

# Public Case Detail

**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

**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 :

<b>Atomoxetine Hydrochloride (Suspected)</b>		<b>Reason :</b> Behavior disorders of childhood	
Capsule	40 Milligram	1 time	Oral
<b>Batch :</b> unknown	<b>Started :</b> 18/06/2004	<b>Stopped :</b> 22/06/2004	

# Public Case Detail

**Case Number : 198545**

**Data Entry Date :** 28/06/2004

**Gender :** M

**Hospitalisation :** Treated in Accident/Emergency Depar

**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 childhod

Capsule

40 Milligram Daily

Oral

**Batch :**

**Started :** 03/05/2004

**Stopped :**

Continuing

# Public Case Detail

**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:**

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

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

# Public Case Detail

**Case Number : 199697**

**Data Entry Date :** 05/08/2004

**Hospitalisation :**

**Onset Date :** 24/07/2004

**Outcome :** 29/07/2004

Recovered

**Gender :** M

**Weight (kg) :** 28

**Age :**

**DOB :** 24/03/1995

**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Gastrointestinal disorder	Required Visit to Doctor	Patient experienced GIT upset with nausea ++, severe headache.	
Headache	Required Visit to Doctor		
Nausea	Required Visit to Doctor		

<b>Medicine details :</b>			
<b>Strattera (Suspected)</b>		<b>Reason :</b> Behavior disorders of childhood	
Capsule	10 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 16/07/2004	<b>Stopped :</b> 28/07/2004	0

# Public Case Detail

**Case Number : 200332**

**Data Entry Date :** 27/08/2004

**Hospitalisation :**

**Onset Date :** 11/08/2004

**Outcome :**  
Recovered

**Gender :** M

**Weight (kg) :** 72

**Age :**

**DOB :** 25/11/1985

**Causality :** Causality possible

**Information:**

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

<b>Medicine details :</b>			
<b>Strattera (Suspected)</b>	<b>Reason :</b>		
Capsule	80 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

**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

**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:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
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		

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



# Public Case Detail

**Case Number : 205312**

**Data Entry Date :** 16/02/2005

**Hospitalisation :**

**Onset Date :** 15/01/2005

**Outcome :**  
Recovered

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 06/04/1997

**Causality :** Causality possible

**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

**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 :

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

# Public Case Detail

**Case Number : 208106**

**Data Entry Date :** 23/05/2005

**Hospitalisation :**

**Onset Date :** 25/03/2005

**Outcome :**  
Recovered

**Gender :** M

**Weight (kg) :** 51

**Age :**

**DOB :** 08/11/1991

**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
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		

<b>Medicine details :</b>			
<b>Strattera (Suspected)</b>		<b>Reason :</b>	
Capsule	Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 10/03/2005	<b>Stopped :</b>	12/05/2005

# Public Case Detail

**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:**

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

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

# Public Case Detail

**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

# Public Case Detail

**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 :**

<b>CARBAMAZEPINE (Interaction)</b>		<b>Reason :</b>	
Tablet	840 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>L TERM</b>	<b>Stopped :</b>
<b>RISPERIDONE (Interaction)</b>		<b>Reason :</b>	
Tablet	4 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 14/04/2004	<b>L TERM</b>	<b>Stopped :</b>
<b>SODIUM VALPROATE (Interaction)</b>		<b>Reason :</b>	
Tablet	800 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/02/2005	<b>S TERM</b>	<b>Stopped :</b>
<b>Strattera (Interaction)</b>		<b>Reason :</b>	
	40 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b> 15/05/2005	<b>S TERM</b>	<b>Stopped :</b> 0
<b>FLUOXETINE HYDROCHLORIDE (Other drug)</b>		<b>Reason :</b>	
	20 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/03/2005	<b>S TERM</b>	<b>Stopped :</b>
<b>MELATONIN (Other drug)</b>		<b>Reason :</b>	
	3 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/01/2005	<b>S TERM</b>	<b>Stopped :</b>

