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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				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)

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

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.

Medical history was not provided.

(Continued on Additional Information Page)

- ☐ 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}

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

15. DAILY DOSE(S)
#1) 150 mg, every three days

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

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

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

18. THERAPY DATES(from/to)
#1) 02-MAY-2025 / Ongoing

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) CALCIUM (CALCIUM) Tablet ; 2024 / Unknown
#2) 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
05-MAY-2025

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

DATE OF THIS REPORT
12-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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. Concomitant chemotherapy was not provided. On 02-May-2025, the first day she took abemaciclib therapy, she experienced dizziness and vomiting only the day of administration. Information regarding corrective treatment was not provided. Outcome of all the events was recovered. The status of abemaciclib therapy was not changed.

The reporting consumer did not provide an opinion of relatedness between the events and abemaciclib therapy.