# 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 |
|---|---|---|---|---|---|---|---|---|---|---|
| LSP | COSTA RICA | | Unk | | 46 Years | Female | Unk | | Unk | |

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

migraine [Migraine]
Headache [Headache]
vomits [Vomiting]
drowsiness [Somnolence]
Intolerance to Lyrica from low to high doses [Drug intolerance]
it improved her pain [Drug effective for unapproved indication]

Case Description: This non-serious spontaneous report originated from the Costa Rica was received by Viatris on 04-Jul-2025.

**(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 ) Lyrica (PREGABALIN) Capsule

| 15. DAILY DOSE(S) | 16. ROUTE(S) OF ADMINISTRATION |
|---|---|
| #1 ) UNK | #1 ) UNK |

17. INDICATION(S) FOR USE
#1 ) Pain (Pain)

| 18. THERAPY DATES(from/to) | 19. THERAPY DURATION |
|---|---|
| #1 ) Unknown | #1 ) Unknown |

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

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

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

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 | Pain (Pain) |

## 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-2025M1057166

24b. MFR CONTROL NO.
**2025M1057166**

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

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

DATE OF THIS REPORT
10-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER
Dr.

COSTA RICA

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

This initial case, received from physician in Costa Rica, involved a 46-years-old female patient who reportedly experienced migraine, headache, vomiting, somnolence and had drug intolerance while receiving Lyrica (pregabalin) and reported drug was effective for unapproved indication.

Medical history and concomitant medications were not reported.

Current condition included pain.

Unknown date: The patient initiated pregabalin capsule at an unknown dose, unit and frequency via unknown route (batch/lot number and expiration date were unknown) for pain. The reporter stated that the patient informed total intolerance to Lyrica from low to high doses, it improved her pain, the adverse effects lead to a total interruption of the therapy, such as migraine, headache, vomits and drowsiness, the first ones being the strongest. The pregabalin was discontinued.

The outcome of the events migraine, headache, vomiting and somnolence was unknown.

Case Comment: The reporter assessed the events migraine, headache, vomiting, somnolence and drug intolerance as certain with Lyrica.

Company Comment: Non-serious: Migraine, drug intolerance and drug effective for unapproved indication are unlisted events whereas headache, vomiting and somnolence are listed events as per company RSI of pregabalin. Causality has been assessed as possible for events migraine, drug intolerance and drug effective for unapproved indication as the contributory role of suspect drug cannot be completely excluded with available information. Causality has been assessed as possible for events headache, vomiting and somnolence as contributory role of suspect drug cannot be completely excluded considering the known safety profile of the drug.