CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :130134(0)

I.REACTION INFORMATION

1.PATIENT INITIALS	1a.COUNTRY	2.DATE OF BIRTH DA	2.DATE OF BIRTH MO	2.DATE OF BIRTH YR	2a. AGE YRS	3. SEX	4.-6. REACTION ONSET DA	4.-6. REACTION ONSET MO	4.-6. REACTION ONSET YR	8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				14	Man	16	DEC	2012	

7.+13. DESCRIBE REACTION(S) (include relevant test/lab data)

Epistaxis (Epistaxis) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company: Icke allvarlig

Case level outcome :Tillfrisknat/resolverad

[redacted]

Cont...

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

Icke allvarlig

II.SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

Cont...

20.DID EVENT ABATE AFTER STOPPING DRUG?

☐ YES ☐ NO ☒ NA

15. DAILY DOSE
50MGD (50 Milligram,On a Daily

16. ROUTE OF ADMINISTRATION
Per oral

21.DID EVENT REAPPEAR AFTER REINTRODUCTION?

Okänt

☐ YES ☐ NO ☐ NA

17. INDICATIONS FOR USE

18. THERAPY DATES(From/To)
09/DEC/2012 -

19. THERAPY DURATION

III.CONCOMITANT DRUGS AND HISTORY

22.CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

RISPERIDON(Risperidone)(Risperidone)

23. OTHER RELEVANT HISTORY

[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b. MFR. CONTROL NO.
130134(0)

24c. DATE RECEIVED BY MANUFACTURER
03/OCT/2013

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☐ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
20/MAR/2014

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Approval ID: 22646 Approval Date: 21/APR/2006
(Strattera 25 mg Kapsel, hård)

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :130134(0)**

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

[redacted]

Suspect Drugs (Cont...)

Product-Reaction level

Seq.No. : 1
Drug : Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)
Daily Dose : 1) 50MGD (50 Milligram,On a Daily Basis)
Route of Admin : 1) Per oral

Causality

1) Epistaxis (Epistaxis)
Action(s) taken with drug : Inte tillämpbart
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Inte applicerbart
Rechallenge : Okänt

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :130183(0)

I.REACTION INFORMATION

1.PATIENT INITIALS	1a.COUNTRY	2.DATE OF BIRTH DA	2.DATE OF BIRTH MO	2.DATE OF BIRTH YR	2a. AGE YRS	3. SEX	4.-6. REACTION ONSET DA	4.-6. REACTION ONSET MO	4.-6. REACTION ONSET YR
	SVERIGE				4	Kvinna	01	JAN	2012

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

7.+13. DESCRIBE REACTION(S) (include relevant test/lab data)

Tics (Tics) - Okänd
Protocol relatedness:
As per reporter:
As per company: Icke allvarlig

Dysartri (Dysarthria) - Okänd
Protocol relatedness:
As per reporter:
As per company: Icke allvarlig

Aggressivitet (Aggressiveness) - Okänd
Protocol relatedness:
As per reporter:
As per company: Icke allvarlig

Case level outcome :Okänd

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

Icke allvarlig

II.SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

Cont...

20.DID EVENT ABATE AFTER STOPPING DRUG?
Okänt
☐ YES ☐ NO ☐ NA

15. DAILY DOSE
18MGD (18 Milligram,On a Daily

16. ROUTE OF ADMINISTRATION
Per oral

21.DID EVENT REAPPEAR AFTER REINTRODUCTION?
Okänt
☐ YES ☐ NO ☐ NA

17. INDICATIONS FOR USE

18. THERAPY DATES(From/To)
24/NOV/2011 - 18/FEB/2012

19. THERAPY DURATION
3 Månader

III.CONCOMITANT DRUGS AND HISTORY

22.CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Theralen(alimemazine tartrate, alimemazine)(alimemazine tartrate, alimemazine)

23. OTHER RELEVANT HISTORY

[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER
MPA
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Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b. MFR. CONTROL NO.
130183(0)

24c. DATE RECEIVED BY MANUFACTURER
05/FEB/2013

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☐ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
20/MAR/2014

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA on 15/JAN/2013
Approval ID: 22645 Approval Date: 21/APR/2006
(Strattera 18 mg Kapsel, hård)

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :130183(0)**

Reaction Information (Cont...)

