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		59 Years	Female	Unk		JAN	2025

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

bleeding in stools / diarrhea with blood [Diarrhoea haemorrhagic]
cannot consume grapefruit because it activates Verzenio since they may not be compatible [Food interaction]
Verzenio dose was reduced to one tablet (150 mg) per day [Off label use]
Diarrhea [Diarrhoea]
Platelets were low [Platelet count decreased]
Nausea [Nausea]
Fatigue [Fatigue]

Case Description: This solicited case, reported by a consumer via a

(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 # 0761191; Exp.Dt. OCT-2026}

(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, bid	#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)	19. THERAPY DURATION
#1) 17-JAN-2025 / 05-FEB-2025	#1) 20 days

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
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.
CR202502006448

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

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

DATE OF THIS REPORT
01-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

patient support program (PSP), with additional information from the initial reporter via a PSP, concern a 59-year-old (at he time of initial report) female patient of unknown origin.

Medical history and concomitant medications were not provided.

The patient received abemaciclib (Verzenio) tablets, 150mg, twice a day, orally, for treatment of breast cancer, beginning on 17-Jan-2025. Concomitant chemotherapy if any was not provided. On 17-Jan-2025, after taking abemaciclib therapy, she started having problems with diarrhea for which she did not take any medication. On an unknown date, she had been eating very poorly out of fear of diarrhea and, if she had to go out, she would not eat. When she ate, the food remained in her body for one hour and then she immediately went to the bathroom. One week after starting abemaciclib, she underwent an unspecified exam and the results indicated that her platelets were low (no values, units and reference ranges provided) but within the normal limit. On 03-Feb-2025, she began radiotherapy concomitantly, she would receive 15 sessions for breast cancer, of which she has received two. On 04-Feb-2025, she experienced bleeding in her diarrhea stools. On 05-Feb-2025, she received the third session of radiotherapy, she recovered from diarrhea with blood, and she went to the hospital where she spoke with both a male doctor and a female doctor, and they indicated that her platelets were very low and that, due to the bleeding, her platelets might have dropped even further. On 05-Feb-2025, abemaciclib was stopped since she could not take abemaciclib during the period in which radiotherapy would be administered. On an unknown date, abemaciclib therapy was restarted and in Mar-2025, it was discontinued due to unknown reasons. On an unknow date in Mar-2025, a day later after discontinuation, abemaciclib was resumed but the dose was reduced to one tablet of 150 mg per day (off label dosing frequency). On an unknown date in Mar-2025, she experienced fatigue. On an unknown date, she could not consume grapefruit because it activated abemaciclib since they may not be compatible. Blood tests were required to confirm her condition; she must discontinue abemaciclib daily dose on 07-May-2025 and resume the full daily dose of 300 mg on 08-May-2025. Information regarding corrective treatment was not provided. Outcome of nausea and diarrhea with blood was recovered, diarrhea was recovering and fatigue was not recovered, while for remaining events was unknown. Abemaciclib was ongoing at a reduced dose of 150 mg daily,

The reporting consumer considered nausea, diarrhea, and fatigue as related to abemaciclib while did not provide an opinion of relatedness between remaining events and abemaciclib therapy.

Update 12-May-2025: Additional information was received from the initial reporter via a PSP on 05-May-2025. Added two dosage regimens of abemaciclib, off label dosing frequency and food interaction as events and outcome of diarrhea. Updated abemaciclib therapy status, the event of hematochezia to diarrhea hemorrhagic and narrative accordingly with new information.

Update 30-Jul-2025: Additional information was received from the initial reporter via a PSP on 24-Jul-2025. Added one new non serious event of fatigue. Updated onset date of diarrhea from 20-Jan-2025 to 17-Jan-2025 and outcome updated as recovering. Updated narrative accordingly with new information.

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)	Unknown / MAR-2025; Unknown
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #3	150 mg, daily; Oral	Breast cancer (Breast cancer)	MAR-2025 / Ongoing; Unknown