six years old in 2000 and 2001 and aggression. The patient commenced the following packet on the 15/11/07, lot number: A129025, exp date 2008. Patient was originally treated with dexamphetamine and clonidine hydrochloride (milder version).

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|--------------------------|----------|---|---|
| Suicide attempt | | On the 18/11/07, approximately three months after beginning Strattera, patient attempted suicide, headache, stomach cramps, muscle rigidity and poor concentration. | Unknown if patient received any corrective treatment. |
| Abdominal pain upper | | | |
| Disturbance in attention | | | |
| Headache | | | |
| Muscle rigidity | | | |

Medicine details :

| | |
|---|---|
| Strattera (Suspected) | Reason : Behavior disorders of childhood |
| Capsule | 40 Milligram Daily Oral |
| Batch : A129025 exp: 08 | Started : 15/08/2007 Stopped : Ongoing. |
| Catapres (Other drug) | Reason : |
| Batch : | Started : Stopped : |
| Clonidine Hydrochloride (Other drug) | Reason : |
| Tablet | Oral |
| Batch : | Started : Stopped : |

Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|------------|-------|-------------|--------|--|
| Other data | | | | No physical findings or laboratory results were provided |

Public Case Detail

Cases Count: 76

Case Number : 237129

Data Entry Date : 21/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 26

Onset Date :

Age :

Outcome : 06/11/2007

DOB : 26/12/2002

Recovered

Causality : Causality certain

Information: Cert/rechallenged.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|----------------------|---------------------|
| Pallor | | Pallor and vomiting. | Ceased atomoxetine. |
| Vomiting | | | |

Medicine details :

Atomoxetine Hydrochloride (Suspected)

Reason :

10 Milligram Daily

Batch :

Started : 31/10/2007

Stopped : 06/11/2007

0

Public Case Detail

Cases Count: 76

Case Number : 238474

Data Entry Date : 29/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 09/02/2008

Age : 25Y

DOB :

Outcome :

Causality : Causality possible

Unknown

Information: Medical history included substance abuse.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--|--------------------------------------|
| Suicidal ideation | | Suicidal thoughts, agitation, panic attacks. | Atomoxetine discontinued 09/02/08 |
| Agitation | | | |
| Panic attack | | | |

Medicine details :

| Strattera (Suspected) | Reason : |
|-----------------------------------|-----------------------------|
| Capsule | 40 Milligram Daily Oral |
| Batch : A344066 Exp Feb 20 | Started : 08/02/2008 |
| | Stopped : 09/02/2008 |

Public Case Detail

Cases Count: 76

Case Number : 238475

Gender : M

Data Entry Date : 29/02/2008

Weight (kg) : 63

Hospitalisation : Required a visit to the doctor

Age : 20Y

Onset Date : 15/02/2008

DOB :

Outcome :
Not yet recovered

Causality : Causality possible

Information:

| Reaction : | | | |
|-------------------------|-----------------|-----------------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Intentional self-injury | | Possible hypoadrenergic syndrome. | |
| Agitation | | | |
| Anger | | | |
| Depressed mood | | | |
| Major depression | | | |
| Mental disorder | | | |
| Psychotic disorder | | | |
| Suicidal ideation | | | |

| Medicine details : | | | |
|---------------------------------|-----------------------------|---|--------------------|
| Strattera (Suspected) | | Reason : Behavior disorders of childhood | |
| Capsule | 60 Milligram | Daily | Oral |
| Batch : | Started : | L TERM | Stopped : 0 |
| Terbinafine (Other drug) | | Reason : | |
| Batch : | Started : 02/02/2008 | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 238517

Data Entry Date : 03/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 49

Onset Date : 06/02/2008

Age : 13Y

DOB :

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|----------------------|-----------|
| Dizziness | | Dizziness, vomiting. | |
| Vomiting | | | |

Medicine details :

| | | | |
|------------------------------|---|------------------|------|
| Strattera (Suspected) | Reason : Behavior disorders of childhood | | |
| Capsule | 20 Milligram | Daily | Oral |
| Batch : | Started : 29/01/2008 | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 239851

Data Entry Date : 11/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 85

Onset Date : 29/02/2008

Age :

