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		63 Years	Female	Unk			2024

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

Dental plaque [Dental plaque]
Teeth are moving out of place [Loose tooth]
The patient indicates that she has decided on her own to take the medication every other day (150 mg every 12 hours) [Intentional product misuse]
Oral inflammation [Stomatitis]
Intermittent continuous diarrhea [Diarrhoea]
Occasional tiredness [Fatigue]

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

(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

(Continued on Additional Information Page)

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) 01-JAN-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)

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.
GT202501016689

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

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

DATE OF THIS REPORT
23-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: GT202501016689

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

support program (PSP) concerned a 63-Year-old female patient of an unknown origin.

Medical history and concomitant medication were not provided.

The patient received abemaciclib (Verzenio), tablet at dose of 150 mg, twice daily, orally, for an indication of breast cancer, beginning on 01-Jan-2024. On an unknown date in 2024, she experienced intermittent continuous diarrhea and received corrective treatment with loperamide. On 10-Dec-2024, after starting on abemaciclib therapy, her teeth were moving out of place due to inflammation and bone structure of the jaw, so the treatment was to clean, remove her teeth and perform dental plaque from the upper part of the mouth. The treating doctor indicates that, Verzenio would be suspended for 15 days for the extraction of teeth. On an unknown date, she has decided on her own to take the medication every other day (150 mg every 12 hours) (intentional drug misuse). On an unknown date, Positron emission tomogram (PET) scan was performed, and results were not provided. On an unknown date in Jan-2025, she experienced mild occasional tiredness. She received corrective treatment as remove her teeth for oral inflammation while for rest of the events was not provided. Outcome of events stomatitis, diarrhea, and tiredness was not recovered and for rest of the events was not provided. The final therapy status of abemaciclib therapy was ongoing.

The reporting consumer related the events of tiredness and diarrhea whereas did not provide an opinion on relatedness of the other events with abemaciclib therapy.

Update 22-Jul-2025: Additional information received from initial reporting consumer via PSP on 16-Jul-2025. Added new dosage regimen of abemaciclib, three non-serious events of intermittent continuous diarrhea, occasional tiredness and intentional drug misuse, treatment medication of loperamide and one lab data of PET scan. Updated narrative accordingly.

Lilly Analysis Statement: 23-Jul-2025: The company considered the event of stomatitis related to Verzenio Therapy.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Positron emission tomogram PET scan was performed, and the results are pending		

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, qod; Oral	Breast cancer (Breast cancer)	01-JAN-2024 / Ongoing; Unknown