Seq. No.	:	1
Reaction	:	Tics (Tics)
Start Date	:	01/Jan/2012
Seq. No.	:	2
Reaction	:	Dysartri (Dysarthria)
Start Date	:	01/Jan/2012
Seq. No.	:	3
Reaction	:	Aggressivitet (Aggressiveness)
Start Date	:	01/Jan/2012

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

[redacted]

Suspect Drugs (Cont...)

Product-Reaction level

Seq.No.	:	1
Drug	:	Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)
Daily Dose	:	1) 18MGD (18 Milligram,On a Daily Basis)
Route of Admin	:	1) Per oral

Causality

1) Tics (Tics)

Action(s) taken with drug	:	Okänd
Causality as per Mfr.(Drug/Vaccine)	:	Possible
Dechallenge	:	Okänt
Rechallenge	:	Okänt

2) Dysartri (Dysarthria)

Action(s) taken with drug	:	Okänd
Causality as per Mfr.(Drug/Vaccine)	:	Possible
Dechallenge	:	Okänt
Rechallenge	:	Okänt

3) Aggressivitet (Aggressiveness)

Action(s) taken with drug	:	Okänd
Causality as per Mfr.(Drug/Vaccine)	:	Possible
Dechallenge	:	Okänt
Rechallenge	:	Okänt

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :130631(0)

I.REACTION INFORMATION

1.PATIENT INITIALS	1a.COUNTRY	2.DATE OF BIRTH DA	2.DATE OF BIRTH MO	2.DATE OF BIRTH YR	2a. AGE YRS	3. SEX	4.-6. REACTION ONSET DA	4.-6. REACTION ONSET MO	4.-6. REACTION ONSET YR
	SVERIGE				18	Kvinna	07	FEB	2013

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

7.+13. DESCRIBE REACTION(S) (include relevant test/lab data)

Anafylaktisk reaktion (Anaphylactic reaction) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Trötthet (Fatigue) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Yrsel (Dizziness) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Konjunktivit (Conjunctivitis) - Tillfrisknat/resolverad
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☒ OTHER MEDICALLY IMPORTANT CONDITION

II.SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

1) Strattera(atomoxetine hydrochloride,
2) Alutard SQ 3-Träd(allergen, Alnus glutinosa pollen, allergen, Betula

Cont...

20.DID EVENT ABATE AFTER STOPPING DRUG?
Okänt
☐ YES ☐ NO ☐ NA

15. DAILY DOSE
1)
2)

16. ROUTE OF ADMINISTRATION
1)
2)

21.DID EVENT REAPPEAR AFTER REINTRODUCTION?
Okänt
☐ YES ☐ NO ☐ NA

17. INDICATIONS FOR USE
[redacted]

18. THERAPY DATES(From/To)
1)
2) /Sep/2011 -

19. THERAPY DURATION
1)
2)

III.CONCOMITANT DRUGS AND HISTORY

22.CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Buventol Easyhaler(salbutamol sulfate, salbutamol)(salbutamol sulfate, salbutamol)

Cont...

23. OTHER RELEVANT HISTORY
[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b. MFR. CONTROL NO.
130631(0)

24c. DATE RECEIVED BY MANUFACTURER
27/FEB/2013

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☐ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
20/MAR/2014

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA on 27/FEB/2013
Approval ID: 22648 Approval Date: 21/APR/2006
(Strattera 60 mg Kapsel, hård)
Approval ID: 90043 Approval Date: 02/NOV/1990
(Alutard SQ 3-Träd 100 000 SQ-E/ml Injektionsvätska, suspension)
Approval ID: 90043 Approval Date: 02/NOV/1990
(Alutard SQ 3-Träd 100 000 SQ-E/ml Injektionsvätska, suspension)

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :130631(0)**

Reaction Information (Cont...)