DOB : 19/01/1990

Outcome :

Causality : Causality possible

Not yet recovered

Information: Acutely distressed. Auditory hallucinations continued after lithium was ceased. Became less after atomoxetine was withdrawn.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|------------------|---|---------------------------------------|
| Suicidal ideation | Life threatening | Auditory hallucinations, suicidal ideation. | Lithium ceased, atomoxetine withdrawn |
| Hallucination, auditory | Life threatening | | Lithium ceased, atomoxetine withdrawn |

Medicine details :

Atomoxetine Hydrochloride (Suspected)

Reason : Behavior disorders of childhood

60 Milligram Daily

Batch :

Started : 27/02/2008

Stopped : 09/03/2008

Lithium Carbonate (Other drug)

Reason :

750 Milligram Daily

Oral

Batch :

Started : 27/02/2008

Stopped : 04/03/2008

Public Case Detail

Cases Count: 76

Case Number : 240530

Gender : M

Data Entry Date : 01/05/2008

Weight (kg) : 0

Hospitalisation : Admitted to hospital

Age : 13Y

Onset Date :

DOB :

Outcome :

Causality : Causality possible

Recovered

Information: History of borderline autism, delusional disorder and psychotic disorder.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|---|--|-------------------------|
| Psychotic disorder | Caused or prolonged inpatient hospitalisation | Psychotic disorder, heart rate increased, dizziness and anxiety. | Strattera discontinued. |
| Anxiety | Caused or prolonged inpatient hospitalisation | | |
| Dizziness | Caused or prolonged inpatient hospitalisation | | |
| Heart rate increased | Caused or prolonged inpatient hospitalisation | | |

Medicine details :

Strattera (Suspected)

Reason :

Capsule

60 Milligram

Daily

Oral

Batch :

Started :

Stopped :

0

Public Case Detail

Cases Count: 76

Case Number : 241010

Data Entry Date : 19/05/2008

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 36

Onset Date :

Age :

DOB : 23/01/1995

Outcome :

Causality : Causality probable

Recovered

Information:

| Reaction : | | | |
|-----------------------|-----------------|---------------------------|-----------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Tachycardia | | Tachycardia | Atomoxetine withdrawn |

| Medicine details : | | | |
|--|------------------|---|--|
| Atomoxetine Hydrochloride (Suspected) | | Reason : Behavior disorders of childhood | |
| | 40 Milligram | Daily | |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 241793

Data Entry Date : 11/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 19/07/1960

Outcome :

Causality : Causality possible

Unknown

Information:

| Reaction : | | | |
|-----------------------|-----------------|---------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Suicidal ideation | | Suicidal ideation. | |

| Medicine details : | | | |
|------------------------------|------------------|----------------------------|------|
| Lovan (Suspected) | | Reason : Depression | |
| Batch : | Started : | Stopped : | Oral |
| Strattera (Suspected) | | Reason : | |
| Capsule | 18 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | 0 |

Public Case Detail

Cases Count: 76

Case Number : 241920

Data Entry Date : 16/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 25Y

Outcome :

DOB :

Unknown

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 |
| Gastroesophageal reflux disease | | | |
| Nausea | | | |

Medicine details :

| | |
|---|---|
| Paroxetine Hydrochloride (Interaction) | Reason : |
| Batch : | Started : |
| | Stopped : |
| Strattera (Interaction) | Reason : Behavior disorders of childhood |
| | 60 Milligram Daily |
| Batch : | Started : |
| | Stopped : |

Public Case Detail

Cases Count: 76

Case Number : 242440

Data Entry Date : 01/07/2008

Gender : M

Hospitalisation :

Weight (kg) : 23.3

Onset Date : 26/05/2008

Age : 7Y

Outcome :

DOB :

Recovered

Causality : Causality probable

Information: Medical condition. Average IQ, sleep disorder, anxiety and history of suicidal ideation.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--------------------|--------------------|
| Suicidal ideation | | Suicidal ideation. | Strattera stopped. |

Medicine details :

| | | | |
|------------------------------|---|-----------------------------|------|
| Strattera (Suspected) | Reason : Behavior disorders of childhood | | |
| Tablet | 1 Dose Unspec | Daily | Oral |
| Batch : | Started : 01/02/2008 | Stopped : 29/05/2008 | |

