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		58 Years	Female	Unk	05	MAY	2024

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

Other Serious Criteria: Med Sig
fall caused four broken ribs [Fall]
Four broken ribs [Rib fracture]
Fall injured the meniscus in knees [Meniscus injury]
Very poorly sleeping, sleeping for about 3 or 4 days, sleeping for only one hour [Poor quality sleep]
If she is sitting, walking and lying down her stomach bothers her [Abdominal discomfort]
Swelling on the side of the wound where they extracted her left breast [Post procedural swelling]

(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

15. DAILY DOSE(S)
#1) 150 mg, bid

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

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

18. THERAPY DATES(from/to)
#1) 02-MAY-2024 / Ongoing

19. THERAPY DURATION
#1) Unknown

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

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

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) ARIMIDEX (ANASTROZOLE) Unknown ; Unknown
#2) VITAMIN D3 (VITAMIN D3) Unknown ; Unknown
#3) ENALAPRIL (ENALAPRIL) Unknown, 20 mg; Unknown
#4) OMEPRAZOLE (OMEPRAZOLE) Tablet ; 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 to Ongoing	Medical Condition	Hiatal hernia (Hiatus hernia)
Unknown to Ongoing	Medical Condition	Gastric ulcer (Gastric ulcer)

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.
CR202405007383

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

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

DATE OF THIS REPORT
06-AUG-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

Dengue (body aches, headache, diarrhea, vomiting, fever, nausea, low platelet in 90) [Dengue fever]
Went to the bathroom six times for diarrhea/ 1, 2 or at most 3 times [Diarrhoea]
Very sick and has felt like vomiting [Vomiting]
Tries to vomit but is unable to vomit [Nausea]

Case Description: This solicited case reported by a consumer via other manufacturer, concerned a 58-year-old (at the time of the initial report) female patient of an unknown origin.

Medical history included hiatal hernia, ulcers, fatty liver, difficulty sleeping and sugar problems. Concomitant medications included cholecalciferol drops and omeprazole for the treatment of an unknown indication and enalapril for the treatment of blood pressure. Surgical procedure included chemotherapy and removal of left breast.

The patient received abemaciclib (Verzenio) tablet, at 150 mg twice daily dose, via orally, for the treatment of breast cancer, beginning on 02-May-2024. She was also using anastrozole concomitantly for the treatment of an unknown indication. On an unknown date in May-2024, while on abemaciclib therapy, she had been very poorly sleeping for only one hour, for about three or four days. Therefore, as a corrective treatment she was put back on diazepam. On 05-May-2024, she went to the bathroom six times for diarrhea and took a loperamide pill as a corrective treatment. On 07-May-2024, she had been very sick and felt like vomiting. If she was sitting, walking, and lying down her stomach bothered her and when she had felt this way, she vomited. She tried to vomit but was unable to vomit. As of information received on 11-Jun-2024, she did not longer have nausea or stomach pain, but continued with diarrhea and took loperamide one or sometimes two pills as indicated by the physician that she could take up to eight loperamide a day. On 09-Jun-2024, she had diarrhea twice, on 10-Jun-2024, she went four to five time and on 11-Jun-2024, she went four time for diarrhea. On 18-Oct-2024, she began to present Dengue fever which had caused symptoms such as body aches, headache, diarrhea, vomiting, fever with a temperature of 40, nausea. She went to the hospital and came out with low platelet count of 90 (no reference range, and units were provided). Additionally on same day, on the side of the wound where they extracted her left breast was bulging, was very swollen (inflamed). She stopped taking medication by her own decision on 18-Oct-2024. She was told that at the time of presenting dengue she should not use any other medication in addition to acetaminophen. On an unknown date in Mar-2025, she fell which caused four broken ribs. She was told it should regenerate on their own. The fall injured the meniscus in her knee. She was advised to begin therapy the following month, and the physician informed her that knee surgery would likely be required for this condition. She underwent physical therapy for fall, fractured ribs and meniscus injury and took unspecified analgesics for the meniscus injury. The events of fall, fractured ribs and meniscus injury were considered serious by the company due to its medical significant reasons. Information regarding further corrective treatment for remaining events was not provided. Outcome of the events of nausea and abdominal discomfort was resolved, for fall, and fractured ribs was recovering however for rest of the events were not resolved. The abemaciclib therapy was ongoing. Follow-up was not possible since the reporter did not agree to be contacted for future follow-up or to contact their treating physician.

The reporting consumer did not relate the event fall, fractured ribs and meniscus injury whereas did not provide relatedness of the remaining events with abemaciclib therapy.

Update 15-Jun-2024: Additional information was received from initially reporting consumer on 11-Jun-2024 via other manufacturer. Updated outcome of nausea and abdominal discomfort from not recovered to recovered, corresponding fields and narrative with new information.

Update 17-Jul-2024: Information was received from initially reporting consumer on 11-Jul-2024 via other manufacturer. No new medically significant information was received and no other changes were done to the case.

Updated 26-Oct-2024: Additional information was received from initially reporting consumer via PSP on 21-Oct-2024. Added procedure of removal of left breast, lab date for body temperature, platelet count, treatment drug of acetaminophen and two non-serious events of dengue and post procedural swelling. Updated action taken from no change to drug discontinued. Updated narrative with new information.

Updated 06-Aug-2025: Additional information was received from initially reporting consumer via PSP on 31-Jul-2025. This case was upgraded from non-serious to serious due to the addition of three serious events. Added three serious events of fall, fractured ribs and meniscus injury. Updated therapy status. Amended narrative with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Body temperature no reference range, and units were provided	40	
2		Platelet count	90	

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
		no reference range, and units were provided		

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Fatty liver (Hepatic steatosis);
Unknown to Ongoing	Medical Condition gave her Diazepam	Difficulty sleeping (Insomnia);
Unknown to Ongoing	Medical Condition	Blood glucose abnormal (Blood glucose abnormal);
Unknown	Procedure	Chemotherapy (Chemotherapy);
2023 to Unknown	Procedure	Mastectomy (Mastectomy);