**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :130053(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 | | | | 14 | Man | 30 | DEC | 2012 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

Perifera ödem (Oedema peripheral) - Inte tillfrisknat/inte resolverad
Protocol relatedness:
As per reporter:
As per company:

Allergisk reaktion (Allergic reaction) - Inte tillfrisknat/inte resolverad
Protocol relatedness:
As per reporter:
As per company:

Exantem (Rash) - Inte tillfrisknat/inte resolverad
Protocol relatedness:
As per reporter:
As per company:

Klåda (Pruritus) - Inte tillfrisknat/inte 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)

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

| 15. DAILY DOSE | 16. ROUTE OF ADMINISTRATION |
|---|---|
| 27MGD (27 Milligram,On a Daily | Per oral |

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

17. INDICATIONS FOR USE

| 18. THERAPY DATES(From/To) | 19. THERAPY DURATION |
|---|---|
| 28/DEC/2012 - 30/DEC/2012 | 3 Dagar |

### 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

No Risk Factor Available

### IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO. 130053(0)

24c. DATE RECEIVED BY MANUFACTURER 06/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 06/FEB/2013
Approval ID: 26554 Approval Date: 13/JUN/2008
(Concerta 27 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :130053(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | Perifera ödem (Oedema peripheral) |
| Start Date | : | 01/Jan/2013 |
| Seq. No. | : | 2 |
| Reaction | : | Allergisk reaktion (Allergic reaction) |
| Start Date | : | 30/Dec/2012 |
| Seq. No. | : | 3 |
| Reaction | : | Exantem (Rash) |
| Start Date | : | 30/Dec/2012 |
| Seq. No. | : | 4 |
| Reaction | : | Klåda (Pruritus) |
| Start Date | : | 30/Dec/2012 |
| Seq. No. | : | 5 |
| Reaction | : | Ögonlockssvullnad (Eyelid oedema) |
| Start Date | : | 01/Jan/2013 |

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

As per reporter:
As per company:

Ögonlockssvullnad (Eyelid oedema) - Inte tillfrisknat/inte resolverad
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Inte tillfrisknat/inte resolverad

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

| | | |
|---|---|---|
| Seq.No. | : | 1 |
| Drug | : | Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate) |
| Daily Dose | : | 1) 27MGD (27 Milligram,On a Daily Basis) |
| Route of Admin | : | 1) Per oral |

## Causality

1) Perifera ödem (Oedema peripheral)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Negativt |
| Rechallenge | : | Ej återinsatt |

2) Allergisk reaktion (Allergic reaction)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Negativt |
| Rechallenge | : | Ej återinsatt |

3) Exantem (Rash)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Negativt |
| Rechallenge | : | Ej återinsatt |

4) Klåda (Pruritus)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Negativt |
| Rechallenge | : | Ej återinsatt |

5) Ögonlockssvullnad (Eyelid oedema)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |

**Continuation Sheet for CIOMS report** **Mfr. Control No. :130053(0)**

| | | |
|---|---|---|
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Negativt |
| Rechallenge | : | Ej återinsatt |

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :130055(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 | | | | 21 | Man | 15 | JUN | 2012 | |

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

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

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

Case level outcome :Tillfrisknat/resolverad

13/0055

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)

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

| 15. DAILY DOSE | 16. ROUTE OF ADMINISTRATION |
|---|---|
| 36MGD (36 Milligram,On a Daily | Per oral |

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

17. INDICATIONS FOR USE

| 18. THERAPY DATES(From/To) | 19. THERAPY DURATION |
|---|---|
| 10/MAY/2012 - 18/JUN/2012 | 6 Veckor |

### 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

No Risk Factor Available

### IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO. 130055(0)

24c. DATE RECEIVED BY MANUFACTURER: 30/JAN/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 30/JAN/2013
Approval ID: 18541 Approval Date: 01/NOV/2002
(Concerta 18 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :130055(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | Hypotension (Hypotension) |
| Start Date | : | 15/Jun/2012 |
| Seq. No. | : | 2 |
| Reaction | : | Yrsel (Dizziness) |
| Start Date | : | 15/Jun/2012 |

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

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

| | | |
|---|---|---|
| Seq.No. | : | 1 |
| Drug | : | Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate) |
| Daily Dose | : | 1) 36MGD (36 Milligram,On a Daily Basis) |
| Route of Admin | : | 1) Per oral |

### Causality

1) Hypotension (Hypotension)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Okänt |

2) Yrsel (Dizziness)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Okänt |

CIOMS FORM

# SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :130056(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 |
|---|---|---|---|---|---|---|---|---|---|
| | SVERIGE | | | | 22 | Man | 31 | OCT | 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)

Tryckkänsla i bröstet (Chest heaviness) - Inte tillfrisknat/inte resolverad
Protocol relatedness:
As per reporter:
As per company:

V.e.s. (Extrasystoles ventricular) - Inte tillfrisknat/inte resolverad
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Inte tillfrisknat/inte resolverad

12/0056

Cont...

## II.SUSPECT DRUG(S) INFORMATION

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

Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

Cont...

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

15. DAILY DOSE
20MGD (20 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)
23/AUG/2012 - 31/OCT/2012

19. THERAPY DURATION
2 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
No Risk Factor Available

## IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
130056(0)

24c. DATE RECEIVED BY MANUFACTURER
30/JAN/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 30/JAN/2013
Approval ID: 20607 Approval Date: 15/JUN/2005
(Ritalin 20 mg Kapsel med modifierad frisättning, hård)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :130056(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | Tryckkänsla i bröstet (Chest heaviness) |
| Start Date | : | 31/Oct/2012 |
| Seq. No. | : | 2 |
| Reaction | : | V.e.s. (Extrasystoles ventricular) |
| Start Date | : | 31/Oct/2012 |

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

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

| | | |
|---|---|---|
| Seq.No. | : | 1 |
| Drug | : | Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate) |
| Daily Dose | : | 1) 20MGD (20 Milligram,On a Daily Basis) |
| Route of Admin | : | 1) Per oral |

## Causality

1) Tryckkänsla i bröstet (Chest heaviness)

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

2) V.e.s. (Extrasystoles ventricular)

| | | |
|---|---|---|
| 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. :130057(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 | | | | 32 | Man | 23 | MAY | 2012 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

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

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

Case level outcome :Tillfrisknat/resolverad

13/0057

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)

Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

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): 17/MAY/2012 - 23/MAY/2012

19. THERAPY DURATION: 7 Dagar

### 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

No Risk Factor Available

### IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO.: 130057(0)

24c. DATE RECEIVED BY MANUFACTURER: 30/JAN/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 30/JAN/2013
Approval ID: 20606 Approval Date: 15/JUN/2005
(Ritalin 10 mg Tablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :130057(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | Hypotension (Hypotension) |
| Start Date | : | 23/May/2012 |
| Seq. No. | : | 2 |
| Reaction | : | Yrsel (Dizziness) |
| Start Date | : | 23/May/2012 |

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

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

| | | |
|---|---|---|
| Seq.No. | : | 1 |
| Drug | : | Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate) |
| Daily Dose | : | 1) 40MGD (40 Milligram,On a Daily Basis) |
| Route of Admin | : | 1) Per oral |

### Causality

1) Hypotension (Hypotension)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Okänt |

2) Yrsel (Dizziness)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Okänt |

**CIOMS FORM**

# SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :130260(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 | | | | 26 | Man | 17 | JAN | 2013 | |

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

Raynaud fenomen (Raynaud-like disorder) - 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)

Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

Cont...