Public Case Detail

Cases Count: 76

Case Number : 242981

Data Entry Date : 16/07/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/06/2008

Age : 10Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---------------------|----------|--|-------------------------------|
| Psychotic behaviour | | Patient developed psychotic symptoms, was being vague and talking about suicide, the reporting healthcare professional also thought that the patient had developed a rash. | Atomoxetine was discontinued. |
| Rash | | | |
| Suicidal ideation | | | |

Medicine details :

| | | | |
|------------------------------|---|-----------------------------|------|
| Strattera (Suspected) | Reason : Behavior disorders of childhood | | |
| Capsule | 10 Milligram | Daily | Oral |
| Batch : | Started : 15/06/2008 | Stopped : 15/06/2008 | |

Public Case Detail

Cases Count: 76

Case Number : 243276

Data Entry Date : 29/07/2008

Gender : F

Hospitalisation :

Weight (kg) : 60

Onset Date : 10/07/2008

Age :

DOB : 23/08/1974

Outcome : 15/07/2008

Causality : Causality probable

Recovered

Information:

| Reaction : | | | |
|-----------------------|-----------------|-----------------------------------|--------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Breast swelling | | Swollen breasts "as if pregnant". | Ceased Atomoxetine |

| Medicine details : | | | |
|--|-----------------------------|---|--|
| Atomoxetine Hydrochloride (Suspected) | | Reason : Behavior disorders of childhood | |
| | 85 Milligram | Daily | |
| Batch : | Started : 09/07/2008 | Stopped : 12/07/2008 | |

Public Case Detail

Cases Count: 76

Case Number : 244192

Gender : M

Data Entry Date : 27/08/2008

Weight (kg) : 0

Hospitalisation : Required a specialist consultation

Age :

Onset Date : 27/07/2008

DOB : 29/12/1993

Outcome :
Recovered

Causality : Causality possible

Information: Experiencing seizures about two years ago while on methylphenidate. Diagnosed as primary generalised epilepsy, manifesting as photosensitive seizures. Treated with Epilim.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------|----------|--|--|
| Convulsion | | Two days after starting atomoxetine, the patient experienced a convulsion. Pt was initially on Ritalin (methylphenidate) but was switched to Strattera (Atomoxetine hydrochloride) because Ritalin had an effect on the pts growth (as stated by the treating physician). the patient had a past history of seizures and was already on on sodium valproate 400mg bd | Ceased Atomoxetine. Methylphenidate recommenced. |

Medicine details :

| | | | |
|------------------------------|-----------------------------|-----------------------------|---|
| Ritalin (Suspected) | Reason : | | |
| Batch : | Started : | Stopped : | |
| Strattera (Suspected) | Reason : | | |
| Capsule | | Oral | |
| Batch : | Started : 25/07/2008 | Stopped : 27/07/2008 | 0 |
| Epilim (Other drug) | Reason : | | |
| | 2 times | Oral | |
| Batch : | Started : | Stopped : | 0 |

Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|-----------------------|--------------------|-------------|--------|--|
| Other data | 350-700 (no units) | 27/07/2008 | 467 | epilim level 467 |
| Electroencephalograph | | 27/07/2008 | abn | abnormal bifrontal spike wave and photo peroxyl response |

Public Case Detail

Cases Count: 76

Case Number : 245184

Gender : M

Data Entry Date : 07/10/2008

Weight (kg) : 30

Hospitalisation : Required a visit to the doctor

Age :

Onset Date :

DOB : 02/12/2000

Outcome :