Seq. No.	:	1
Reaction	:	Anafylaktisk reaktion (Anaphylactic reaction)
Start Date	:	07/Feb/2013
Seq. No.	:	2
Reaction	:	Trötthet (Fatigue)
Start Date	:	07/Feb/2013
Seq. No.	:	3
Reaction	:	Yrsel (Dizziness)
Start Date	:	07/Feb/2013
Seq. No.	:	4
Reaction	:	Konjunktivit (Conjunctivitis)
Start Date	:	07/Feb/2013
Seq. No.	:	5
Reaction	:	Miktionsbesvär (Micturition disorder)
Start Date	:	07/Feb/2013

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Miktionsbesvär (Micturition disorder) - Okänd
Protocol relatedness:
As per reporter:
As per company: Icke allvarlig

Case level outcome :Okänd

[redacted]

Suspect Drugs (Cont...)

Product-Reaction level

Seq.No.	:	1
Drug	:	Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

Causality

1) Miktionsbesvär (Micturition disorder)

Continuation Sheet for CIOMS report

Mfr. Control No. :130631(0)

Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt

Seq.No. : 2
Drug : Alutard SQ 3-Träd(allergen, Alnus glutinosa pollen, allergen, Betula verrucosa pollen, allergen, Corylus avellana pollen)(allergen, Alnus glutinosa pollen, allergen, Betula verrucosa pollen, allergen, Corylus avellana pollen)
Therapy Dates/Duration : 1) /Sep/2011 -

Causality

1) Anafylaktisk reaktion (Anaphylactic reaction)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt
2) Trötthet (Fatigue)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt
3) Yrsel (Dizziness)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt
4) Konjunktivit (Conjunctivitis)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt

Concomitant drugs (Cont...)

Seq.No. : 2
Drug : LORATADIN(Loratadine)(Loratadine)

Causality

1) Anafylaktisk reaktion (Anaphylactic reaction)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt
2) Trötthet (Fatigue)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt
3) Yrsel (Dizziness)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt
4) Konjunktivit (Conjunctivitis)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt

Seq.No. : 3
Drug : Giona Easyhaler(budesonide)(budesonide)

Causality

1) Anafylaktisk reaktion (Anaphylactic reaction)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt
2) Trötthet (Fatigue)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt
3) Yrsel (Dizziness)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt
4) Konjunktivit (Conjunctivitis)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt

Continuation Sheet for CIOMS report **Mfr. Control No. :130631(0)**

Seq.No. : 4
Drug : Betapred(betamethasone, betamethasone sodium phosphate)(betamethasone, betamethasone sodium phosphate)

Causality

1) Anafylaktisk reaktion (Anaphylactic reaction)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt

2) Trötthet (Fatigue)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt

3) Yrsel (Dizziness)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt

4) Konjunktivit (Conjunctivitis)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Okänt
Rechallenge : Okänt

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :131239(0)

I.REACTION INFORMATION

1.PATIENT INITIALS	1a.COUNTRY	2.DATE OF BIRTH DA	2.DATE OF BIRTH MO	2.DATE OF BIRTH YR	2a. AGE YRS	3. SEX	4.-6. REACTION ONSET DA	4.-6. REACTION ONSET MO	4.-6. REACTION ONSET YR	8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				19	Man		FEB	2013	

7.+13. DESCRIBE REACTION(S) (include relevant test/lab data)

Klåda (Pruritus) - Inte tillfrisknat/inte resolverad
Protocol relatedness:
As per reporter:
As per company: Icke allvarlig

Case level outcome :Inte tillfrisknat/inte resolverad

[redacted]