20.DID EVENT ABATE AFTER STOPPING DRUG?

☐ YES ☐ NO ☒ NA

15. DAILY DOSE
120MGD (120 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)
18/MAY/2012 -

19. THERAPY DURATION
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
No Risk Factor Available

## IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
130260(0)

24c. DATE RECEIVED BY MANUFACTURER
09/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: 20608 Approval Date: 15/JUN/2005
(Ritalin 30 mg Kapsel med modifierad frisättning, hård)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :130260(0)**

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

[redacted]

**Suspect Drugs (Cont...)**

**Product-Reaction level**

| | | |
|---|---|---|
| Seq.No. | : | 1 |
| Drug | : | Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate) |
| Daily Dose | : | 1) 120MGD (120 Milligram,On a Daily Basis) |
| Route of Admin | : | 1) Per oral |

**Causality**

1) Raynaud fenomen (Raynaud-like disorder)

| | | |
|---|---|---|
| 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. :130508(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 |
|---|---|---|---|---|---|---|---|---|---|
| | SVERIGE | | | | 52 | Man | 15 | DEC | 2012 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

Personlighetsförändring (Personality disorder NOS) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Konfusion (Confusion) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Tillfrisknat/resolverad

13/0508

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)

Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

Cont...

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

| 15. DAILY DOSE | 16. ROUTE OF ADMINISTRATION |
|---|---|
| 300MGD (300 Milligram,On a Daily | Per oral |

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

17. INDICATIONS FOR USE

| 18. THERAPY DATES(From/To) | 19. THERAPY DURATION |
|---|---|
| 26/OCT/2012 - 18/DEC/2012 | 8 Veckor |

### III.CONCOMITANT DRUGS AND HISTORY

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

ENALAPRIL(Enalapril)(Enalapri-
l)

23. OTHER RELEVANT HISTORY

No Risk Factor Available

### IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO. 130508(0)

24c. DATE RECEIVED BY MANUFACTURER 11/JUL/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 12/JUL/2013
Approval ID: 20606 Approval Date: 15/JUN/2005
(Ritalin 10 mg Tablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :130508(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | Personlighetsförändring (Personality disorder NOS) |
| Start Date | : | 15/Dec/2012 |
| Seq. No. | : | 2 |
| Reaction | : | Konfusion (Confusion) |
| Start Date | : | 15/Dec/2012 |

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

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

| | | |
|---|---|---|
| Seq.No. | : | 1 |
| Drug | : | Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate) |
| Daily Dose | : | 1) 300MGD (300 Milligram,On a Daily Basis) |
| Route of Admin | : | 1) Per oral |

## Causality

1) Personlighetsförändring (Personality disorder NOS)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Ej återinsatt |

2) Konfusion (Confusion)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Ej återinsatt |

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :130950(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 | | | | 29 | Kvinna | 21 | FEB | 2013 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

Medvetslöshet (Unconsciousness) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Intoxikation (Drug intoxication) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Konvulsioner (Seizure) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Tillfrisknat/resolverad

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)

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate,

Cont...

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

15. DAILY DOSE
108MGD (108 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)

Omeprazol
Teva(omeprazole)(omeprazole)

Cont...

23. OTHER RELEVANT HISTORY
No Risk Factor Available

### IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
130950(0)

24c. DATE RECEIVED BY MANUFACTURER
08/MAY/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 08/MAY/2013
Approval ID: 18543 Approval Date: 01/NOV/2002
(Concerta 54 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :130950(0)**

## Reaction Information ( Cont...)

Seq. No. : 1
Reaction : Medvetslöshet (Unconsciousness)
Start Date : 21/Feb/2013

Seq. No. : 2
Reaction : Intoxikation (Drug intoxication)
Start Date : 21/Feb/2013

Seq. No. : 3
Reaction : Konvulsioner (Seizure)
Start Date : 21/Feb/2013

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

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

Seq.No. : 1
Drug : Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate, methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate, methylphenidate hydrochloride, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)
Daily Dose : 1) 108MGD (108 Milligram,On a Daily Basis)
Route of Admin : 1) Per oral

### Causality

1) Medvetslöshet (Unconsciousness)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
2) Intoxikation (Drug intoxication)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
3) Konvulsioner (Seizure)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt

## Concomitant drugs (Cont...)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :130950(0)**

Seq.No. : 2
Drug : Venlafaxine Bluefish(venlafaxine hydrochloride, venlafaxine)(venlafaxine hydrochloride, venlafaxine)

## Causality

1) Medvetslöshet (Unconsciousness)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
2) Intoxikation (Drug intoxication)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
3) Konvulsioner (Seizure)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt

Seq.No. : 3
Drug : Aerius(desloratadine)(desloratadine)

## Causality

1) Medvetslöshet (Unconsciousness)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
2) Intoxikation (Drug intoxication)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
3) Konvulsioner (Seizure)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt

Seq.No. : 4
Drug : Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)

## Causality

1) Medvetslöshet (Unconsciousness)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
2) Intoxikation (Drug intoxication)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
3) Konvulsioner (Seizure)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt

Seq.No. : 5
Drug : Citodon(codeine phosphate hemihydrate, paracetamol, codeine anhydrous)(codeine phosphate hemihydrate, paracetamol, codeine anhydrous)

## Causality

1) Medvetslöshet (Unconsciousness)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
2) Intoxikation (Drug intoxication)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
3) Konvulsioner (Seizure)
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. :130950(0)**

Seq.No. : 6
Drug : Oxascand(oxazepam)(oxazepam)

## Causality

1) Medvetslöshet (Unconsciousness)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
2) Intoxikation (Drug intoxication)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
3) Konvulsioner (Seizure)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt

Seq.No. : 7
Drug : Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

## Causality

1) Medvetslöshet (Unconsciousness)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
2) Intoxikation (Drug intoxication)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
3) Konvulsioner (Seizure)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt

Seq.No. : 8
Drug : Prionelle 28(levonorgestrel, ethinylestradiol)(levonorgestrel, ethinylestradiol)

## Causality

1) Medvetslöshet (Unconsciousness)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
2) Intoxikation (Drug intoxication)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
3) Konvulsioner (Seizure)
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. :130968(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 | | | | 41 | Man | 27 | FEB | 2013 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

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

Case level outcome :Okänd

QC 2013-10-10 MG/EH

- ☐ 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)

Medikinet(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

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

15. DAILY DOSE

16. ROUTE OF ADMINISTRATION

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)

Concomitant Drug Not Available

23. OTHER RELEVANT HISTORY

No Risk Factor Available

### IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO.
130968(0)

24c. DATE RECEIVED BY MANUFACTURER
10/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: 23835 Approval Date: 15/DEC/2006
(Medikinet 5 mg Tablett)
Approval ID: 23835 Approval Date: 15/DEC/2006
(Medikinet 5 mg Tablett)

Cont . . . = Continuation attached sheet(s)

## Continuation Sheet for CIOMS report

## Mfr. Control No. :130968(0)

### Suspect Drugs (Cont...)

### Product-Reaction level

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

### Causality

1) Hypertension (Hypertension)
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. :131083(0)

## I.REACTION INFORMATION

| 1.PATIENT INITIALS | 1a.COUNTRY | 2.DATE OF BIRTH | | | 2a. AGE | 3. SEX | 4.-6. REACTION ONSET | | |
|---|---|---|---|---|---|---|---|---|---|
| | | DA | MO | YR | YRS | | DA | MO | YR |
| | SVERIGE | | | | 31 | Man | 05 | MAR | 2013 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