Causality : Causality probable

Recovered

Information:

| Reaction : | | | |
|-----------------------|---|--|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Agitation | Caused or prolonged inpatient hospitalisation | Aggressive outbursts, agitation, poor appetite, weight loss of 2 kg, night sweats. | |
| Aggression | Caused or prolonged inpatient hospitalisation | | |
| Decreased appetite | Caused or prolonged inpatient hospitalisation | | |
| Night sweats | Caused or prolonged inpatient hospitalisation | | |
| Weight decreased | Caused or prolonged inpatient hospitalisation | | |

| Medicine details : | | | |
|---|---|-----------------------------|------|
| Strattera (Suspected) | Reason : Behavior disorders of childhood | | |
| Capsule | 40 Milligram | Daily | Oral |
| Batch : | Started : 19/05/2008 | Stopped : 25/07/2008 | |
| Lovan (Other drug) | Reason : | | |
| Batch : | Started : | Stopped : | |
| Omeprazole (Other drug) | Reason : | | |
| Batch : | Started : | Stopped : | |
| Ranitidine (Other drug) | Reason : | | |
| Batch : | Started : | Stopped : | |
| Seretide 125/25 MDI (Other drug) | Reason : | | |
| Batch : | Started : | Stopped : | |
| Singulair (Other drug) | Reason : | | |
| Batch : | Started : | Stopped : | |

Medicine details :

Ventolin (Other drug)

Reason :

Batch :

Started :

Stopped :

Public Case Detail

Cases Count: 76

Case Number : 245264

Data Entry Date : 08/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 28/02/1992

Outcome :

Causality : Causality possible

Recovered

Information:

| Reaction : | | | |
|-----------------------|-----------------|---------------------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Urinary retention | | Experienced severe urinary retention. | |

| Medicine details : | | | |
|------------------------------|-----------------------------|---|------|
| Strattera (Suspected) | | Reason : Behavior disorders of childhood | |
| Capsule | 40 Milligram | Daily | Oral |
| Batch : | Started : 29/07/2008 | Stopped : | 0 |

Public Case Detail

Cases Count: 76

Case Number : 245627

Data Entry Date : 20/10/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 40Y

Outcome :

DOB :

Recovered

Causality : Causality probable

Information: Medical condition: deafness neurosensory partial - took her son's medication and said that her hearing improved - dexamphetamine.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------------|---|--|-----------|
| Psychotic disorder | Caused or prolonged inpatient hospitalisation | Patient's son started on Strattera 60mg daily. Patient took large amounts of her sons medication and became psychotic. | |
| Intentional drug misuse | Caused or prolonged inpatient hospitalisation | | |
| Overdose | Caused or prolonged inpatient hospitalisation | | |

Medicine details :

Strattera (Suspected)

Reason :

Batch :

Started :

Stopped :

Public Case Detail

Cases Count: 76

Case Number : 245849

Data Entry Date : 27/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 11Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|---|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Overdose | | Patient experienced a psychotic episode and took an overdose of his mother's thyroxine. | |

| Medicine details : | |
|------------------------------|---|
| Strattera (Suspected) | Reason : Behavior disorders of childhood |
| | Oral |
| Batch : | Started : |
| | Stopped : |

Public Case Detail

Cases Count: 76

Case Number : 246156

Data Entry Date : 11/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/06/2008

Age :

DOB : 13/11/1989

Outcome : 20/06/2008

Causality : Causality possible

Recovered

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------------------|---|--|---|
| Abdominal pain upper | Caused or prolonged inpatient hospitalisation | Patient received Strattera, 40-60mg daily orally beginning on 2/06/2008, on the night of the 19/06/2008, patient was admitted to hospital, it was reported that the patient had acute onset of severe sharp epigastric pain with radiation to the back, nausea. The pain was so severe that the patient felt he could not breathe, he was initially diagnosed with acute pancreatitis. The patient was also reported to have preceded with signs of viral infection with probable viral induced pancreatitis. Increased neutrophils and CRP increased from 43 to 73. | Strattera had been temporarily withheld since 19/06/2008. |
| Dyspnoea | Caused or prolonged inpatient hospitalisation | | |
| Nausea | Caused or prolonged inpatient hospitalisation | | |
| Neutrophil count increased | Caused or prolonged inpatient hospitalisation | | |
| Pancreatitis viral | Caused or prolonged inpatient hospitalisation | | |

Medicine details :

Strattera (Suspected)

Reason : Behavior disorders of childhood

Tablet

40 Milligram

Daily

Oral

Batch :