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

Icke allvarlig

II.SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

20.DID EVENT ABATE AFTER STOPPING DRUG? ☒ YES ☐ NO ☐ NA

15. DAILY DOSE: 1DFN (1 Doseringsform,Vid beh.)

16. ROUTE OF ADMINISTRATION: Per oral

21.DID EVENT REAPPEAR AFTER REINTRODUCTION? ☒ YES ☐ NO ☐ NA

17. INDICATIONS FOR USE

18. THERAPY DATES(From/To)

19. THERAPY DURATION

III.CONCOMITANT DRUGS AND HISTORY

22.CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23. OTHER RELEVANT HISTORY

[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b. MFR. CONTROL NO. 131239(0)

24c. DATE RECEIVED BY MANUFACTURER: 21/OCT/2013

24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☐ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT: 20/MAR/2014

25a. REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Approval ID: 22644 Approval Date: 21/APR/2006
(Strattera 10 mg Kapsel, hård)

Cont . . . = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :131239(0)**

Suspect Drugs (Cont...)

Product-Reaction level

Seq.No. : 1
Drug : Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

Causality

1) Klåda (Pruritus)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Causality as per Mfr.(Drug/Vaccine) : Probable
Dechallenge : Positivt
Rechallenge : Positivt

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :131785(0)

I.REACTION INFORMATION

1.PATIENT INITIALS	1a.COUNTRY	2.DATE OF BIRTH			2a. AGE	3. SEX	4.-6. REACTION ONSET			8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION
		DA	MO	YR	YRS		DA	MO	YR	
	SVERIGE					Kvinna				

7.+13. DESCRIBE REACTION(S) (include relevant test/lab data)

Psykos (Psychosis NOS) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Minnesbortfall (Amnesia) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Tillfrisknat/resolverad

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II.SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

20.DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE

16. ROUTE OF ADMINISTRATION

21.DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17. INDICATIONS FOR USE

18. THERAPY DATES(From/To)

19. THERAPY DURATION

III.CONCOMITANT DRUGS AND HISTORY

22.CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23. OTHER RELEVANT HISTORY

[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

MPA
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Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b. MFR. CONTROL NO. 131785(0)

24c. DATE RECEIVED BY MANUFACTURER 26/APR/2013

24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☐ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 20/MAR/2014

25a. REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Approval ID: 22647 Approval Date: 21/APR/2006
(Strattera 40 mg Kapsel, hård)

= Continuation attached sheet(s)

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :132536(0)

I.REACTION INFORMATION

1.PATIENT INITIALS	1a.COUNTRY	2.DATE OF BIRTH DA	2.DATE OF BIRTH MO	2.DATE OF BIRTH YR	2a. AGE YRS	3. SEX	4.-6. REACTION ONSET DA	4.-6. REACTION ONSET MO	4.-6. REACTION ONSET YR
	SVERIGE				35	Man	11	APR	2012

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☒ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7.+13. DESCRIBE REACTION(S) (include relevant test/lab data)

Blödning cerebral (Cerebral haemorrhage) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Hypertension (Hypertension) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

[redacted]

Cont...

II.SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

1) Strattera(atomoxetine hydrochloride,
2) Medikinet(methylphenidate hydrochloride, methylphenidate,

Cont...

20.DID EVENT ABATE AFTER STOPPING DRUG?
Okänt
☐ YES ☐ NO ☐ NA

15. DAILY DOSE
1) 80MGD (80 Mill- 2) 1.2GMD (1.2 Gra-

16. ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21.DID EVENT REAPPEAR AFTER REINTRODUCTION?
Okänt
☐ YES ☐ NO ☐ NA

17. INDICATIONS FOR USE
[redacted]

18. THERAPY DATES(From/To)
1) 25/JAN/2012 2) 26/JAN/2012

19. THERAPY DURATION
1) 13 Månader 2) 13 Månader

III.CONCOMITANT DRUGS AND HISTORY

22.CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23. OTHER RELEVANT HISTORY

[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b. MFR. CONTROL NO.
132536(0)

24c. DATE RECEIVED BY MANUFACTURER
28/JUN/2013

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☐ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
20/MAR/2014

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA on 01/JUL/2013
Approval ID: 25646 Approval Date: 13/JUN/2008
(Strattera 80 mg Kapsel, hård)
Approval ID: 23843 Approval Date: 15/DEC/2006
(Medikinet 40 mg Kapsel med modifierad frisättning, hård)
Approval ID: 23843 Approval Date: 15/DEC/2006
(Medikinet 40 mg Kapsel med modifierad frisättning, hård)

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :132536(0)**

Reaction Information (Cont...)