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

Missbruk (Drug abuse) - Okänd
Protocol relatedness:
As per reporter:
As per company:

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

Kreatinin stegring (Creatinine blood increased) - Okänd
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)

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

15. DAILY DOSE

16. ROUTE OF ADMINISTRATION

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)

Concomitant Drug Not Available

23. OTHER RELEVANT HISTORY

No Risk Factor Available

## IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO.
131083(0)

24c. DATE RECEIVED BY MANUFACTURER
22/MAY/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 28/MAY/2013
Approval ID: 18541 Approval Date: 01/NOV/2002
(Concerta 18 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :131083(0)**

## Reaction Information ( Cont...)

Seq. No. : 1
Reaction : Intoxikation (Drug intoxication)
Start Date : 05/Mar/2013

Seq. No. : 2
Reaction : Missbruk (Drug abuse)
Start Date : 05/Mar/2013

Seq. No. : 3
Reaction : Aggressivitet (Aggressiveness)
Start Date : 05/Mar/2013

Seq. No. : 4
Reaction : Kreatinin stegring (Creatinine blood increased)
Start Date : 05/Mar/2013

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

As per reporter:
As per company:

Case level outcome :Okänd

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

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

2) Missbruk (Drug abuse)
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

4) Kreatinin stegring (Creatinine blood increased)
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. :131258(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)

Svullnad munhåla/svalg (Throat oedema) - Inte tillfrisknat/inte resolverad
Protocol relatedness:
As per reporter:
As per company:

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

Case level outcome :Inte tillfrisknat/inte 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)

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

No Risk Factor Available

### IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO. 131258(0)

24c. DATE RECEIVED BY MANUFACTURER 28/MAR/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: 18541 Approval Date: 01/NOV/2002
(Concerta 18 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :131258(0)**

**Suspect 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) |

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :131432(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 |
|---|---|---|---|---|---|---|---|---|---|
| | SVERIGE | | | | 18 | Kvinna | 03 | APR | 2013 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

Blekhet (Pallor) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Bröstsmärtor (Chest pain) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Cyanos (Cyanosis) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Hjärtklappning (Palpitation) - 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)

Medikinet(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

Cont...

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

| 15. DAILY DOSE | 16. ROUTE OF ADMINISTRATION |
|---|---|
| 140MGD (140 Milligram,On a Daily | Per oral |

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

17. INDICATIONS FOR USE

| 18. THERAPY DATES(From/To) | 19. THERAPY DURATION |
|---|---|
| 16/JAN/2013 - 03/APR/2013 | 3 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

No Risk Factor Available

### IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO. 131432(0)

24c. DATE RECEIVED BY MANUFACTURER 05/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 10/JUN/2013
Approval ID: 23835 Approval Date: 15/DEC/2006 (Medikinet 5 mg Tablett)
Approval ID: 23835 Approval Date: 15/DEC/2006 (Medikinet 5 mg Tablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :131432(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | Blekhet (Pallor) |
| Start Date | : | 03/Apr/2013 |
| Seq. No. | : | 2 |
| Reaction | : | Bröstsmärtor (Chest pain) |
| Start Date | : | 03/Apr/2013 |
| Seq. No. | : | 3 |
| Reaction | : | Cyanos (Cyanosis) |
| Start Date | : | 03/Apr/2013 |
| Seq. No. | : | 4 |
| Reaction | : | Hjärtklappning (Palpitation) |
| Start Date | : | 03/Apr/2013 |
| Seq. No. | : | 5 |
| Reaction | : | Oro (Anxiety) |
| Start Date | : | 03/Apr/2013 |
| Seq. No. | : | 6 |
| Reaction | : | Synrubbning (Vision abnormal) |
| Start Date | : | 03/Apr/2013 |

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

As per reporter:
As per company:

Oro (Anxiety) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Synrubbning (Vision abnormal) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Tillfrisknat/resolverad

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

| | | |
|---|---|---|
| Seq.No. | : | 1 |
| Drug | : | Medikinet(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate) |
| Daily Dose | : | 1) 140MGD (140 Milligram,On a Daily Basis) |
| Route of Admin | : | 1) Per oral |

### Causality

1) Blekhet (Pallor)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Okänt |

2) Bröstsmärtor (Chest pain)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Okänt |

3) Cyanos (Cyanosis)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Okänt |

4) Hjärtklappning (Palpitation)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :131432(0)**

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

5) Oro (Anxiety)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Positivt
Rechallenge : Okänt

6) Synrubbning (Vision abnormal)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Positivt
Rechallenge : Okänt

CIOMS FORM

# SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :131828(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 | | | | 20 | Kvinna | 18 | SEP | 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)

Huvudvärk (Headache) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Diplopi (Diplopia) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Strabism (Strabismus) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

## II.SUSPECT DRUG(S) INFORMATION

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

Medikinet(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride)(methylphenidate hydrochloride, methylphenidate,

Cont...

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

15. DAILY DOSE
60MGD (60 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)
05/SEP/2012 -

19. THERAPY DURATION

## 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)

Cont...

23. OTHER RELEVANT HISTORY
No Risk Factor Available

## IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
131828(0)

24c. DATE RECEIVED BY MANUFACTURER
05/JUL/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 05/JUL/2013
Approval ID: 23841 Approval Date: 15/DEC/2006
(Medikinet 20 mg Kapsel med modifierad frisättning, hård)
Approval ID: 23841 Approval Date: 15/DEC/2006
(Medikinet 20 mg Kapsel med modifierad frisättning, hård)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :131828(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | Huvudvärk (Headache) |
| Start Date | : | 18/Sep/2012 |
| Seq. No. | : | 2 |
| Reaction | : | Diplopi (Diplopia) |
| Start Date | : | 18/Sep/2012 |
| Seq. No. | : | 3 |
| Reaction | : | Strabism (Strabismus) |
| Start Date | : | 18/Sep/2012 |

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

[redacted]

## Suspect Drugs (Cont...)

### Product-Reaction level

| | | |
|---|---|---|
| Seq.No. | : | 1 |
| Drug | : | Medikinet(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride) |
| Daily Dose | : | 1) 60MGD (60 Milligram,On a Daily Basis) |
| Route of Admin | : | 1) Per oral |

### Causality

1) Huvudvärk (Headache)

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

2) Diplopi (Diplopia)

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

3) Strabism (Strabismus)

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

## Concomitant drugs (Cont...)

| | | |
|---|---|---|
| Seq.No. | : | 2 |
| Drug | : | Nozinan(levomepromazine maleate, levomepromazine)(levomepromazine maleate, levomepromazine) |

### Causality

1) Huvudvärk (Headache)

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

2) Diplopi (Diplopia)

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

3) Strabism (Strabismus)

## Continuation Sheet for CIOMS report

## Mfr. Control No. :131828(0)

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

Seq.No. : 3
Drug : Circadin(melatonin)(melatonin)

### Causality

1) Huvudvärk (Headache)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
2) Diplopi (Diplopia)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
3) Strabism (Strabismus)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt

Seq.No. : 4
Drug : Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)

### Causality

1) Huvudvärk (Headache)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
2) Diplopi (Diplopia)
Action(s) taken with drug : Okänd
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt
Rechallenge : Okänt
3) Strabism (Strabismus)
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. :131978(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 | | | | 39 | Man | 10 | MAY | 2013 | |

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

Hjärtinfarkt (Myocardial infarction) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Tillfrisknat/resolverad

[redacted]

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)

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

15. DAILY DOSE
54MGD (54 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)
15/APR/2013 - 13/MAY/2013

19. THERAPY DURATION
4 Veckor

## III.CONCOMITANT DRUGS AND HISTORY

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

ZOLPIDEM(Zolpidem)(Zolpidem)

Cont...