Started : 02/06/2008

Stopped : 19/06/2008

Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|-------------------------------|-------|-------------|--------|---|
| Computerised axial tomography | | | | CT normal, no incidence of serious pancreatitis. 20/06/2008 |
| Neutrophils | | | | Neutrophil increased 20/06/2008. |
| C-Reactive Protein | | 20/06/2008 | 43 | |

Public Case Detail

Cases Count: 76

Case Number : 246181

Data Entry Date : 12/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 16Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|----------------------|----------|---|-----------|
| Raynaud's phenomenon | | Patient received atomoxetine hydrochloride for the treatment of attention deficit/hyperactivity disorder, beginning on an unknown day in 2006. On an unknown date the patient experienced Raynaud's phenomenon. | |

Medicine details :

| | | | |
|-------------------------------|-----------------------------|---|------|
| Strattera (Suspected) | | Reason : Behavior disorders of childhood | |
| Capsule | 40 Milligram | Daily | Oral |
| Batch : | Started : 01/10/2007 | Stopped : | 0 |
| Risperdal (Other drug) | | Reason : | |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 246386

Gender : M

Data Entry Date : 19/11/2008

Weight (kg) : 0

Hospitalisation :

Age :

Onset Date :

DOB : 12/12/1976

Outcome :

Causality : Causality possible

Unknown

Information: The patient was having abnormal rhythm for many years. Minor raynaud's syndrome. Recurrence of ADHD symptoms was observed and the dosage was increased to 85mg (60/25) on 11/8/08. The patient was continuing 85mg daily without recurrence of palpitations but not so good control of ADHD symptoms and the psychiatrist was planning to increase the dose to 25mg three times and 18.5mg once per day. The reporting psychiatrist stated that the event palpitation was possibly due to exacerbation of sinus tachycardia which may have been secondary to low blood pressure (BP) or could be due to atomoxetine with benign ventricular and supraventricular beats.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|----------|---|---|
| Palpitations | | Patient experienced palpitations, supraventricular extrasystoles, weight decreased, dry mouth, hypoaesthesia. upper central chest pain. | Dosage of atomoxetine was dropped to 60mg and then increased to 85mg and dropped to 80mg. |
| Chest pain | | | |
| Dry mouth | | | |
| Hypoaesthesia | | | |
| Ventricular extrasystoles | | | |
| Weight decreased | | | |

Medicine details :

| | |
|------------------------------|---|
| Strattera (Suspected) | Reason : Behavior disorders of childhood |
| Capsule | 85 Milligram Daily Oral |
| Batch : | Started : Stopped : |

Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|---------------------|-------|-------------|--------|---|
| Electrocardiography | | | | Ambulatory ECG analysis was performed for 24-hours total of 131742 beats (QRS) were analysed. Average heart rate was 91 beats per minute with a maximum rate of 167 BPM at 18:38 hours and a minimum of 53 BPM at 04:55. Shows Sinus rhythm with multiple nodal beat, discussed with electrocardiophysilogist, feels it a benign rhythm and the need for ADD treatment may out weight the annoyance of the frequent junctional beats. |

Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|------------|-------|-------------|--------|--|
| Heart Rate | | | | Maximum heart rate was 167/min. Was noted but no bouts of paroxysmal tachycardia were seen patient signalled two events these showed sinus tachycardia and rapid sinus rhythm. |

Public Case Detail

Cases Count: 76

Case Number : 246522

Gender : M

Data Entry Date : 25/11/2008

Weight (kg) : 27

Hospitalisation : Required a visit to the doctor

Age :

Onset Date : 15/10/2008

DOB : 22/05/1999

Outcome :
Unknown

Causality : Causality possible

Information: DOCI report.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--|----------------------------|
| Suicidal ideation | | Child experienced suicidal thoughts, ongoing nausea and taste disturbance. | Strattera reduced to 25mg. |
| Dysgeusia | | | |
| Nausea | | | |

Medicine details :

| | |
|------------------------------|---|
| Strattera (Suspected) | Reason : Behavior disorders of childhood |
| 35 Milligram Daily | |
| Batch : | Started : 15/08/2008 Stopped : 14/10/2008 |
| Concerta (Other drug) | Reason : Behavior disorders of childhood |
| 27 Milligram Daily | |
| Batch : | Started : Stopped : |

