

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH Day Month Year PRIVACY	2a. AGE 54 Years	3. SEX Female	3a. WEIGHT 52.00 kg	4-6 REACTION ONSET Day Month Year 02 MAY 2025	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
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] Vomiting when eating cabbage [Vomiting] Case Description: This solicited case, reported by a consumer via a patient support program (PSP), concerned a 54-year-old female patient of (Continued on Additional Information Page)							<input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> 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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) 150 mg, every three days #2) UNK, unknown	16. ROUTE(S) OF ADMINISTRATION #1) Oral #2) Oral	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
17. INDICATION(S) FOR USE #1) Breast cancer (Breast cancer) #2) Nausea (Nausea)	19. THERAPY DURATION #1) Unknown #2) Unknown	
18. THERAPY DATES(from/to) #1) 02-MAY-2025 / Unknown #2) MAY-2025 / MAY-2025		

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	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 30-JUL-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT 04-AUG-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 3	

04-Aug-2025 03:12

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

unknown origin.

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 anastrozole 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. On an unknown date in Jun-2025, she experienced vomiting when eating cabbage which recovered on Jul-2025. She also indicated that nausea still sometime occurred and that she was able to eat and continue with her normal life. She has not vomited. 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 and vomiting (second episode) 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.

Update 09-Jul-2025: Additional information was received from the initial reporter via PSP on 03-Jul-2025. Added on non-serious event of vomiting when eating cabbage. Updated outcome for nausea from not recovered to recovered. Updated narrative with new information.

Update 03-Aug-2025. Additional information was received from the initial reporter via PSP on 30-Jul-2025. Event outcome for the event of nausea was updated from recovered to not recovered and outcome of the event of vomiting when eating cabbage was updated from not recovered to recovered. Updated narrative with new information.

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

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) Abemaciclib (Abemaciclib) Tablet; Regimen #2	150 mg, bid; Oral	Breast cancer (Breast cancer)	02-MAY-2025 / Ongoing; Unknown