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
UNKNOWN	PANAMA		Unk		Unk	Male	Unk		Unk	

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

Diplopia [Diplopia]
Decreased cognition [Cognitive disorder]

Case Description: This non-serious spontaneous report originated from Panama received by Viatris on 24-Apr-2025 and follow-up report received on 02-May-2025 which is non-significant.

(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) Unknown
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 600 milligram, qd (Daily)

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) 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)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
From/To Dates | Type of History / Notes | Description
Unknown

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 #: PA-MYLANLABS-2025M1038233

24b. MFR CONTROL NO.
2025M1038233

25b. NAME AND ADDRESS OF REPORTER
Dr. J P

PANAMA

24c. DATE RECEIVED BY MANUFACTURER
24-APR-2025

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

DATE OF THIS REPORT
08-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 2025M1038233

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Initial and follow-up reports were processed together.

This initial case, received from physician in Panama, involved male patient of an unknown age who reportedly experienced diplopia and cognitive disorder while receiving Lyrica (pregabalin).

Medical history, current conditions and concomitant medications were not reported.

Unknown date: The patient initiated pregabalin unknown formulation at a dose of 600 milligram qd (daily) via an unknown route (batch/lot number and expiration date were unknown) for an unknown indication. The patient experienced decreased cognition and diplopia.

Action taken with pregabalin was unknown.

The outcome of events diplopia and cognitive disorder were unknown.

Case Comment: Reporter causality for the events diplopia and cognitive disorder with pregabalin was unassessable.

Company Comment: Non-serious: Diplopia and cognitive disorder are listed events as per company RSI of pregabalin. Causality has been assessed as possible for events diplopia and cognitive disorder as the contributory role of the suspect drug cannot be completely excluded considering the compatible chronology and known safety profile of the drug.

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) Lyrica (PREGABALIN) Unknown; Regimen #1	600 milligram, qd (Daily); UNK	Drug use for unknown indication (Product used for unknown indication)	Unknown; Unknown