# 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 | | 67 Years | Female | Unk | | OCT | 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: medically significant
No appetite, eats like a baby, had it before Verzenio but now feels it is more serious [Decreased appetite]
Insomnia [Insomnia]
Diarrhea (first episode) [Diarrhoea]
Diarrhea (second episode) [Diarrhoea]
Moderate tiredness [Fatigue]
Patient feels a little out of energy [Asthenia]

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
#2 ) ANASTROZOLE (ANASTROZOLE) Unknown

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 |
| #2 ) 1 dosage form, daily | #2 ) Unknown |

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

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

| 18. THERAPY DATES(from/to) | 19. THERAPY DURATION |
|---|---|
| #1 ) 09-SEP-2024 / Ongoing | #1 ) Unknown |
| #2 ) Ongoing | #2 ) Unknown |

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1 ) METFORMIN (METFORMIN) Unknown ; Unknown
#2 ) CALCIUM (CALCIUM) Unknown ; Unknown
#3 ) VITAMIN D NOS (VITAMIN D NOS) 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 Unknown | Medical Condition for four years | Diabetes (Diabetes mellitus) |
| Unknown | Medical Condition | Decreased appetite (Decreased appetite) |

## 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.
**CR202409006651**

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: 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) and business partner (BP), with additional information from the reporting consumer, concerned a 67-year-old (at the time of initial report) female patient of an unknown ethnicity.

Medical history included diabetes for four years, poor appetite and was generally constipated, to the point of having to take mineral oil or sometimes buy a laxative. However, since chemotherapy, she has been regulating her constipation. Concomitant medications included metformin, calcium and vitamin D; all for an unknown indication.

The patient received abemaciclib (Verzenio) tablets, 150 mg twice a day, orally, for the treatment of breast cancer, beginning on 09-Sep-2024. She also received anastrozole (unknown manufacturer), one dosage form daily for breast cancer. Formulation, route of administration and start date were not reported. On an unknown date, after starting abemaciclib and anastrozole therapies, she experienced no appetite, and she ate like a baby. She already had a poor appetite before the start of the treatment with abemaciclib, but since abemaciclib and anastrozole, it was more serious. The event of decreased appetite was considered as serious by the reporter due to its medically significant reasons. On an unknown date, she experienced diarrhea. She went for two days without going to the bathroom, then had four to five diarrhea episodes. The first two to three diarrhea were solid and the fourth and fifth were a little more liquid. She took one loperamide if the last two diarrhea were very liquid. On an unknown date, she administered unspecified cholesterol medication (unknown manufacturer) at an unknown dose, and frequency, via an unknown route and formulation. On an unknown date, she experienced insomnia so she temporarily discontinued taking medication that she took to control her cholesterol. She was waiting for the doctor’s appointment as her doctor suggested she take it at night only. Sometimes she felt a little out of energy, she took rest during the day, and it did not prevent her from performing her functions, only that she performed them with laziness. Since an unknown date in Oct-2024, she experienced moderate tiredness. She did not consult a physician, nor did she take corrective treatment for this event. On an unknown date in Jul-2025, she experienced mild diarrhea in the morning, and she was receiving loperamide for it. Information regarding corrective treatments for the remaining events was not provided. The outcome of the events of diarrhea (first episode) and decreased appetite was recovered, not recovered for the events of diarrhea (second episode) and fatigue, and unknown for the remaining events. Abemaciclib and anastrozole therapies were ongoing, and unspecified cholesterol medication was discontinued. Follow-up could not be pursued as reporter consumer did not accept further contact and did not give permission to contact treating physician.

The reporting consumer did not know relatedness of the event of decreased appetite, related the events of diarrhea (second episode) and fatigue, while did not provide relatedness of the remaining events with abemaciclib therapy. The reporting consumer did not know relatedness of the event of decreased appetite, while did not provide relatedness of the other events with anastrozole therapy. The reporting consumer related the event of insomnia and did not provide relatedness of remaining events with unspecified cholesterol medicine.

Update 23-Oct-2024: Additional information from the initial reporter via PSP was received on 17-Oct-2024. Added one co-suspect drug unspecified cholesterol medicine, one corrective treatment loperamide and two non-serious events of diarrhea and insomnia. Updated narrative with new information.

Update 29-Jan-2025: Additional information received on 23-Jan-2025 from the initial reporter via a PSP. Added a non-serious event of fatigue. Updated narrative with new information.

Update 25-Apr-2025: Additional information received on 21-Apr-2025 from the initial reporter via a PSP. Added dose, frequency and status of co-suspect anastrozole and one non-serious event of energy decreased. Updated outcome of the event decreased appetite and diarrhea from not recovered to recovered. Upon review, updated reference type no.3 to E2B report duplicate. Narrative was updated with new information.

Update 06-Aug-2025: Additional information received from the initial reporting consumer via a PSP on 31-Jul-2025. Added a non-serious event of diarrhea (second episode). Updated start date from 04-Sep-2024 to 09-Sep-2024, outcome from unknown to not recovered and as reported causality from not reported to yes for the event of fatigue, and narrative with new information.

Lilly Analysis Statement: 06-Aug-2025: The company considered the events of diarrhea, decreased appetite and asthenia as related to abemaciclib.

**23. OTHER RELEVANT HISTORY continued**

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| Unknown | Medical Condition | Constipation (Constipation);<br>Had to take mineral oil or buy a laxative. Since chemotherapy, she has been regulating her constipation. |