# Public Case Detail

**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

**Case Number : 211490**

**Data Entry Date :** 07/09/2005

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

**Onset Date :**

**Outcome :**

Recovered

**Information:** Suspected drug positive rechallenge.

**Gender :** M

**Weight (kg) :** 36

**Age :**

**DOB :** 16/03/1996

**Causality :** Causality certain

## Reaction :

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

**Case Number : 211934**

**Data Entry Date :** 23/09/2005

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

**Onset Date :**

**Outcome :** 15/08/2005

Recovered

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 30/07/1993

**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Anorexia		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			

<b>Medicine details :</b>			
<b>Strattera (Suspected)</b>	<b>Reason :</b>		
Capsule	60 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/12/2004	<b>Stopped :</b> 15/08/2005	

# Public Case Detail

**Case Number : 212597**

**Data Entry Date :** 17/10/2005

**Hospitalisation :**

**Onset Date :** 15/02/2005

**Outcome :**  
Recovered

**Gender :** M

**Weight (kg) :** 0

**Age :** 11Y

**DOB :**

**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Suicidal ideation		Patient experienced suicidal ideation.	

<b>Medicine details :</b>			
<b>Strattera (Suspected)</b>		<b>Reason :</b> Behavior disorders of childhood	
Capsule	25 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/02/2005	<b>Stopped :</b> 15/05/2005	

# Public Case Detail

**Case Number : 212705**

**Data Entry Date :** 19/10/2005

**Hospitalisation :**

**Onset Date :** 30/05/2004

**Outcome :**

Not yet recovered

**Gender :** M

**Weight (kg) :** 25

**Age :** 8Y

**DOB :**

**Causality :** Causality possible

**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 :

<b>Strattera (Suspected)</b>		<b>Reason :</b> Behavior disorders of childhood	
Capsule	20 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 27/05/2004	<b>Stopped :</b>	Continuing

# Public Case Detail

**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:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Syncope	Caused or prolonged inpatient hospitalisation		
Fall	Caused or prolonged inpatient hospitalisation	Approximately one year after commencing Atomoxetine treatment the patient woke up and fainted.	
Syncope	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>Strattera (Suspected)</b>	<b>Reason :</b>		
Capsule	80 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

**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:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
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.

<b>Medicine details :</b>			
<b>EPILIM (Suspected)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b> 29/07/2005	<b>Stopped :</b> 19/10/2005	0
<b>Strattera (Suspected)</b>	<b>Reason :</b> Behavior disorders of childhood		
Capsule	10 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 09/09/2005	<b>Stopped :</b> 09/10/2005	0

<b>Laboratory Investigations :</b>				
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

**Case Number : 220681**

**Data Entry Date :** 09/08/2006

**Gender :** M

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

**Weight (kg) :** 25

**Onset Date :** 17/07/2006

**Age :**

**DOB :** 21/10/1998

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**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 :**

<b>Atomoxetine Hydrochloride (Suspected)</b>	<b>Reason :</b> Behavior disorders of childhood
25 Milligram Daily	
<b>Batch :</b>	<b>Started :</b> 15/07/2006 <b>Stopped :</b>
<b>CEPHALEXIN (Other drug)</b>	<b>Reason :</b> Othr diseases of urinary tract
<b>Batch :</b>	<b>Started :</b> 15/05/2006 <b>Stopped :</b>

# Public Case Detail

**Case Number : 220852**

**Data Entry Date :** 17/08/2006

**Gender :** M

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

**Weight (kg) :** 34.5

**Onset Date :**

**Age :**

**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

**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>
Anorexia			
Drug interaction			
Feeling hot			
Nausea			



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

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Other data				

# Public Case Detail

**Case Number : 221914**

**Data Entry Date :** 26/09/2006

**Hospitalisation :**

**Onset Date :** 15/06/2006

**Outcome :**  
Recovered

**Gender :** M

**Weight (kg) :** 0

**Age :** 9Y

**DOB :**

**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Blood pressure increased		Significant increase in blood pressure.	Strattera discontinued.