23. OTHER RELEVANT HISTORY
No Risk Factor Available

## IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
131978(0)

24c. DATE RECEIVED BY MANUFACTURER
15/MAY/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 16/MAY/2013
Approval ID: 18541 Approval Date: 01/NOV/2002
(Concerta 18 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :131978(0)**

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

[redacted]

**Suspect Drugs (Cont...)**

**Product-Reaction level**

Seq.No. : 1
Drug : Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)
Daily Dose : 1) 54MGD (54 Milligram,On a Daily Basis)
Route of Admin : 1) Per oral

**Causality**

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

**Concomitant drugs (Cont...)**

Seq.No. : 2
Drug : Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

**Causality**

1) Hjärtinfarkt (Myocardial infarction)
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. :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

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

13/2536 epikris

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) 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

17. INDICATIONS FOR USE
1) 2)

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

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

No Risk Factor Available

### 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. :132558(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)

Perifera ödem (Oedema peripheral) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Exantem vesiko-bullöst (Rash vesiculo-bullous) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Exantem fjällande (Rash scaly) - 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)

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

No Risk Factor Available

### IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO.
132558(0)

24c. DATE RECEIVED BY MANUFACTURER
19/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

Approval ID: 21654 Approval Date: 26/JAN/2005
(Concerta 18 mg Depottablett)
Approval ID: 21654 Approval Date: 26/JAN/2005
(Concerta 18 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :132558(0)**

**Suspect 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)

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :132691(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)

Minskad libido (Libido decreased) - 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)

1) Oxascand(oxazepam)(oxazepam)

2) Medikinet(methylphenidate hydrochloride, methylphenidate,

Cont...

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

| 15. DAILY DOSE | 16. ROUTE OF ADMINISTRATION | 21.DID EVENT REAPPEAR AFTER REINTRODUCTION? |
|---|---|---|
| 1) 2) | 1) 2) | ☐ YES ☐ NO ☐ NA |
| 17. INDICATIONS FOR USE 1) 2) | | |
| 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

No Risk Factor Available

### IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO. 132691(0)

24c. DATE RECEIVED BY MANUFACTURER 02/JUL/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: 11083 Approval Date: 02/FEB/1990 (Oxascand 25 mg Tablett)
Approval ID: 23842 Approval Date: 15/DEC/2006 (Medikinet 30 mg Kapsel med modifierad frisättning, hård)
Approval ID: 23842 Approval Date: 15/DEC/2006 (Medikinet 30 mg Kapsel med modifierad frisättning, hård)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :132691(0)**

**Suspect Drugs (Cont...)**

Seq.No. : 2
Drug : Medikinet(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride)

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :132794(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 |
|---|---|---|---|---|---|---|---|---|---|
| | SVERIGE | | | | 35 | Man | 25 | JUN | 2013 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

St-sänkning (ST segment depressed) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company: Icke allvarlig

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

Case level outcome :Tillfrisknat/resolverad

Dnr 13/2794 (journal)

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)

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate,

Cont...

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

15. DAILY DOSE
54MG1 (54 Milligram,1 in 1 Dagar)

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)
- 25/JUN/2013

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
No Risk Factor Available

### IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
132794(0)

24c. DATE RECEIVED BY MANUFACTURER
30/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

Informed EMA on 02/OCT/2013
Approval ID: 18543 Approval Date: 01/NOV/2002
(Concerta 54 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :132794(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | St-sänkning (ST segment depressed) |
| Start Date | : | 25/Jun/2013 |
| Seq. No. | : | 2 |
| Reaction | : | Hjärtklappning (Palpitation) |
| Start Date | : | 25/Jun/2013 |

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

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

| | | |
|---|---|---|
| Seq.No. | : | 1 |
| Drug | : | Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate, methylphenidate hydrochloride, methylphenidate, methylphenidate hydrochloride, methylphenidate, methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate, methylphenidate hydrochloride, methylphenidate, methylphenidate hydrochloride, methylphenidate) |
| Route of Admin | : | 1) Per oral |

## Causality

1) St-sänkning (ST segment depressed)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Okänt |

2) Hjärtklappning (Palpitation)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Okänt |

CIOMS FORM

# SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :133128(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 | | | | 9 | Kvinna | 24 | JUN | 2013 | |

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

Hudreaktion övriga (Skin reaction) - 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)

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

20.DID EVENT ABATE AFTER STOPPING DRUG?

Okänt

☐ YES ☐ NO ☐ NA

15. DAILY DOSE

16. ROUTE OF ADMINISTRATION

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)

Atarax(hydroxyzine hydrochloride, hydroxyzine)(hydroxyzine hydrochloride, hydroxyzine)

23. OTHER RELEVANT HISTORY

No Risk Factor Available

## IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO.
133128(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: 18542 Approval Date: 01/NOV/2002
(Concerta 36 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :133128(0)**

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

SPC: exfoliativa tillstånd listat

[redacted]

**Suspect Drugs (Cont...)**

**Product-Reaction level**

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) Hudreaktion övriga (Skin reaction)
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. :133430(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 |
|---|---|---|---|---|---|---|---|---|---|
| | SVERIGE | | | | 16 | Kvinna | 02 | SEP | 2013 |

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

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

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

Case level outcome :Tillfrisknat/resolverad

[redacted]

Cont...

## II.SUSPECT DRUG(S) INFORMATION

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

Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

Cont...

20.DID EVENT ABATE AFTER STOPPING DRUG?

☒ YES ☐ NO ☐ NA

15. DAILY DOSE
20MGD (20 Milligram,On a Daily

16. ROUTE OF ADMINISTRATION
Per oral

21.DID EVENT REAPPEAR AFTER REINTRODUCTION?

☐ YES ☐ NO ☐ NA

17. INDICATIONS FOR USE

18. THERAPY DATES(From/To)
02/SEP/2013 - 02/SEP/2013

19. THERAPY DURATION
1 Dagar

## 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
No Risk Factor Available

## IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
133430(0)

24c. DATE RECEIVED BY MANUFACTURER
20/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: 20607 Approval Date: 15/JUN/2005
(Ritalin 20 mg Kapsel med modifierad frisättning, hård)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :133430(0)**

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

[redacted]

**Suspect Drugs (Cont...)**

**Product-Reaction level**

Seq.No. : 1
Drug : Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)
Daily Dose : 1) 20MGD (20 Milligram,On a Daily Basis)
Route of Admin : 1) Per oral

**Causality**

1) Parestesi (Paraesthesia)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Positivt
Rechallenge : Ej återinsatt

CIOMS FORM

# SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :133744(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 |
|---|---|---|---|---|---|---|---|---|---|
| | SVERIGE | | | | 11 | Man | 15 | APR | 2013 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

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

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

Case level outcome :Tillfrisknat/resolverad

13/3744

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)

Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

Cont...

