SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
UNKNOWN	COSTA RICA		Unk		35 Years	Female	Unk	20	JUN	2025

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

Marked agitation, especially at nigh [Agitation]

Case Description: This non-serious spontaneous report originated from Costa Rica was received by Viatris on 15-Jul-2025 (Local reference number VIA-2025-CR-0008).

This initial case, received from physician in Costa Rica, involved a 35-years-old female patient who reportedly experienced agitation while receiving Altruline (sertraline).

(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) Altruline (SERTRALINE) Unknown
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) UNK

16. ROUTE(S) OF ADMINISTRATION
#1) UNK

17. INDICATION(S) FOR USE
#1) Drug use for unknown indication (Produ
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) 2025 / Unknown

19. THERAPY DURATION
#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Enalapril (Enalapril) Unknown ; Unknown
#2) Atorvastatin (Atorvastatin) Unknown ; Unknown
#3) Amlodipine (Amlodipine) Unknown ; Unknown

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	Hypertensive (Hypertension)
Unknown to Ongoing	Current Condition	Dyslipidemia (Dyslipidaemia)

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
World Wide #: CR-MYLANLABS-2025M1060420

24b. MFR CONTROL NO.
2025M1060420

25b. NAME AND ADDRESS OF REPORTER
Dr.

COSTA RICA

24c. DATE RECEIVED BY MANUFACTURER
15-JUL-2025

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

DATE OF THIS REPORT
24-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 2025M1060420

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Medical history was not reported.

Current condition included hypertension, and dyslipidaemia.

Concomitant medications were enalapril, atorvastatin, and amlodipine

Unknown date in 2025: The patient initiated sertraline of an unknown formulation at an unknown dose, unit and frequency and route (batch/lot number and expiration date unknown) for an unknown indication.

20-Jun-2025: The reporter stated patient experienced marked agitation, especially at night.

Action taken with sertraline was unknown.

On 15-Jul-2025 at the time of reporting the was recovering from the event agitation (currently, patient under control).

Case Comment: Reporter causality for event agitation was unasssable for Altruline.

Company Comment: Non-Serious: Agitation is a listed event as per company RSI of sertraline. Causality has been assessed as possible for event agitation as contributory role of suspect drug cannot be completely excluded considering the temporal association and known safety profile of the drug. Concomitant therapy with enalapril, atorvastatin, and amlodipine could be a possible co-founding factor.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Altruline (SERTRALINE) Unknown; Regimen #1	UNK; UNK	Drug use for unknown indication (Product used for unknown indication)	2025 / Unknown; Unknown