Public Case Detail

Cases Count: 76

Case Number : 246545

Data Entry Date : 25/11/2008

Gender : M

Hospitalisation : Required a specialist consultation

Weight (kg) : 34.8

Onset Date : 01/09/2008

Age :

DOB : 20/04/1997

Outcome :

Causality : Causality possible

Not yet recovered

Information: Several years ago the child had a 2 week trial of Ritalin which caused depression and a trial of Dexamphetamine which had no effect on concentration. DOCI report.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|----------|--|--|
| Agitation | | Child was taking 25mg of Strattera when his behaviour deteriorated on 01/09/08. He became extremely agitated, terrified and talked about wanting to die. | Given 25mg of diazepam. Strattera stopped. |
| Fear | | | |
| Suicidal ideation | | | |

Medicine details :

Strattera (Suspected)

Reason : Behavior disorders of childhood

Capsule

25 Milligram

Daily

Oral

Batch :

Started : 11/08/2008

Stopped : 03/09/2008

Public Case Detail

Cases Count: 76

Case Number : 248257

Data Entry Date : 04/02/2009

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date :

Age : 13Y

Outcome : 04/12/2008

DOB :

Recovered

Causality : Causality probable

Information: Began Strattera 25mg for one week, increased to 40mg for one week, then increased to 65mg.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|----------|---|------------------|
| Mood swings | | By 2nd week on 40mg dose of Strattera parents noticed patient was more moody, irritable, but patient noticed concentration had improved at school, by 4th week-suicidal ideation (wanting to end it all, life not worth living), no specific plans, physical and verbal aggression to family, school teachers and peers, roughly handling pets. Crying excessively, angry, withdrawn, socially isolatory, impulsive, moody, stopped being affectionate to family. | Ceased Strattera |
| Aggression | | | |
| Anger | | | |
| Crying | | | |
| Impulsive behaviour | | | |
| Irritability | | | |
| Social avoidant behaviour | | | |
| Suicidal ideation | | | |

Medicine details :

| | | | |
|------------------------------|-----------------------------|-----------------------------|------|
| Strattera (Suspected) | Reason : | | |
| Capsule | 65 Milligram | Daily | Oral |
| Batch : | Started : 28/10/2008 | Stopped : 26/11/2008 | |

Public Case Detail

Cases Count: 76

Case Number : 248387

Gender : M

Data Entry Date : 09/02/2009

Weight (kg) : 0

Hospitalisation : Required a specialist consultation

Age :

Onset Date :

DOB : 07/02/1994

Outcome :

Causality : Causality possible

Not yet recovered

Information: DOCI report. Medical condition: substance abuse, low grade dysthymia. Patient was suffering from low mood, probably since 2007. Concomitant medications included ethanol and cannabis sativa (self-administered by the patient). The reporting pediatrician stated that she did not know if the events were related to atomoxetine treatment as the patient had low grade dysthymia. The reporting pediatrician also stated that the patient already had depressed mood, so may have experienced suicidal thoughts even without atomoxetine.

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|-------------------|------------------|--|--|
| Depressed mood | Life threatening | Patient experienced lower mood swings that became worse and also was expressing suicidal thoughts. | Atomoxetine was discontinued in response to the events. It was stated that the patient had been referred to a psychiatrist for the management of depression. |
| Suicidal ideation | Life threatening | | |

Medicine details :

| | | |
|---|---|-----------------------------|
| Alcohol (Suspected) | Reason : | Oral |
| Batch : | Started : | Stopped : 0 |
| Cannabis Preparation (Suspected) | Reason : | |
| Batch : | Started : | Stopped : |
| Strattera (Suspected) | Reason : Behavior disorders of childhood | |
| Capsule | 80 Milligram Daily | Oral |
| Batch : | Started : 10/06/2008 | Stopped : 29/10/2008 |

Public Case Detail

Cases Count: 76

Case Number : 248437

Gender : M

Data Entry Date : 09/02/2009

Weight (kg) : 48.25

Hospitalisation : Required a visit to the doctor

Age :