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

15. DAILY DOSE: 20MGD (20 Milligram,On a Daily

16. ROUTE OF ADMINISTRATION: Per oral

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

17. INDICATIONS FOR USE

18. THERAPY DATES(From/To): 20/MAR/2013 - 24/APR/2013

19. THERAPY DURATION: 5 Veckor

## 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

No Risk Factor Available

## IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO.: 133744(0)

24c. DATE RECEIVED BY MANUFACTURER: 09/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: 20607 Approval Date: 15/JUN/2005 (Ritalin 20 mg Kapsel med modifierad frisättning, hård)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :133744(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | Arthralgi (Arthralgia) |
| Start Date | : | 15/Apr/2013 |
| Seq. No. | : | 2 |
| Reaction | : | Myalgi (Myalgia) |
| Start Date | : | 15/Apr/2013 |

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

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

| | | |
|---|---|---|
| Seq.No. | : | 1 |
| Drug | : | Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate) |
| Daily Dose | : | 1) 20MGD (20 Milligram,On a Daily Basis) |
| Route of Admin | : | 1) Per oral |

### Causality

1) Arthralgi (Arthralgia)

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

2) Myalgi (Myalgia)

| | | |
|---|---|---|
| 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. :133829(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)

Raynaud fenomen (Raynaud-like disorder) - 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)

Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

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

No Risk Factor Available

### IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO.
133829(0)

24c. DATE RECEIVED BY MANUFACTURER
11/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: 20607 Approval Date: 15/JUN/2005
(Ritalin 20 mg Kapsel med modifierad frisättning, hård)

= Continuation attached sheet(s)

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :133866(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)

Exantem (Rash) - Inte tillfrisknat/inte resolverad
Protocol relatedness:
As per reporter:
As per company:

Ögonlockssvullnad (Eyelid oedema) - Inte tillfrisknat/inte resolverad
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Inte tillfrisknat/inte 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)

Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

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

No Risk Factor Available

### IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO.
133866(0)

24c. DATE RECEIVED BY MANUFACTURER
14/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: 20608 Approval Date: 15/JUN/2005
(Ritalin 30 mg Kapsel med modifierad frisättning, hård)

= Continuation attached sheet(s)

CIOMS FORM

# SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :1358504004952(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 | | | | 11.94 | Man | | | 2007 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

Epilepsianfall
(Epileptic seizure)
Protocol relatedness:
As per reporter:
As per company:

[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)

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

15. DAILY DOSE
7GA913

16. ROUTE OF ADMINISTRATION

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

17. INDICATIONS FOR USE
ADHD

18. THERAPY DATES(From/To)
//2007 - //2010

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
No Risk Factor Available

## IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
1358504004952(0)

24c. DATE RECEIVED BY MANUFACTURER
18/JAN/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: 18542 Approval Date: 01/NOV/2002
(Concerta 36 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :1358504004952(0)**

## Suspect Drugs (Cont...)

## Product-Reaction level

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) Epilepsianfall
(Epileptic seizure)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Ingen förändring
Outcome after reintro. of dose : Biverkan återkom
Dechallenge : Negativt
Rechallenge : Positivt

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :1363524188272(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 | | | DA | MO | YR | |
| | SVERIGE | | | | YRS | Man | | | | |

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

Erektionsproblem
(Erection failure)
Protocol relatedness:
As per reporter:
As per company:

- ☐ 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)

Concerta (methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

15. DAILY DOSE
2st morgon

16. ROUTE OF ADMINISTRATION

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

17. INDICATIONS FOR USE
ADHD

18. THERAPY DATES(From/To)
13/DEC/2004 -

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
No Risk Factor Available

### IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
1363524188272(0)

24c. DATE RECEIVED BY MANUFACTURER
17/MAR/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: 18542 Approval Date: 01/NOV/2002
(Concerta 36 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :1363524188272(0)**

## Suspect Drugs (Cont...)

## Product-Reaction level

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) Erektionsproblem
(Erection failure)

Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Outcome after reintro. of dose : Biverkan återkom
Dechallenge : Positivt
Rechallenge : Positivt

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :1364293890580(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)

Muskelspänningar
(Muscle tension)
Protocol relatedness:
As per reporter:
As per company:

Orolighet
(Anxiety)
Protocol relatedness:
As per reporter:
As per company:

- ☐ 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)

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

15. DAILY DOSE
1 gång per dag

16. ROUTE OF ADMINISTRATION

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

17. INDICATIONS FOR USE
ADHD

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
No Risk Factor Available

### IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
1364293890580(0)

24c. DATE RECEIVED BY MANUFACTURER
26/MAR/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: 18541 Approval Date: 01/NOV/2002
(Concerta 18 mg Depottablett)

Cont... = Continuation attached sheet(s)

## Continuation Sheet for CIOMS report

## Mfr. Control No. :1364293890580(0)

### Suspect Drugs (Cont...)

### Product-Reaction level

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) Muskelspänningar
(Muscle tension)
Action(s) taken with drug : Ökad dos
Outcome after Change in dose : Resolving
Outcome after reintro. of dose : Biverkan återkom inte
Dechallenge : Positivt
Rechallenge : Negativt

2) Orolighet
(Anxiety)
Action(s) taken with drug : Ökad dos
Outcome after Change in dose : Resolving
Outcome after reintro. of dose : Biverkan återkom inte
Dechallenge : Positivt
Rechallenge : Negativt

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :1367413704001(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 | | | | 14 | Man | | SEP | 2012 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

HUMÖRSVÄNGNINGAR (Mood swings) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

PERSONLIGHETSFÖRÄNDRINGAR (Personality change) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

OBEHAGSKÄNSLA (Discomfort) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Tillfrisknat utan men

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)

Concerta (methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

15. DAILY DOSE
1 tablett om dagen

16. ROUTE OF ADMINISTRATION

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

17. INDICATIONS FOR USE
ADHD liknande besvär, förvärvad hjärnskada.

18. THERAPY DATES(From/To)
13/AUG/2012 - 10/DEC/2012

19. THERAPY DURATION
119 Dagar

### 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
No Risk Factor Available

### IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
1367413704001(1)

24c. DATE RECEIVED BY MANUFACTURER
15/JAN/2014

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
Approval ID: 18541 Approval Date: 01/NOV/2002
(Concerta 18 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :1367413704001(1)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | HUMÖRSVÄNGNINGAR (Mood swings) |
| Start Date | : | /Sep/2012 |
| Seq. No. | : | 2 |
| Reaction | : | PERSONLIGHETSFÖRÄNDRINGAR (Personality change) |
| Start Date | : | /Sep/2012 |
| Seq. No. | : | 3 |
| Reaction | : | OBEHAGSKÄNSLA (Discomfort) |
| Start Date | : | 26/Sep/2012 |

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

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

| | | |
|---|---|---|
| Seq.No. | : | 1 |
| Drug | : | Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate) |
| Daily Dose | : | 1) 1 tablett om dagen<br>En kort period 27mg. (18 Milligram,1 in 1 Dagar) |

## Causality

1) HUMÖRSVÄNGNINGAR (Mood swings)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Inte tillämpbart |
| Outcome after reintro. of dose | : | Icke applicerbart |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Rechallenge | : | Inte applicerbart |

2) PERSONLIGHETSFÖRÄNDRINGAR (Personality change)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Inte tillämpbart |
| Outcome after reintro. of dose | : | Icke applicerbart |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Rechallenge | : | Inte applicerbart |

3) OBEHAGSKÄNSLA (Discomfort)

| | | |
|---|---|---|
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :1371157966755(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 |
|---|---|---|---|---|---|---|---|---|---|
| | SVERIGE | | | | 25.04 | Man | | OCT | 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)

spänningshuvudvärk
(Tension headache)
Protocol relatedness:
As per reporter:
As per company:

muskelryckningar (ansikte, händer)
(Muscle twitching)
Protocol relatedness:
As per reporter:
As per company:

glömmer bort saker hela tiden
(Memory impairment)
Protocol relatedness:
As per reporter:
As per company:

Cont...