Seq. No. : 1
Reaction : Blödning cerebral (Cerebral haemorrhage)
Start Date : 23/Feb/2013

Seq. No. : 2
Reaction : Hypertension (Hypertension)
Start Date : 11/Apr/2012

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

[redacted]

Suspect Drugs (Cont...)

Product-Reaction level

Seq.No. : 1
Drug : Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)
Daily Dose : 1) 80MGD (80 Milligram,On a Daily Basis)
Route of Admin : 1) Per oral
Therapy Dates/Duration : 1) 25/JAN/2012 - 23/FEB/2013

Causality

1) Blödning cerebral (Cerebral haemorrhage)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
2) Hypertension (Hypertension)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt

Seq.No. : 2
Drug : Medikinet(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride)
Daily Dose : 1) 1.2GMD (1.2 Gram,On a Daily Basis)
Route of Admin : 1) Per oral
Therapy Dates/Duration : 1) 26/JAN/2012 - 23/FEB/2013

Causality

1) Blödning cerebral (Cerebral haemorrhage)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
2) Hypertension (Hypertension)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt

Continuation Sheet for CIOMS report **Mfr. Control No. :132536(0)**

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :132863(0)

I.REACTION INFORMATION

1.PATIENT INITIALS	1a.COUNTRY	2.DATE OF BIRTH DA	MO	YR	2a. AGE YRS	3. SEX	4.-6. REACTION ONSET DA	MO	YR	8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				8	Kvinna				

7.+13. DESCRIBE REACTION(S) (include relevant test/lab data)

Blåsor i munnen (Blistering of mouth) - Okänd
Protocol relatedness:
As per reporter:
As per company: Icke allvarlig

Case level outcome :Okänd

[redacted]

Cont...

☐ PATIENT DIED
☐ LIFE THREATENING
☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
☐ CONGENITAL ANOMALY
☐ OTHER MEDICALLY IMPORTANT CONDITION

Icke allvarlig

II.SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

Cont...

20.DID EVENT ABATE AFTER STOPPING DRUG?
Okänt
☐ YES ☐ NO ☐ NA

15. DAILY DOSE
40MGD (40 Milligram,On a Daily

16. ROUTE OF ADMINISTRATION
Per oral

21.DID EVENT REAPPEAR AFTER REINTRODUCTION?
Okänt
☐ YES ☐ NO ☐ NA

17. INDICATIONS FOR USE

18. THERAPY DATES(From/To)

19. THERAPY DURATION

III.CONCOMITANT DRUGS AND HISTORY

22.CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Cont...

23. OTHER RELEVANT HISTORY

[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b. MFR. CONTROL NO.
132863(0)

24c. DATE RECEIVED BY MANUFACTURER
06/SEP/2013

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☐ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
20/MAR/2014

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Approval ID: 22644 Approval Date: 21/APR/2006
(Strattera 10 mg Kapsel, hård)

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :132863(0)**

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

[redacted]

Suspect Drugs (Cont...)

Product-Reaction level

Seq.No. : 1
Drug : Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)
Daily Dose : 1) 40MGD (40 Milligram,On a Daily Basis)
Route of Admin : 1) Per oral

Causality

1) Blåsor i munnen (Blistering of mouth)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt

Concomitant drugs (Cont...)