Onset Date : 15/11/2008

DOB : 22/02/1997

Outcome :
Not yet recovered

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|--|------------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Suicidal ideation | | Emergence of suicidal ideation, emotional lability and somnolence when reached 40 mg daily dose. | Strattera ceased immediately |
| Affect lability | | | |
| Somnolence | | | |

| Medicine details : | | | |
|---------------------------------|-----------------------------|---|--|
| Strattera (Suspected) | | Reason : Behavior disorders of childhood | |
| | 40 Milligram | Daily | |
| Batch : | Started : 19/09/2008 | Stopped : 27/11/2008 | |
| Melatonin (Other drug) | | Reason : | |
| | Milligram | Daily | |
| Batch : | Started : | Stopped : | |
| Risperidone (Other drug) | | Reason : | |
| | Milligram | Daily | |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 249446

Data Entry Date : 19/03/2009

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 12Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

| Reaction : | | | |
|-------------------------|-----------------|--|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Intentional self-injury | | Ripped out her fingernails and toenails. | |

| Medicine details : | |
|------------------------------|---|
| Strattera (Suspected) | Reason : Behavior disorders of childhood |
| Batch : | Started : |
| | Stopped : |

Public Case Detail

Cases Count: 76

Case Number : 249447

Data Entry Date : 19/03/2009

Gender : F

Weight (kg) : 0

Hospitalisation :

Age : 9Y

Onset Date :

DOB :

Outcome :

Causality : Causality possible

Unknown

Information:

| Reaction : | | | |
|-------------------------|-----------------|-----------------------------------|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Intentional self-injury | | Patient experienced self-harming. | |

| Medicine details : | | | |
|------------------------------|------------------|------------------|--|
| Strattera (Suspected) | | Reason : | |
| Batch : | Started : | Stopped : | |
| | | | |

Public Case Detail

Cases Count: 76

Case Number : 249950

Gender : M

Data Entry Date : 06/04/2009

Weight (kg) : 0

Hospitalisation :

Age :

Onset Date : 15/07/2008

DOB : 23/11/1980

Outcome :

Causality : Causality possible

Unknown

Information:

| Reaction : | | | |
|-----------------------|---|---|--------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Suicidal ideation | Caused or prolonged inpatient hospitalisation | After three or four days of not taking atomoxetine, he experienced extreme agitation and anxiety and an uncontrollable sensation of coldness and shaking and withdrawal symptoms, the patient was reported as being suicidal and expressed suicidal ideation. | Diazepam and olanzapine. |
| Agitation | Caused or prolonged inpatient hospitalisation | | |
| Anxiety | Caused or prolonged inpatient hospitalisation | | |
| Feeling cold | Caused or prolonged inpatient hospitalisation | | |
| Tremor | Caused or prolonged inpatient hospitalisation | | |
| Withdrawal syndrome | Caused or prolonged inpatient hospitalisation | | |

| Medicine details : | | | |
|------------------------------|------------------|---|------|
| Strattera (Suspected) | | Reason : Behavior disorders of childhood | |
| Capsule | 80 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 250025

Data Entry Date : 08/04/2009

Gender : M

Hospitalisation :

Weight (kg) : 23

Onset Date :

Age :

DOB : 21/07/2000

Outcome :

Causality : Causality possible

Unknown

Information:

| Reaction : | | | |
|-------------------------|---|---|---------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Suicidal ideation | Caused or prolonged inpatient hospitalisation | Suicidal ideation, drawings of him hanging upside down from tree, in ocean (ADHD 2007), long history DV, recent escalation of behaviour problems, mum and school finding his behaviour difficulty to manage, aggression, self harm. | Strattera withheld. |
| Aggression | Caused or prolonged inpatient hospitalisation | | |
| Intentional self-injury | Caused or prolonged inpatient hospitalisation | | |

| Medicine details : | | | |
|--------------------------------|-----------------------------|------------------|------|
| Risperidone (Suspected) | | Reason : | |
| Tablet | 250 Milligram | Daily | Oral |
| Batch : | Started : 25/11/2005 | Stopped : | |
| Strattera (Suspected) | | Reason : | |
| Capsule | 30 Milligram | Daily | Oral |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 250615

Data Entry Date : 29/04/2009

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 30

Onset Date : 03/04/2009

Age :

DOB : 24/10/2003

Outcome :