### II.SUSPECT DRUG(S) INFORMATION

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

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate,

Cont...

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

15. DAILY DOSE: 108mg

16. ROUTE OF ADMINISTRATION:

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

17. INDICATIONS FOR USE: adhd

18. THERAPY DATES(From/To): //2010 -

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

No Risk Factor Available

### IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO. 1371157966755(0)

24c. DATE RECEIVED BY MANUFACTURER: 13/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

Approval ID: 18543 Approval Date: 01/NOV/2002
(Concerta 54 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :1371157966755(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | spänningshuvudvärk<br>(Tension headache) |
| Start Date | : | /Oct/2012 |
| Seq. No. | : | 2 |
| Reaction | : | muskelryckningar (ansikte, händer)<br>(Muscle twitching) |
| Start Date | : | /Oct/2012 |
| Seq. No. | : | 3 |
| Reaction | : | glömmer bort saker hela tiden<br>(Memory impairment) |
| Start Date | : | //2013 |

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

[redacted]

## Suspect Drugs (Cont...)

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

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :1371844980774(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 |
|---|---|---|---|---|---|---|---|---|---|
| | SVERIGE | | | | 35.55 | Kvinna | 20 | JUN | 2013 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

Plötslig hjärtklappning
(Palpitation)
Protocol relatedness:
As per reporter:
As per company:

yrsel
(Dizziness)
Protocol relatedness:
As per reporter:
As per company:

värmevallningar
(Hot flushes)
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)

Concerta (methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

15. DAILY DOSE
1-2 tabletter dagligen

16. ROUTE OF ADMINISTRATION

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

17. INDICATIONS FOR USE
ADHD

18. THERAPY DATES(From/To)
07/JUN/2012 -

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
No Risk Factor Available

### IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
1371844980774(0)

24c. DATE RECEIVED BY MANUFACTURER
21/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

Approval ID: 18542 Approval Date: 01/NOV/2002
(Concerta 36 mg Depottablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :1371844980774(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | Plötslig hjärtklappning (Palpitation) |
| Start Date | : | 20/Jun/2013 |
| Seq. No. | : | 2 |
| Reaction | : | yrsel (Dizziness) |
| Start Date | : | 20/Jun/2013 |
| Seq. No. | : | 3 |
| Reaction | : | värmevallningar (Hot flushes) |
| Start Date | : | 20/Jun/2013 |
| Seq. No. | : | 4 |
| Reaction | : | Andfåddhet (Breathlessness) |
| Start Date | : | 20/Jun/2013 |
| Seq. No. | : | 5 |
| Reaction | : | domningar i händer och ben (Numbness of extremities) |
| Start Date | : | 20/Jun/2013 |
| Seq. No. | : | 6 |
| Reaction | : | krypningar i händer och ben (Tingling of extremity) |
| Start Date | : | 20/Jun/2013 |
| Seq. No. | : | 7 |
| Reaction | : | krampaktig känsla i händer (Cramp in hand) |
| Start Date | : | 20/Jun/2013 |
| Seq. No. | : | 8 |
| Reaction | : | förhöjt blodtryck (Blood pressure high) |
| Start Date | : | 20/Jun/2013 |

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

Andfåddhet
(Breathlessness)
Protocol relatedness:
As per reporter:
As per company:

domningar i händer och ben
(Numbness of extremities)
Protocol relatedness:
As per reporter:
As per company:

krypningar i händer och ben
(Tingling of extremity)
Protocol relatedness:
As per reporter:
As per company:

krampaktig känsla i händer
(Cramp in hand)
Protocol relatedness:
As per reporter:
As per company:

förhöjt blodtryck
(Blood pressure high)
Protocol relatedness:
As per reporter:
As per company:

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

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

## Causality

**Continuation Sheet for CIOMS report** **Mfr. Control No. :1371844980774(0)**

1) Plötslig hjärtklappning
(Palpitation)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
2) yrsel
(Dizziness)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
3) värmevallningar
(Hot flushes)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
4) Andfåddhet
(Breathlessness)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
5) domningar i händer och ben
(Numbness of extremities)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
6) krypningar i händer och ben
(Tingling of extremity)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
7) krampaktig känsla i händer
(Cramp in hand)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
8) förhöjt blodtryck
(Blood pressure high)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt

## Concomitant drugs (Cont...)

Seq.No. : 1
Drug : L-Glutamin 1400mg(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)
Daily Dose : 1) 1-2 tabletter dagligen

### Causality

1) Plötslig hjärtklappning
(Palpitation)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
2) yrsel
(Dizziness)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
3) värmevallningar
(Hot flushes)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
4) Andfåddhet
(Breathlessness)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
5) domningar i händer och ben
(Numbness of extremities)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
6) krypningar i händer och ben
(Tingling of extremity)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
7) krampaktig känsla i händer
(Cramp in hand)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt
8) förhöjt blodtryck
(Blood pressure high)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt

**Continuation Sheet for CIOMS report** **Mfr. Control No. :1371844980774(0)**

Seq.No. : 2
Drug : Magnesium 300mg(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)
Daily Dose : 1) 1-2 tabletter dagligen

## Causality

1) Plötslig hjärtklappning
(Palpitation)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt

2) yrsel
(Dizziness)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt

3) värmevallningar
(Hot flushes)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt

4) Andfåddhet
(Breathlessness)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt

5) domningar i händer och ben
(Numbness of extremities)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt

6) krypningar i händer och ben
(Tingling of extremity)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt

7) krampaktig känsla i händer
(Cramp in hand)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt

8) förhöjt blodtryck
(Blood pressure high)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Outcome after Change in dose : Resolving
Dechallenge : Positivt

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :1378452605304(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 | | | | 7.9 | Man | | MAY | 2013 |

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

ökade humörsvängningar
(Mood swings)
Protocol relatedness:
As per reporter:
As per company:

självmordsförsök
(Suicide attempt)
Protocol relatedness:
As per reporter:
As per company:

ökad våldsamhet
(Violent behavior)
Protocol relatedness:
As per reporter:
As per company:

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)

Medikinet(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride)(methylphenidate hydrochloride, methylphenidate,

Cont...