<b>Medicine details :</b>			
<b>Strattera (Suspected)</b>		<b>Reason :</b> Behavior disorders of childhood	
Capsule	40 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 15/08/2006	

# Public Case Detail

**Case Number : 222837**

**Data Entry Date :** 01/11/2006

**Hospitalisation :**

**Onset Date :** 20/06/2006

**Outcome :**  
Not yet recovered

**Gender :** F

**Weight (kg) :** 36

**Age :**

**DOB :** 21/01/1991

**Causality :** Causality possible

**Information:**

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

<b>Medicine details :</b>			
<b>Strattera (Suspected)</b>		<b>Reason :</b>	
	40 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b> 12/05/2006	<b>Stopped :</b>	

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

# Public Case Detail

**Case Number : 223047**

**Data Entry Date :** 13/11/2006

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** M

**Weight (kg) :** 0

**Age :**

**DOB :** 27/06/1984

**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 :

<b>Strattera (Suspected)</b>		<b>Reason :</b> Behavior disorders of childhood	
	10 Milligram		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0
<b>ZYPREXA (Suspected)</b>		<b>Reason :</b> Unspecifid affective psychosis	
	5 Milligram Daily		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0
<b>LITHIUM CARBONATE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

**Case Number : 223348**

**Data Entry Date :** 20/11/2006

**Hospitalisation :**

**Onset Date :** 15/07/2006

**Outcome :**

Not yet recovered

**Gender :** M

**Weight (kg) :** 41.5

**Age :**

**DOB :** 28/05/1996

**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
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			

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

# Public Case Detail

**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 disturbance			
Vomiting			

## Medicine details :

### Strattera (Suspected)

Reason : Behavior disorders of childhood

Capsule

40 Milligram

Daily

Oral

Batch :

Started : 18/09/2006

Stopped :

0

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### SERENACE (Other drug)

Reason :

Batch :

Started :

Stopped :

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# Public Case Detail

**Case Number : 223950**

**Data Entry Date :** 08/12/2006

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Recovered

**Gender :** M

**Weight (kg) :** 0

**Age :** 9Y

**DOB :**

**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

**Case Number : 226118**

**Data Entry Date :** 26/02/2007

**Hospitalisation :**

**Onset Date :** 28/01/2007

**Outcome :**  
Recovered

**Gender :** M

**Weight (kg) :** 26

**Age :** 7Y

**DOB :**

**Causality :** Causality probable

**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 :

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

## Laboratory Investigations :

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

# Public Case Detail

**Case Number : 226323**

**Data Entry Date :** 05/03/2007

**Hospitalisation :**

**Onset Date :** 15/07/2006

**Outcome :**  
Recovered

**Gender :** M

**Weight (kg) :** 0

**Age :** 9Y

**DOB :**

**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
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		

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

<b>Laboratory Investigations :</b>				
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

**Case Number : 227053**

**Data Entry Date :** 28/03/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 26

**Onset Date :** 30/01/2007

**Age :**

**DOB :** 07/01/2000

**Outcome :** 07/01/2007

**Causality :** Causality possible

Recovered

**Information:** Was on 10mg for 6 months with no cardiac side effect.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient experienced acute tachycardia.	Ceased Strattera.

## Medicine details :

<b>Strattera (Suspected)</b>	<b>Reason :</b> Behavior disorders of childhood		
Capsule	25 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 18/01/2007	<b>Stopped :</b> 30/01/2007	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				Acute tachycardia >180/mins 15 mins.

# Public Case Detail

**Case Number : 227168**

**Data Entry Date :** 30/03/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 25/02/2007

**Age :** 48Y

**Outcome :**

**DOB :**

Not yet recovered

**Causality :** Causality possible

**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 :**

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

# Public Case Detail

**Case Number : 227440**

**Data Entry Date :** 10/04/2007

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** M

**Weight (kg) :** 0

**Age :** 99U

**DOB :**

**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

**Case Number : 229120**

**Data Entry Date :** 30/05/2007

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Recovered

**Gender :** M

**Weight (kg) :** 0

**Age :** 11Y

**DOB :**

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Suicidal ideation		The patient tookStrattera for the treatment of ADHD to complement Ritalin, under the influence of which he became suicidal and depressed.	Ceased medication.
Depression			
Drug ineffective			

<b>Medicine details :</b>			
<b>RITALIN (Suspected)</b>		<b>Reason :</b> Behavior disorders of childhod	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>Strattera (Suspected)</b>		<b>Reason :</b> Behavior disorders of childhod	
Capsule			Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