Causality : Causality possible

Recovered

Information:

| Reaction : | | | |
|-----------------------|---|--|-------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Dystonia | Caused or prolonged inpatient hospitalisation | Mother report about son: Patient experienced seizures and dystonic reaction. | Cogentin for dystonia . |
| Convulsion | Caused or prolonged inpatient hospitalisation | | |

| Medicine details : | | | |
|------------------------------|-----------------------------|-----------------------------|--|
| Risperdal (Suspected) | Reason : | | |
| | 1 Milligram Daily | Oral | |
| Batch : | Started : 30/03/2009 | Stopped : 03/04/2009 | |
| Strattera (Suspected) | Reason : | | |
| Batch : | Started : | Stopped : | |

Public Case Detail

Cases Count: 76

Case Number : 250791

Data Entry Date : 07/05/2009

Gender : M

Hospitalisation :

Weight (kg) : 32

Onset Date : 20/04/2009

Age :

DOB : 27/03/1998

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|---------------------------|----------|---|-------------------------|
| Social avoidant behaviour | | Withdrawn, increased lability, increased impulsivity, negative behaviours, oppositional behaviours, emotional disturbance | Cessation of medication |
| Abnormal behaviour | | | |
| Affect lability | | | |
| Impulsive behaviour | | | |

Medicine details :

| | | | |
|------------------------------|---|-----------------------------|------|
| Strattera (Suspected) | Reason : Behavior disorders of childhood | | |
| Capsule, soft | 40 Milligram | Daily | Oral |
| Batch : | Started : 20/02/2009 | Stopped : 07/05/2009 | |

Laboratory Investigations :

| Type | Range | Date Tested | Result | Details |
|------------|-------|-------------|--------|---|
| Other data | | | | Child already having psychology treatment for emotional/mood issues - worsened on medication. |

Public Case Detail

Cases Count: 76

Case Number : 254404

Data Entry Date : 24/07/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 10Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information:

| Reaction : | | | |
|-------------------------|-----------------|---|-------------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Hallucination, auditory | | 24 hours after the initial dose of Strattera therapy, patient displayed psychosis for the first time and experienced "hearing voices in his head to kill his sister". | Strattera discontinued. |

| Medicine details : | |
|------------------------------|---|
| Strattera (Suspected) | Reason : Behavior disorders of childhood |
| Capsule | Oral |
| Batch : | Started : |
| | Stopped : |

Public Case Detail

Cases Count: 76

Case Number : 254536

Data Entry Date : 26/07/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 25/04/1997

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

| Preferred Term | Severity | Report Description | Treatment |
|------------------------------|----------|---|-----------|
| Sinus tachycardia | | Experienced sinus tachycardia, episodes of flushing, exercise intolerance, exhausted, episodes of sweating, lethargy, marked increase in appetite and anorexia. | |
| Decreased appetite | | | |
| Exercise tolerance decreased | | | |
| Fatigue | | | |
| Flushing | | | |
| Hyperhidrosis | | | |
| Increased appetite | | | |
| Lethargy | | | |

Medicine details :

| | | |
|------------------------------|------------------|------------------|
| Strattera (Suspected) | Reason : | |
| Capsule | | Oral |
| Batch : | Started : | Stopped : |

Public Case Detail

Cases Count: 76

Case Number : 255654

Data Entry Date : 20/08/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 8Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

| Reaction : | | | |
|-----------------------|-----------------|--|------------------|
| Preferred Term | Severity | Report Description | Treatment |
| Homicidal ideation | | Child had lost appetite, was homicidal, losing weight and lashing out/angry, patient had bruising. | |
| Anger | | | |
| Contusion | | | |
| Decreased appetite | | | |
| Weight decreased | | | |

| Medicine details : | | | |
|------------------------------|-----------------------------|------------------|------|
| Strattera (Suspected) | | Reason : | |
| Capsule | 40 Milligram | Daily | Oral |
| Batch : | Started : 18/06/2009 | Stopped : | |

Selection Parameters : Date Range: 01/01/1960 To 31/08/2009 Medicine Status: General marketing Unclear causality excluded Medicine Names: Atomoxetine Hydrochloride, Strattera