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
Koncentrationsbesvär, ADHD

18. THERAPY DATES(From/To)
/May/2013 - 03/SEP/2013

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
No Risk Factor Available

### IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
1378452605304(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: 23841 Approval Date: 15/DEC/2006
(Medikinet 20 mg Kapsel med modifierad frisättning, hård)
Approval ID: 23841 Approval Date: 15/DEC/2006
(Medikinet 20 mg Kapsel med modifierad frisättning, hård)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :1378452605304(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | ökade humörsvängningar (Mood swings) |
| Start Date | : | /May/2013 |
| Seq. No. | : | 2 |
| Reaction | : | självmordsförsök (Suicide attempt) |
| Start Date | : | 02/Sep/2013 |
| Seq. No. | : | 3 |
| Reaction | : | ökad våldsamhet (Violent behavior) |
| Start Date | : | /Jun/2013 |
| Seq. No. | : | 4 |
| Reaction | : | mord tankar (Morbid thoughts) |
| Start Date | : | /Aug/2013 |

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

mord tankar
(Morbid thoughts)
Protocol relatedness:
As per reporter:
As per company:

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

| | | |
|---|---|---|
| Seq.No. | : | 1 |
| Drug | : | Medikinet(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride) |

## Causality

1) ökade humörsvängningar
(Mood swings)

| | | |
|---|---|---|
| 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) självmordsförsök
(Suicide attempt)

| | | |
|---|---|---|
| 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) ökad våldsamhet
(Violent behavior)

| | | |
|---|---|---|
| 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) mord tankar
(Morbid thoughts)

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

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :1382097438352(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 | | | | 54.11 | Kvinna | 15 | OCT | 2012 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

Högt blodtryck
(Blood pressure high)
Protocol relatedness:
As per reporter:
As per company:

Svettningar
(Sweating)
Protocol relatedness:
As per reporter:
As per company:

Rapport med nummer 1382097438352 är en spontan rapport som skickats in av en konsument. En 55-årig kvinna med AV-block III rapporterar att hon drabbats av högt blodtryck och svettningar cirka 14 dagar efter behandlingsstart med Ritalin eller

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) Ritalin eller Medikinet
2) Ritalin(methylphenidate hydrochloride,

Cont...

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

| 15. DAILY DOSE | 16. ROUTE OF ADMINISTRATION |
|---|---|
| 1) 1 tab. morgon i- 2) 1 tab. morgon i- | 1) 2) |

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

17. INDICATIONS FOR USE
1) Kataplexi, Narkolepsi
2) Kataplexi, Narkolepsi

| 18. THERAPY DATES(From/To) | 19. THERAPY DURATION |
|---|---|
| 1) 01/OCT/2012 2) 01/OCT/2012 | 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
No Risk Factor Available

### IV. MANUFACTURER

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

24b. MFR. CONTROL NO. 1382097438352(0)

24c. DATE RECEIVED BY MANUFACTURER 18/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: 20606 Approval Date: 15/JUN/2005
(Ritalin 10 mg Tablett)
Approval ID: 23836 Approval Date: 15/DEC/2006
(Medikinet 10 mg Tablett)
Approval ID: 23836 Approval Date: 15/DEC/2006
(Medikinet 10 mg Tablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :1382097438352(0)**

## Reaction Information ( Cont...)

Seq. No. : 1
Reaction : Högt blodtryck (Blood pressure high)
Start Date : 15/Oct/2012

Seq. No. : 2
Reaction : Svettningar (Sweating)
Start Date : 15/Oct/2012

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

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

Seq.No. : 1
Drug : Ritalin eller Medikinet
Daily Dose : 1) 1 tab. morgon innan kl. 14.00, 13004/02
Therapy Dates/Duration : 1) 01/OCT/2012 -

### Causality

1) Högt blodtryck (Blood pressure high)
Action(s) taken with drug : Inte tillämpbart
Outcome after reintro. of dose : Okänd
Rechallenge : Okänt
2) Svettningar (Sweating)
Action(s) taken with drug : Inte tillämpbart
Outcome after reintro. of dose : Okänd
Rechallenge : Okänt

Seq.No. : 2
Drug : Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)
Daily Dose : 1) 1 tab. morgon innan kl. 14.00, 13004/02
Therapy Dates/Duration : 1) 01/OCT/2012 -

### Causality

1) Högt blodtryck (Blood pressure high)
Action(s) taken with drug : Inte tillämpbart
Outcome after reintro. of dose : Okänd
Rechallenge : Okänt
2) Svettningar (Sweating)
Action(s) taken with drug : Inte tillämpbart
Outcome after reintro. of dose : Okänd
Rechallenge : Okänt

Seq.No. : 3
Drug : Medikinet(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)
Daily Dose : 1) 1 tab. morgon innan kl. 14.00, 13004/02
Indication for use : 1) Kataplexi, Narkolepsi
Therapy Dates/Duration : 1) 01/OCT/2012 -

### Causality

1) Högt blodtryck (Blood pressure high)
Action(s) taken with drug : Inte tillämpbart
Outcome after reintro. of dose : Okänd
Rechallenge : Okänt
2) Svettningar (Sweating)
Action(s) taken with drug : Inte tillämpbart
Outcome after reintro. of dose : Okänd
Rechallenge : Okänt

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2013-000004(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 |
|---|---|---|---|---|---|---|---|---|---|
| | SVERIGE | | | | 20 | Kvinna | 08 | SEP | 2013 |

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)

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

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

Case level outcome :Tillfrisknat utan men

2013-000004( 0.0 )

Rapport från läkare gällande 20-årig kvinna med ADD (Attention Deficit Disord

Cont...

### II.SUSPECT DRUG(S) INFORMATION

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

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

15. DAILY DOSE

16. ROUTE OF ADMINISTRATION

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

17. INDICATIONS FOR USE
ADD (ATTENTION DEFICIT DISORDER)

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)

Imovane(zopiclone)(zopiclone)

23. OTHER RELEVANT HISTORY
No Risk Factor Available

### IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
2013-000004(0)

24c. DATE RECEIVED BY MANUFACTURER
24/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

Informed EMA

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :2013-000004(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | SYNHALLUCINATIONER (Visual hallucinations) |
| Start Date | : | 08/Sep/2013 |
| Seq. No. | : | 2 |
| Reaction | : | HÖRSELHALLUCINATIONER (Auditory hallucinations) |
| Start Date | : | 08/Sep/2013 |

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

[redacted]

## Suspect Drugs (Cont...)

### Product-Reaction level

| | | |
|---|---|---|
| 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) SYNHALLUCINATIONER (Visual hallucinations)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Okänt |

2) HÖRSELHALLUCINATIONER (Auditory hallucinations)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Avslutad läkemedelsbehandling |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Okänt |

**CIOMS FORM**

# SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2013-000228(1)

## 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 | | | | 27 | Man | 01 | NOV | 2013 | |

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

HJÄRTINFARKT (Infarction) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Tillfrisknat utan men

[redacted]

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) Ritalin 30 mg Kapsel med modifierad frisättning, hård(Ritali

2) Ritalin 10 mg Tablett(Ritalin)(methylphenidate

Cont...

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

15. DAILY DOSE
1) 270 Milligram (- 2) 10 Milligram (1-

16. ROUTE OF ADMINISTRATION
1) 2)

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

17. INDICATIONS FOR USE
1) ADD 2) ADD

18. THERAPY DATES(From/To)
1) //2008 - 01 2) - 01/NOV/2

19. THERAPY DURATION
1) 5 År 2)

## III.CONCOMITANT DRUGS AND HISTORY

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

metformin(Metformin)(Metformi-
n)
simvastatin
venlafaxine (1 in 1 En gång)

23. OTHER RELEVANT HISTORY
No Risk Factor Available

## IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
2013-000228(1)

24c. DATE RECEIVED BY MANUFACTURER
11/DEC/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 EMA
Informed MPA
Approval ID: 20608 Approval Date: 15/JUN/2005
(Ritalin 30 mg Kapsel med modifierad frisättning, hård)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :2013-000228(1)**

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

[redacted]

**Suspect Drugs (Cont...)**

**Product-Reaction level**

Seq.No. : 1
Drug : Ritalin 30 mg Kapsel med modifierad frisättning, hård(Ritalin)(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)
Daily Dose : 1) 270 Milligram (90 Milligram,3 in 1 Dagar)
Therapy Dates/Duration : 1) //2008 - 01/NOV/2013

**Causality**

1) HJÄRTINFARKT (Infarction)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt

Seq.No. : 2
Drug : Ritalin 10 mg Tablett(Ritalin)(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)
Daily Dose : 1) 10 Milligram (10 Milligram,1 in 1 Dagar)
Therapy Dates/Duration : 1) - 01/NOV/2013

**Causality**

1) HJÄRTINFARKT (Infarction)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Causality as per Mfr.(Drug/Vaccine) : Possible
Dechallenge : Okänt

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2013-000324(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 | | | | 29 | Kvinna | 11 | OCT | 2013 | |

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

ALLERGISK CHOCK (Allergic shock) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Tillfrisknat utan men

[redacted]

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)

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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)
11/OCT/2013 - 11/OCT/2013

19. THERAPY DURATION

### III.CONCOMITANT DRUGS AND HISTORY

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

| | | |
|---|---|---|
| Omeprazol Sandoz(omeprazole)(omeprazole) | 10/MAY/2013 - | 40 Milligram (40 Milligram,1 in 1 Dagar) |

Cont...

