CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2014-000670(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)

ILLAMÅENDE (Nausea) - Ännu ej tillfrisknat
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Ännu ej tillfrisknat

[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)

Elvanse 30 mg Kapsel, hård(Elvanse)(lisdexamfetamine dimesilate, lisdexamfetamine)(lis dexamfetamine dimesilate, lisdexamfetamine)

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.
2014-000670(0)

24c. DATE RECEIVED BY MANUFACTURER
18/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

Approval ID: 47382 Approval Date: 22/JUL/2013
(Elvanse 30 mg Kapsel, hård)

= Continuation attached sheet(s)