**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 :**

<b>Strattera (Suspected)</b>	<b>Reason :</b> Behavior disorders of childhood
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>



# Public Case Detail

**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:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Rash		truncal rash	
Balanitis			
Periorbital oedema			

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



# Public Case Detail

**Case Number : 236378**

**Data Entry Date :** 17/12/2007

**Hospitalisation :**

**Onset Date :** 01/12/2007

**Outcome :**

Not yet recovered

**Gender :** U

**Weight (kg) :** 23

**Age :**

**DOB :** 04/02/2000

**Causality :** Causality possible

**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

**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:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Tic		Increase in pre-existing motor tics.	

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

# Public Case Detail

**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 :**

<b>Strattera (Suspected)</b>		<b>Reason :</b> Behavior disorders of childhod	
Capsule	10 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

**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 :

<b>Strattera (Suspected)</b>	<b>Reason :</b> Behavior disorders of childhood
Capsule	10 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 15/11/2007 <b>Stopped :</b> 15/11/2007 0
<b>RITALIN (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

## Laboratory Investigations :

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

# Public Case Detail

**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 :

<b>Strattera (Suspected)</b>	<b>Reason :</b> Behavior disorders of childhood
Capsule	40 Milligram Daily Oral
<b>Batch :</b> A129025 exp: 08	<b>Started :</b> 15/08/2007 <b>Stopped :</b> Ongoing.
<b>CATAPRES (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>CLONIDINE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>
Tablet	Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

## Laboratory Investigations :

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

# Public Case Detail

**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

**Case Number : 238474**

**Data Entry Date :** 29/02/2008

**Hospitalisation :**

**Onset Date :** 09/02/2008

**Outcome :**  
Unknown

**Gender :** M

**Weight (kg) :** 0

**Age :** 25Y

**DOB :**

**Causality :** Causality possible

**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
<b>Batch :</b> A344066 Exp Feb 20	<b>Started :</b> 08/02/2008 <b>Stopped :</b> 09/02/2008

# Public Case Detail

**Case Number : 238475**

**Data Entry Date :** 29/02/2008

**Gender :** M

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

**Weight (kg) :** 63

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

**Age :** 20Y

**Outcome :**

**DOB :**

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 :**

<b>Strattera (Suspected)</b>		<b>Reason :</b> Behavior disorders of childhood	
Capsule	60 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	L TERM	<b>Stopped :</b> 0
<b>TERBINAFINE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b> 02/02/2008	<b>Stopped :</b>	



# Public Case Detail

**Case Number : 238517**

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

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 49

**Onset Date :** 06/02/2008

**Age :** 13Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

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

**Medicine details :**

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

# Public Case Detail

**Case Number : 239523**

**Data Entry Date :** 03/04/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 85

**Onset Date :** 29/02/2008

**Age :**

**DOB :** 19/01/1990

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Hallucination, auditory	Incapacity/disability	Sudden-onset auditory hallucinations (AH). No history of psychosis in the patient. No use of illicit drugs (urine drug screen negative).	Needed antipsychotic medication (quetiapine)

**Medicine details :**

Atomoxetine Hydrochloride (Suspected)		Reason :	
Capsule	60 Milligram	Daily	Oral
<b>Batch :</b> U/270L69/196	<b>Started :</b> 27/02/2008	<b>Stopped :</b> 09/03/2008	
LITHIUM CARBONATE (Suspected)		Reason :	
Tablet	Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 27/02/2008	<b>Stopped :</b> 04/03/2008	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Computerised axial tomography				CT brain was normal. EEG was unremarkable.

# Public Case Detail

**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

**Case Number : 240530**

**Data Entry Date :** 01/05/2008

**Hospitalisation :** Admitted to hospital

**Onset Date :**

**Outcome :**  
Recovered

**Gender :** M

**Weight (kg) :** 0

**Age :** 13Y

**DOB :**

**Causality :** Causality possible

**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 :

<b>Strattera (Suspected)</b>		<b>Reason :</b>	
Capsule	60 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

Selection Parameters : Date Range: 01/01/1960 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: Strattera, Atomoxetine Hydrochloride