23. OTHER RELEVANT HISTORY
No Risk Factor Available

### IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
2013-000324(0)

24c. DATE RECEIVED BY MANUFACTURER
12/DEC/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

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :2013-000324(0)**

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

[redacted]

**Suspect Drugs (Cont...)**

**Product-Reaction level**

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) ALLERGISK CHOCK (Allergic shock)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Causality as per Mfr.(Drug/Vaccine) : Possible
Rechallenge : Positivt

**Concomitant drugs (Cont...)**

Seq.No. : 2
Drug : Propyless(propylene glycol)(propylene glycol)
Daily Dose : 1) smörjes flera gånger dagligen
Therapy Dates/Duration : 1) 10/MAY/2013 -

Seq.No. : 3
Drug : Cipralex(escitalopram, escitalopram oxalate)(escitalopram, escitalopram oxalate)
Daily Dose : 1) 10 Milligram (10 Milligram,1 in 1 Dagar)
Therapy Dates/Duration : 1) 22/AUG/2013 -

Seq.No. : 4
Drug : Antabus(disulfiram)(disulfiram)
Daily Dose : 1) enligt schema
Therapy Dates/Duration : 1) 12/NOV/2012 -

Seq.No. : 5
Drug : Campral(acamprosate)(acamprosate)
Daily Dose : 1) 1998 Milligram (666 Milligram,3 in 1 Dagar)
Therapy Dates/Duration : 1) 02/FEB/2012 -

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

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

### 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 | | | | 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...

- ☐ 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
1) 2)

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

No Risk Factor Available

### 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. :2013-000633(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 | | | | 35 | Kvinna | | NOV | 2013 | |

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

LEDVÄRK (Joint pain) - Ännu ej tillfrisknat
Protocol relatedness:
As per reporter:
As per company:

HUVUDVÄRK (Headache) - Ännu ej tillfrisknat
Protocol relatedness:
As per reporter:
As per company:

RASTLÖSHET (Restlessness) - Ännu ej tillfrisknat
Protocol relatedness:
As per reporter:
As per company:

DARRNINGAR (Trembling) - Ännu ej tillfrisknat
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)

Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

No Risk Factor Available

### IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO.
2013-000633(0)

24c. DATE RECEIVED BY MANUFACTURER
05/DEC/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. :2013-000633(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | LEDVÄRK (Joint pain) |
| Start Date | : | /Nov/2013 |
| Seq. No. | : | 2 |
| Reaction | : | HUVUDVÄRK (Headache) |
| Start Date | : | /Nov/2013 |
| Seq. No. | : | 3 |
| Reaction | : | RASTLÖSHET (Restlessness) |
| Start Date | : | /Nov/2013 |
| Seq. No. | : | 4 |
| Reaction | : | DARRNINGAR (Trembling) |
| Start Date | : | /Nov/2013 |

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

As per reporter:
As per company:

Case level outcome :Ännu ej tillfrisknat

/ML

## Suspect 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) |

**CIOMS FORM**

## SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2014-000068(1)

### 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 |
|---|---|---|---|---|---|---|---|---|---|
| | SVERIGE | | | | 9 | Man | 29 | NOV | 2013 |

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)

UTSLAG (Rash) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

KLÅDA (Pruritus) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Tillfrisknat utan men

[redacted]

Cont...

### II.SUSPECT DRUG(S) INFORMATION

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

Medikinet 5 mg Tablett(Medikinet)(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)

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

15. DAILY DOSE
3+3+0+0 (15 Milligram,2 in 1 Dagar)

16. ROUTE OF ADMINISTRATION
Per oral

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

17. INDICATIONS FOR USE
MOT ADHD-SYMTOM

18. THERAPY DATES(From/To)
07/NOV/2013 -

19. THERAPY DURATION

### III.CONCOMITANT DRUGS AND HISTORY

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

Risperdal(risperidone)(risperidone)

Cont...

23. OTHER RELEVANT HISTORY
No Risk Factor Available
Past Disease:
ALLERGI MOT ÄGG

Cont...

### IV. MANUFACTURER

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

24b. MFR. CONTROL NO.
2014-000068(1)

24c. DATE RECEIVED BY MANUFACTURER
20/DEC/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 EMA
Approval ID: 23835 Approval Date: 15/DEC/2006
(Medikinet 5 mg Tablett)

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :2014-000068(1)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | UTSLAG (Rash) |
| Start Date | : | 29/Nov/2013 |
| Seq. No. | : | 2 |
| Reaction | : | KLÅDA (Pruritus) |
| Start Date | : | 29/Nov/2013 |

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

[redacted]

## Suspect Drugs (Cont...)

## Product-Reaction level

| | | |
|---|---|---|
| Seq.No. | : | 1 |
| Drug | : | Medikinet 5 mg Tablett(Medikinet)(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate) |

### Causality

1) UTSLAG (Rash)

| | | |
|---|---|---|
| Action(s) taken with drug | : | Dose återintroducerad |
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Negativt |

2) KLÅDA (Pruritus)

| | | |
|---|---|---|
| Causality as per Mfr.(Drug/Vaccine) | : | Possible |
| Dechallenge | : | Positivt |
| Rechallenge | : | Negativt |

## Concomitant drugs (Cont...)

| | | |
|---|---|---|
| Seq.No. | : | 2 |
| Drug | : | Circadin 2 mg Depottablett(Circadin)(melatonin)(melatonin) |

## Other relevant history (Cont...)

ALLERGI MOT MJÖLK

CIOMS FORM

# SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2014-000101(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 | | | | 23 | Kvinna | 04 | DEC | 2013 |

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

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

MAGSMÄRTOR (Abdominal pain) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Tillfrisknat utan men

AB/AA

- ☐ 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)

Concerta (methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride,

Cont...

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

No Risk Factor Available

## IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO. 2014-000101(0)

24c. DATE RECEIVED BY MANUFACTURER 20/DEC/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

Cont... = Continuation attached sheet(s)

**Continuation Sheet for CIOMS report** **Mfr. Control No. :2014-000101(0)**

## Reaction Information ( Cont...)

| | | |
|---|---|---|
| Seq. No. | : | 1 |
| Reaction | : | ILLAMÅENDE (Nausea) |
| Start Date | : | 04/Dec/2013 |
| Seq. No. | : | 2 |
| Reaction | : | MAGSMÄRTOR (Abdominal pain) |
| Start Date | : | 04/Dec/2013 |

## Suspect 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) |