CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :133074(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				13	Man	01	JUN	2013

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

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

Koordinationsrubbning (Coordination abnormal) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

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

Agitation (Agitation) - 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)

VYVANSE(Lisdexamfetamine)(Lisdexamfetamine)

Cont...

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

15. DAILY DOSE: 30MGD (30 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): 01/JUN/2013 - 02/JUN/2013

19. THERAPY DURATION: 2 Dagar

III.CONCOMITANT DRUGS AND HISTORY

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

MELATONIN(Melatonin)(Melatoni-
n)

23. OTHER RELEVANT HISTORY

[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO.: 133074(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

Informed EMA on 05/SEP/2013

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :133074(0)**

Reaction Information (Cont...)

Seq. No. : 1
Reaction : Exantem (Rash)
Start Date : 01/Jun/2013

Seq. No. : 2
Reaction : Koordinationsrubbning (Coordination abnormal)
Start Date : 01/Jun/2013

Seq. No. : 3
Reaction : Yrsel (Dizziness)
Start Date : 01/Jun/2013

Seq. No. : 4
Reaction : Agitation (Agitation)
Start Date : 01/Jun/2013

Seq. No. : 5
Reaction : Hyperaktivitet (Hyperactivity)
Start Date : 01/Jun/2013

Seq. No. : 6
Reaction : Affektiv störning (Affective disorder NOS)
Start Date : 01/Jun/2013

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

As per reporter:
As per company:

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

Affektiv störning (Affective disorder NOS) - 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 : VYVANSE(Lisdexamfetamine)(Lisdexamfetamine)
Daily Dose : 1) 30MGD (30 Milligram,On a Daily Basis)
Route of Admin : 1) Per oral

Causality

1) Exantem (Rash)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Causality as per Mfr.(Drug/Vaccine) : Unclassfiable
Dechallenge : Positivt
Rechallenge : Okänt
2) Koordinationsrubbning (Coordination abnormal)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Causality as per Mfr.(Drug/Vaccine) : Unclassfiable
Dechallenge : Positivt

Continuation Sheet for CIOMS report **Mfr. Control No. :133074(0)**

Rechallenge : Okänt
3) Yrsel (Dizziness)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Causality as per Mfr.(Drug/Vaccine) : Unclassfiable
Dechallenge : Positivt
Rechallenge : Okänt
4) Agitation (Agitation)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Causality as per Mfr.(Drug/Vaccine) : Unclassfiable
Dechallenge : Positivt
Rechallenge : Okänt
5) Hyperaktivitet (Hyperactivity)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Causality as per Mfr.(Drug/Vaccine) : Unclassfiable
Dechallenge : Positivt
Rechallenge : Okänt
6) Affektiv störning (Affective disorder NOS)
Action(s) taken with drug : Avslutad läkemedelsbehandling
Causality as per Mfr.(Drug/Vaccine) : Unclassfiable
Dechallenge : Positivt
Rechallenge : Okänt