Seq.No. : 1
Drug : Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)

Causality

1) Blåsor i munnen (Blistering of mouth)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :132864(0)

I.REACTION INFORMATION

1.PATIENT INITIALS	1a.COUNTRY	2.DATE OF BIRTH DA	2.DATE OF BIRTH MO	2.DATE OF BIRTH YR	2a. AGE YRS	3. SEX	4.-6. REACTION ONSET DA	4.-6. REACTION ONSET MO	4.-6. REACTION ONSET YR
	SVERIGE				11	Man	16	JUL	2013

7.+13. DESCRIBE REACTION(S) (include relevant test/lab data)

Blåsor i munnen (Blistering of mouth) - Inte tillfrisknat/inte resolverad
Protocol relatedness:
As per reporter:
As per company: Icke allvarlig

Case level outcome :Inte tillfrisknat/inte resolverad

[redacted]

Cont...

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

Icke allvarlig

II.SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

Cont...

20.DID EVENT ABATE AFTER STOPPING DRUG?

☐ YES ☐ NO ☒ NA

15. DAILY DOSE
40MGD (40 Milligram,On a Daily

16. ROUTE OF ADMINISTRATION
Per oral

17. INDICATIONS FOR USE

21.DID EVENT REAPPEAR AFTER REINTRODUCTION?

Okänt

☐ YES ☐ NO ☐ NA

18. THERAPY DATES(From/To)

19. THERAPY DURATION
Kontinuerlig behandling

III.CONCOMITANT DRUGS AND HISTORY

22.CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23. OTHER RELEVANT HISTORY

[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b. MFR. CONTROL NO.
132864(0)

24c. DATE RECEIVED BY MANUFACTURER
05/SEP/2013

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☐ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
20/MAR/2014

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Approval ID: 22647 Approval Date: 21/APR/2006
(Strattera 40 mg Kapsel, hård)

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :132864(0)**

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

[redacted]

Suspect Drugs (Cont...)

Product-Reaction level

Seq.No.	:	1
Drug	:	Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)
Daily Dose	:	1) 40MGD (40 Milligram,On a Daily Basis)
Route of Admin	:	1) Per oral

Causality

1) Blåsor i munnen (Blistering of mouth)

Action(s) taken with drug	:	Inte tillämpbart
Causality as per Mfr.(Drug/Vaccine)	:	Possible
Dechallenge	:	Inte applicerbart
Rechallenge	:	Okänt

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :1361347336605(0)

I.REACTION INFORMATION

1.PATIENT INITIALS	1a.COUNTRY	2.DATE OF BIRTH			2a. AGE	3. SEX	4.-6. REACTION ONSET			8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION
		DA	MO	YR	YRS		DA	MO	YR	
	SVERIGE				18.61	Man		JAN	2011	

7.+13. DESCRIBE REACTION(S) (include relevant test/lab data)

Sömnparalys
(Sleep paralysis)
Protocol relatedness:
As per reporter:
As per company:

Psykosliknande tillstånd nattetid
(Nocturnal psychotic delusions)
Protocol relatedness:
As per reporter:
As per company:

Hallucinatoriskt tillstånd nattetid
(Hallucination)
Protocol relatedness:
As per reporter:
As per company:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II.SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

20.DID EVENT ABATE AFTER STOPPING DRUG?
☐ YES ☒ NO ☐ NA

15. DAILY DOSE
Minns ej

16. ROUTE OF ADMINISTRATION

21.DID EVENT REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO ☒ NA

17. INDICATIONS FOR USE
[redacted]

18. THERAPY DATES(From/To)
/Oct/2010 - /JAN/2011

19. THERAPY DURATION

III.CONCOMITANT DRUGS AND HISTORY

22.CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Melatonin(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine) /Mar/2010 -

Cont...

23. OTHER RELEVANT HISTORY
[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b. MFR. CONTROL NO.
1361347336605(0)

24c. DATE RECEIVED BY MANUFACTURER
20/FEB/2013

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☐ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
20/MAR/2014

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Approval ID: 22644 Approval Date: 21/APR/2006
(Strattera 10 mg Kapsel, hård)

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :1361347336605(0)**

Reaction Information (Cont...)

