# 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 |
|---|---|---|---|---|---|---|---|---|---|---|
| PRIVACY | COSTA RICA | | PRIVACY | | 54 Years | Female | 52.00 kg | 02 | MAY | 2025 |

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

Physician prescribed to take one 150 mg tablet in the morning every 3 days [Off label use]
drowsy [Somnolence]
Dizziness [Dizziness]
Vomiting [Vomiting]
Nausea [Nausea]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), concerned a 54-year-old female patient of unknown origin.

**(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

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1 ) Abemaciclib (Abemaciclib) Tablet {Lot # D763191; Exp.Dt. OCT-2026}
#2 ) METOCLOPRAMIDE (METOCLOPRAMIDE) Tablet **(Continued on Additional Information Page)**

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

| 15. DAILY DOSE(S) | 16. ROUTE(S) OF ADMINISTRATION |
|---|---|
| #1 ) 150 mg, every three days | #1 ) Oral |
| #2 ) UNK, unknown | #2 ) Oral |

17. INDICATION(S) FOR USE
#1 ) Breast cancer (Breast cancer)
#2 ) Nausea (Nausea)

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

| 18. THERAPY DATES(from/to) | 19. THERAPY DURATION |
|---|---|
| #1 ) 02-MAY-2025 / Unknown | #1 ) Unknown |
| #2 ) MAY-2025 / MAY-2025 | #2 ) Unknown |

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1 ) ANASTROZOLE (ANASTROZOLE) Unknown ; Unknown
#2 ) CALCIUM (CALCIUM) Tablet ; 2024 / Unknown
#3 ) VITAMIN D [COLECALCIFEROL] (COLECALCIFEROL) Capsule ; 2024 / 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 | | |

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Eli Lilly Interamerica Inc (AR Branch)
Tronador 4890 - Piso 12
Buenos Aires, Capital Federal CP: 1430 ARGENTINA
Phone: 54 1145464000

26. REMARKS

24b. MFR CONTROL NO.
**CR202505006552**

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

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

DATE OF THIS REPORT
10-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

## ADDITIONAL INFORMATION

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

Medical history was not provided. Concomitant medications included calcium and colecalciferol, both for unknown indications.

The patient received abemaciclib (Verzenio) tablets, 150 mg, orally, every three days for the first week, one 150 mg tablet daily in the morning the following week, and for the next 15 days, one 150 mg tablet every 12 hours (off label use), for the treatment of breast cancer, starting on 02-May-2025. She also received metoclopramide (trade name not provided) tablet, at an unknown dose and frequency via oral route for the treatment of nausea, beginning on an unknown date in May-2025. She also received anastrazole as a combination therapy. On 02-May-2025, the first day she took abemaciclib therapy, she experienced dizziness and vomiting only the day of administration. On an unknown date in May-2025, she experienced mild nausea which recurred with the third dose of the medication. She took Metoclopramide for nausea, but she only took it for a few days because it made her drowsy. Additionally, her dose was modified to 1 tablet twice daily. Information regarding corrective treatment for the remaining events was not provided. Outcome of the event nausea was not resolved, unknown for event drowsiness and for all the remaining events, it was resolved. The status of abemaciclib therapy was ongoing while the therapy status of metoclopramide was discontinued on an unknown date in May-2025.

The reporting consumer related the event nausea while did not provide relatedness assessment of the remaining events with abemaciclib therapy. The reporting consumer related the event drowsiness  while did not provide relatedness assessment of the remaining events with metoclopramide therapy.

Update 09-Jun-2025: Additional information was received from the initial reporter via PSP on 03-Jun-2025. Added an additional dosage regimen of abemaciclib, one concomitant, one co-suspect drug and two non-serious events of nausea and drowsiness. Updated listedness for event dizziness in CORE from unlisted to listed. Updated narrative with new information.

Lilly Analysis Statement: 09-Jun-2025: The company considered the listed event of dizziness related to the abemaciclib.

**14-19. SUSPECT DRUG(S) continued**

| 14. SUSPECT DRUG(S) (include generic name) | 15. DAILY DOSE(S);<br>16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to);<br>19. THERAPY DURATION |
|---|---|---|---|
| #1 ) Abemaciclib (Abemaciclib) Tablet;<br>Regimen #2 | 150 mg, every three days;<br>Oral | Breast cancer (Breast cancer) | Ongoing;<br>Unknown |