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		52 Years	Female	Unk			2023	

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

sweating [Hyperhidrosis]
blood level of 400 [Blood glucose increased]
mouth was burning [Oral discomfort]
Burning sensation in heels [Burning sensation]
sometimes has difficulty going to the bathroom/chronic constipation [Constipation]
she fell from her own height [Fall]
moderate pain [Pain]
without being able to sit well [Mobility decreased]
pain in the right back that irradiates to the right leg/Back pain [Back

(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

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)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 17-NOV-2023 / Ongoing	#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) ANASTROZOLE (ANASTROZOLE) Unknown ; Unknown
#2) LETROZOLE (LETROZOLE) Unknown ; Unknown
#3) IONIC CALCIUM (CALCIUM CHLORIDE, TRACE ELEMENTS NOS) Unknown ; Unknown
#4) VITAMIN D3 (VITAMIN D3) Unknown ; Unknown
#5) VOLTAREN [DICLOFENAC] (DICLOFENAC) Unknown ; Unknown
#6) CALCIUM (CALCIUM) Unknown ; Unknown

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
2020 to Ongoing	Medical Condition	Constipation (Constipation)
Unknown to Ongoing	Medical Condition	Diabetes (Diabetes mellitus)
	was taking a pill to control her blood sugar but she had been under control so does not take it	

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.
CR202406002378

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

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

DATE OF THIS REPORT
24-JUL-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

pain]
stomach was burning [Dyspepsia]
she felt like vomiting [Nausea]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) conducted by a business partner, concerned a 52-year-old (at the time of reporting) female patient of an unknown origin.

Medical history included diabetes and during chemotherapy she started to not see well. She had constipation since 2020. In 2022, she broke her coccyx in two places due to fall on stairs. Historical drug included an unspecified pill to control her blood sugar. Concomitant medication included calcium chloride, trace elements nos, colecalciferol, unspecified sleeping pill, depression pill, pain pill, diclofenac and calcium.

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice daily via oral route for the treatment of breast cancer, beginning on 17-Nov-2023. She also received letrozole and anastrozole as a combination therapy. On an unknown date in 2023, while on abemaciclib therapy, she experienced back pain that was left by her broken coccyx (medical history), and she took gabapentin and tramadol hydrochloride as corrective treatment for the same. On an unknown date, she did not get diarrhoea but sometimes has difficulty going to the bathroom. If she ate little breakfast and took the therapy, she felt like vomiting, started sweating and had to look for something to eat. On 12-Apr-2024 she had a blood and urine test. Her doctor told her that everything was fine, but showed her the result of the blood test, which indicated that she was eating a lot of bread and that she had a blood level of 400. Since, 25-May-2024 she felt that her stomach and mouth were burning, like when you burn yourself with something hot. She also indicated that she felt the same sensation in her heels. On an unknown date, she fell from her own height, and fell on her buttocks, strong blow, from that moment she had moderate pain, without being able to sit well. Now, with analgesia she only had pain in the right back that irradiated to the right leg. Her constipation (medical history) became chronic and she followed a high fiber diet to help with the constipation. Information regarding corrective treatment for the remaining events was not provided. Outcome of the event mobility decreased was not provided, back pain was recovering and for rest of the events it was not resolved. Abemaciclib therapy status was ongoing. The reporter refused to be contacted and did not give permission to contact the treating physician.

The initial reporting consumer did not relate the event of constipation and back pain, while did not provide relatedness assessment of the events with abemaciclib therapy.

Update 20-Aug-2024: Additional information was received from the initial reporter via PSP on 12-Aug-2024. Added two concomitant drugs and four non-serious events of fall, pain, mobility decreased and back pain (with radiation). Updated narrative with new information.

Update 23-Jul-2025: Additional information was received from the initial reporter via PSP conducted by a business partner, on 17-Jul-2025. Added three medical histories (fall, fractured coccyx and constipation), two treatment drugs (gabapentin and tramadol hydrochloride), and onset date of event back pain. Removed onset date on event constipation (previously captured as 2020). Updated description as reported and outcome of event back pain from not recovered to recovering. Updated description as reported of event constipation and its coding to constipation aggravated. Update as reported causality of events back pain and constipation from not provided to not related, and narrative with new information.

Lilly Analysis Statement: 23-Jul-2025: The company considered the events of nausea and dyspepsia as related to the abemaciclib.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	12-APR-2024	Blood test (unit and reference value was not provided)	400	
2	12-APR-2024	Urine analysis everything was fine (result, unit and reference value was not provided)		

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition	Visual impairment (Visual impairment);
Unknown	Medical Condition	Fall (Fall);

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
	fall on some stairs	
2022 to Unknown	Medical Condition Intensity: Moderate	Fractured coccyx (Fractured coccyx);
Unknown	Procedure	Chemotherapy (Chemotherapy);