Seq. No.	:	1
Reaction	:	Sömnparalys (Sleep paralysis)
Start Date	:	/Jan/2011
Seq. No.	:	2
Reaction	:	Psykosliknande tillstånd nattetid (Nocturnal psychotic delusions)
Start Date	:	/Jan/2011
Seq. No.	:	3
Reaction	:	Hallucinatoriskt tillstånd nattetid (Hallucination)
Start Date	:	/Jan/2011
Seq. No.	:	4
Reaction	:	"Nattskräck" (Night terrors)
Start Date	:	/Jan/2011

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

"Nattskräck"
(Night terrors)
Protocol relatedness:
As per reporter:
As per company:

[redacted]

Suspect Drugs (Cont...)

Product-Reaction level

Seq.No.	:	1
Drug	:	Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

Causality

1) Sömnparalys (Sleep paralysis)		
Action(s) taken with drug	:	Avslutad läkemedelsbehandling
Outcome after Change in dose	:	Ingen förändring
Outcome after reintro. of dose	:	Icke applicerbart
Dechallenge	:	Negativt
Rechallenge	:	Inte applicerbart
2) Psykosliknande tillstånd nattetid (Nocturnal psychotic delusions)		
Action(s) taken with drug	:	Avslutad läkemedelsbehandling
Outcome after Change in dose	:	Ingen förändring
Outcome after reintro. of dose	:	Icke applicerbart
Dechallenge	:	Negativt
Rechallenge	:	Inte applicerbart
3) Hallucinatoriskt tillstånd nattetid (Hallucination)		
Action(s) taken with drug	:	Avslutad läkemedelsbehandling
Outcome after Change in dose	:	Ingen förändring
Outcome after reintro. of dose	:	Icke applicerbart
Dechallenge	:	Negativt
Rechallenge	:	Inte applicerbart
4) "Nattskräck" (Night terrors)		
Action(s) taken with drug	:	Avslutad läkemedelsbehandling
Outcome after Change in dose	:	Ingen förändring
Outcome after reintro. of dose	:	Icke applicerbart
Dechallenge	:	Negativt
Rechallenge	:	Inte applicerbart

Concomitant drugs (Cont...)

Seq.No.	:	1
Drug	:	Melatonin(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)
Indication for use	:	1) Sömn

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2013-000226(0)

I.REACTION INFORMATION

1.PATIENT INITIALS	1a.COUNTRY	2.DATE OF BIRTH			2a. AGE	3. SEX	4.-6. REACTION ONSET			8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION
		DA	MO	YR	YRS		DA	MO	YR	
	SVERIGE					Man				

7.+13. DESCRIBE REACTION(S) (include relevant test/lab data)

HÖRSELHALLUCINATIONER (Auditory hallucinations) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

SYNHALLUCINATIONER (Visual hallucinations) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

ILLAMÅENDE (Nausea) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

KRÄKNINGAR (Vomiting) - Tillfrisknat utan men
Protocol relatedness:

Cont...

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☒ OTHER MEDICALLY IMPORTANT CONDITION

II.SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

20.DID EVENT ABATE AFTER STOPPING DRUG? ☒ YES ☐ NO ☐ NA

15. DAILY DOSE

16. ROUTE OF ADMINISTRATION

21.DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17. INDICATIONS FOR USE

18. THERAPY DATES(From/To)

19. THERAPY DURATION

III.CONCOMITANT DRUGS AND HISTORY

22.CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23. OTHER RELEVANT HISTORY

[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b. MFR. CONTROL NO.
2013-000226(0)

24e. DATE RECEIVED BY MANUFACTURER
05/NOV/2013

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
20/MAR/2014

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2013-000226(0)**

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

ANDRA OCH ICKE SPECIFIKA SMÄRTOR I BUKEN (Abdominal pain NOS) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Tillfrisknat utan men

[redacted]

Suspect Drugs (Cont...)

