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	GUATEMALA		PRIVACY		64 Years	Female	126.00 kg	24	MAY	2025

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

Colic/ cramps [Abdominal pain]
Lower back pain [Back pain]
Chills [Chills]
tiredness [Fatigue]
Diarrhea [Diarrhoea]
Low white blood cell count [White blood cell count decreased]

Case Description: This solicited case, reported by a consumer via a business partner who was contacted by the company via patient support program (PSP) to report adverse events, concerned a 64-years-old female

(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) 24-MAY-2025 / 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) LETROZOL (LETROZOL) Unknown ; Unknown
#2) FEMARA (LETROZOLE) Unknown ; Unknown
#3) OMEGA 3 [FISH OIL] (FISH OIL) Unknown ; Unknown
#4) CALCIUM (CALCIUM) Unknown ; Unknown
#5) ZINC (ZINC) Unknown ; Unknown
#6) MAGNESIUM (MAGNESIUM) Unknown ; Unknown

(Continued on Additional Information Page)

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.
GT202506005781

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

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

Mfr. Control Number: GT202506005781

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

patient of an unknown origin.

Medical history was not provided. Concomitant medications included esomeprazole, magnesium, zinc, calcium, fish oil all for unknown indication.

The patient received abemaciclib (Verzenio) tablet, 150 mg twice daily, orally, for the treatment of breast cancer beginning on 24-May-2025. She was taking letrozole concomitantly. On 24-May-2025, since she started taking abemaciclib, she had mild cramps/colic and moderate tiredness but no diarrhea. On 26-May-2025, she went to eat at a restaurant, then she had mild diarrhea. Since that day, she had sporadic diarrhea therefore, she took loperamide when she had diarrhea as corrective treatment. Since 26-May-2025, she also experienced mild chills. On 30-May-2025, she experienced lower back pain. On 11-Jun-2025, she had a low white blood cell count (value, units, reference range were not provided). Her diarrhea treated with loperamide and bacillus clausii. Information regarding the corrective treatment for event white blood cell count low was not reported and she did not receive corrective treatment for rest of the events. The outcome of all the events was not recovered. The therapy status of abemaciclib was ongoing.

The reporting consumer related the events of diarrhea, tiredness, cramps, and white blood cell count low with abemaciclib therapy while did not know the relatedness of the events of lower back pain and chills with abemaciclib therapy.

Update 09-Jul-2025: Additional information was received from initial reporting consumer on 03-Jul-2025 and 04-Jul-2024 from a business partner via PSP. Added one new laboratory test (white blood cell count), concomitant medication, two treatment medications for event diarrhea and one new non-serious event of white blood cell count low. Updated narrative with new information.

Lilly Analysis Statement: 09-Jun-2025: The company considered the events of chills and lowback pain as unrelated to abemaciclib.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11-JUN-2025	White blood cell count Low (value, units, reference range were not provided)		

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#7) ESOMEPRAZOLE (ESOMEPRAZOLE) Unknown ; Unknown