CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :131613(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				9 Månad	Man	04	APR	2013

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

Temperatur stegring (Temperature elevation) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

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

Blodtrycksstegring (Blood pressure increased) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

Intoxikation (Drug intoxication) - Tillfrisknat/resolverad
Protocol relatedness:

Cont...

8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

II.SUSPECT DRUG(S) INFORMATION

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

METAMINA (Dexamfetamine sulfate) (Dexamfetamine sulfate)

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

15. DAILY DOSE

16. ROUTE OF ADMINISTRATION

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

17. INDICATIONS FOR USE

18. THERAPY DATES(From/To)

19. THERAPY DURATION

III.CONCOMITANT DRUGS AND HISTORY

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

Concomitant Drug Not Available

23. OTHER RELEVANT HISTORY

[redacted]

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

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

24b. MFR. CONTROL NO.
131613(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

Informed EMA on 20/JUN/2013

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :131613(0)**

Reaction Information (Cont...)

Seq. No.	:	1
Reaction	:	Temperatur stegring (Temperature elevation)
Start Date	:	04/Apr/2013
Seq. No.	:	2
Reaction	:	Takykardi (Tachycardia)
Start Date	:	04/Apr/2013
Seq. No.	:	3
Reaction	:	Blodtryckssstegring (Blood pressure increased)
Start Date	:	04/Apr/2013
Seq. No.	:	4
Reaction	:	Intoxikation (Drug intoxication)
Start Date	:	04/Apr/2013
Seq. No.	:	5
Reaction	:	Excitation (Excitement excessive)
Start Date	:	04/Apr/2013
Seq. No.	:	6
Reaction	:	Oro (Anxiety)
Start Date	:	04/Apr/2013

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

As per reporter:
As per company:

Excitation (Excitement excessive) - Tillfrisknat/resolverad
Protocol relatedness:
As per reporter:
As per company:

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

Case level outcome :Tillfrisknat/resolverad