Product-Reaction level

Seq.No. : 1
Drug : Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

Causality

1) HÖRSELHALLUCINATIONER (Auditory hallucinations)
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Positivt
2) SYNHALLUCINATIONER (Visual hallucinations)
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Positivt
3) ILLAMÅENDE (Nausea)
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Positivt
4) KRÅKNINGAR (Vomiting)
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Positivt
5) ANDRA OCH ICKE SPECIFIKA SMÄRTOR I BUKEN (Abdominal pain NOS)
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Positivt

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2013-000355(1)

I.REACTION INFORMATION

1.PATIENT INITIALS	1a.COUNTRY	2.DATE OF BIRTH DA	2.DATE OF BIRTH MO	2.DATE OF BIRTH YR	2a. AGE YRS	3. SEX	4.-6. REACTION ONSET DA	4.-6. REACTION ONSET MO	4.-6. REACTION ONSET YR
	SVERIGE				25	Man	31	JUL	2013

7.+13. DESCRIBE REACTION(S) (include relevant test/lab data)

INTOXIKATION (Drug intoxication) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

[redacted]

Cont...

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II.SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

1) Ritalin(methylphenidate hydrochloride,

2) Strattera(atomoxetine hydrochloride,

Cont...

20.DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE 1) 2)

16. ROUTE OF ADMINISTRATION 1) 2)

21.DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17. INDICATIONS FOR USE

[redacted]

18. THERAPY DATES(From/To) 1) 2)

19. THERAPY DURATION 1) 2)

III.CONCOMITANT DRUGS AND HISTORY

22.CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23. OTHER RELEVANT HISTORY

[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b. MFR. CONTROL NO. 2013-000355(1)

24c. DATE RECEIVED BY MANUFACTURER 25/NOV/2013

24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 20/MAR/2014

25a. REPORT TYPE ☐ INITIAL ☒ FOLLOW UP ☐ FINAL

Informed EMA
Informed MPA
Informed MPA
Informed MPA
Informed MPA
Informed EMA
Informed MPA
Informed MPA
Informed MPA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2013-000355(1)**

Reaction Information (Cont...)

Seq. No. : 1
Reaction : INTOXIKATION (Drug intoxication)
Start Date : 31/Jul/2013

Seq. No. : 2
Reaction : AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date : 31/Jul/2013

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

[redacted]

Suspect Drugs (Cont...)

Seq.No. : 1
Drug : Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

Seq.No. : 2
Drug : Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

Seq.No. : 3
Drug : sertraline(Sertraline)(Sertraline)
Therapy Dates/Duration :

Seq.No. : 4
Drug : Oxascand(Oxazepam)(Oxazepam)

Seq.No. : 5
Drug : Imovane(zopiclone)(zopiclone)

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2013-000395(0)

I.REACTION INFORMATION

1.PATIENT INITIALS	1a.COUNTRY	2.DATE OF BIRTH			2a. AGE	3. SEX	4.-6. REACTION ONSET			8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION
		DA	MO	YR	YRS		DA	MO	YR	
	SVERIGE				43	Man	03	SEP	2013	

7.+13. DESCRIBE REACTION(S) (include relevant test/lab data)

MÖRK URIN (Discolouration urine) - Okänd
Protocol relatedness:
As per reporter:
As per company:

BLODDROPPAR I URINEN (Blood in urine) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

[redacted]

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II.SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)

20.DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE

16. ROUTE OF ADMINISTRATION

21.DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17. INDICATIONS FOR USE

18. THERAPY DATES(From/To)

19. THERAPY DURATION

III.CONCOMITANT DRUGS AND HISTORY

22.CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23. OTHER RELEVANT HISTORY

[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b. MFR. CONTROL NO. 2013-000395(0)

24c. DATE RECEIVED BY MANUFACTURER 06/NOV/2013

24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 20/MAR/2014

25a. REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed MPA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2013-000395(0)**

Reaction Information (Cont...)

Seq. No.	:	1
Reaction	:	MÖRK URIN (Discolouration urine)
Start Date	:	03/Sep/2013
Seq. No.	:	2
Reaction	:	BLODDROPPAR I URINEN (Blood in urine)
Start Date	:	03/Sep/2013