CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
RFP	COSTA RICA	29	AUG	1958	66 Years	Female	70.00 kg		Unk	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

She forgets things [Memory impairment]
Insomnia disorder [Insomnia]
Blood pressure problems [Blood pressure abnormal]
She becomes very nervous [Nervousness]
She has a condition that causes her hands to move [Movement disorder]

Case Description: This non-serious post market survey report originated from Costa Rica was received by Viatris on 10-Jun-2025 (Local Ref No: VIA-2025-CR-0005).

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Lipitor 40 mg (ATORVASTATIN) Tablet, 40 milligram
#2) Clonazepam (Clonazepam) Unknown

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) UNK	#1) UNK
#2) UNK	#2) Oral use

17. INDICATION(S) FOR USE
#1) Cholesterol (Blood cholesterol abnormal)
#2) Insomnia (Insomnia)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Ongoing	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Vitamin b12 (Cyanocobalamin) Unknown ; Ongoing

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Blood cholesterol abnormal (Blood cholesterol abnormal)
Unknown to Ongoing	Current Condition	Insomnia (Insomnia)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
MYLANLABS
Balwant Heer
Building 4, Trident Place, Mosquito Way
Hatfield, Hertfordshire AL10 9UL UNITED KINGDOM
Phone: 44 01707853232

26. REMARKS
Medically Confirmed: No
World Wide #: CR-MYLANLABS-2025M1049722
Study ID: 9790

24b. MFR CONTROL NO.
2025M1049722

25b. NAME AND ADDRESS OF REPORTER
R F P

COSTA RICA

24c. DATE RECEIVED BY MANUFACTURER
10-JUN-2025

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

DATE OF THIS REPORT
17-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 2025M1049722

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient participated in 9790: Increase adherence of our chronic patients by ensuring proper patient stay on treatment and compliance. Our Program is designed to accompany the patient and provide benefits throughout their treatment.

This initial case, received from consumer, non-health professional in Costa Rica, involved a 66-years-old female patient who reportedly experienced memory impairment, insomnia, blood pressure abnormal, nervousness, movement disorder while receiving Lipitor 40 mg (atorvastatin).

Medical history was not reported.

Current conditions included blood cholesterol abnormal, insomnia and memory impairment.

Concomitant medication included vitamin b12 (cyanocobalamin).

Non company suspect drug included clonazepam.

Unknown date: The patient initiated atorvastatin 40 milligram tablet at an unknown dose, unit and frequency via unknown route (batch/lot number and expiration date was unknown) for cholesterol and clonazepam unknown formulation at an unknown dose, unit and frequency via oral route (batch/lot number and expiration date was unknown) for insomnia . The patient indicated that she stopped taking Lipitor 40 mg three years ago, but after blood tests, high cholesterol was detected, and she had to restart the medication. She also mentioned that she forgets things, which has happened progressively over the years. She also reported that she has an insomnia disorder, which was why she sometimes goes to bed around 2 or 3 in the morning and sleeps during the day, and that this situation was taking a toll on her health. She also indicated that she was undergoing psychiatric treatment because she becomes very nervous, and that she has a condition that causes her hands to move and has blood pressure problems. The patient also indicated that she takes several medications and believes that the ones that may be affecting her health are the generic products she receives from the clinic, specifically clonazepam. Laboratory data included blood cholesterol was high and blood pressure measurement was abnormal.

No action was taken with atorvastatin in response to the events.

Action taken with clonazepam was unknown.

On 10-Jun-2025, at the time of reporting the patient had not yet recovered from the events memory impairment, insomnia, blood pressure abnormal, nervousness, movement disorder.

Case Comment: Reporter assessed causality as unrelated for memory impairment, insomnia, blood pressure abnormal, nervousness and movement disorder.

Company Comment: Non-Serious: Memory impairment, insomnia, blood pressure abnormal, nervousness and movement disorder are unlisted events as per company RSI of atorvastatin. Causality has been assessed as possible for events memory impairment, insomnia, blood pressure abnormal, nervousness and movement disorder, as contributory role of suspect drug cannot be completely excluded as per available information. Non company suspect and existing medical condition could be a cofounder in this case.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood cholesterol High		
2		Blood pressure measurement Abnormal		

13. Relevant Tests

Unknown date: Laboratory data included blood cholesterol result was high and blood pressure result was abnormal.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Forgetfulness (Memory impairment);