

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

| | | | | | | | | | | | |
|--|----------------------------------|------------------|----------------|------|-------------------------------|-------------------------|--------------------------|--------------------|------------|-------------|--|
| 1. PATIENT INITIALS (first, last) PRIVACY | 1a. COUNTRY COSTA RICA | 2. DATE OF BIRTH | | | 2a. AGE 55 Years | 3. SEX Female | 3a. WEIGHT Unk | 4-6 REACTION ONSET | | | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING |
| | | Day | Month | Year | | | | Day | Month | Year | |
| | | | PRIVACY | | | | | | DEC | 2023 | |

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
 Anal burning sensation [Anorectal discomfort]
 Anal pain [Proctalgia]
 Soft stool [Faeces soft]
 It hurts when the stool passes through the area and it burns/pain in the area between the division of the vagina and the anus [Dyschezia]
 Losing weight [Weight decreased]
 Dengue/fever/platelets were low [Dengue fever]
 Sick [Illness]
 swelling in the right cheek [Swelling face]
 Pain in the joints in general [Arthralgia]
 (Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

| | | |
|---|---|--|
| 14. SUSPECT DRUG(S) (include generic name) #1) Abemaciclib (Abemaciclib) Tablet (Continued on Additional Information Page) | | 20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA |
| 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) | | 21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA |
| 18. THERAPY DATES(from/to) #1) 07-DEC-2023 / Unknown | 19. THERAPY DURATION #1) Unknown | |

III. CONCOMITANT DRUG(S) AND HISTORY

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| 22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) ARIMIDEX (ANASTROZOLE) Unknown, 1 mg; Unknown #2) CALCIUM (CALCIUM) Unknown ; Unknown #3) VITAMIN D3 (VITAMIN D3) 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 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. CR202402006401 | 25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD. |
| 24c. DATE RECEIVED BY MANUFACTURER 17-MAR-2025 | 24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER: | |
| DATE OF THIS REPORT 22-MAR-2025 | 25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP: | |

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

Anaemia [Anaemia]

Diarrhea/ stool is loose [Diarrhoea]

Case Description: This solicited case, reported by a consumer via business partner via patient support program (PSP), with additional information from reporting consumer via PSP, concerned a 55-year-old female patient of unknown origin.

Medical history was not provided. Concomitant medication included calcium and vitamin D3, both for unknown indication and unspecified medication to regenerate the intestinal flora.

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice daily, orally for the treatment of breast cancer beginning on 07-Dec-2023. She also received anastrozole therapy for treatment of an unknown indication, concomitantly. On an unknown date, while on abemaciclib therapy, she was very affected in the anal area, it felt like burning in that area with anal pain. On an unknown date in Dec-2023, a week after starting abemaciclib, she began to have loose stools. She also had diarrhea, soft stool and it did hurt as the stool passed through the area, and it burned during painful defecation. She had also bought creams to help her anorectal discomfort and proctalgia, but it did not work. Her doctor prescribed pills (unspecified) for the treatment of her diarrhea and suggest her to take 1 pill if she had a lot of diarrheas, and if the diarrhea persisted she should take 2 pills and if it was too much then she should visit the doctor. Primarily, she took 1 pill and followed by 2 pills when she went to the bathroom a lot. On 05-Feb-2024, she only went to the bathroom once and did not take the pill for diarrhea. On 06-Feb-2024, she took 1 pill for diarrhea in the morning and went to the bathroom more than once and she could not tolerate the situation. As she went to the bathroom too much, she had lost her weight (value, unit, and reference range were not provided). As of 14-May-2024, she requested a nutrition consultation because she felt that her diarrhea was same because the medication caused it, according to what she ate makes her went directly to the bathroom. The episodes of diarrhea did decrease when she started taking loperamide hydrochloride 2 mg (indicated by her physician), and when she stopped taking it and took only Alka AD, the episodes returned, so she restarted treatment with loperamide 2 mg approximately since 08-May-2024, and has had improvement, but she continue to have episodes of diarrhea 3 to 4 times a day. On an unknown date, she had diarrhoea four times a day, she has a lot of pain in the area between the division of the vagina and the anus like little bone was there. On 28-May-2024, she got dengue fever, and her platelets were low (no values, units and reference range were provided). On 30-May-2024, she went for examination (unspecified) and her dengue was improving (her platelets had gone up) but she had significant anaemia. On 06-Jun-2024, she was sick, she ate a barbecued rib, she only ate one fourth of a piece. At 12 o'clock at night she had to go to the bathroom and the area was very painful (between the division of the vagina and the anus) and it was difficult for her to sleep. So, she took one loperamide and when she woke up at 6 am she felt like going to the toilet (due to diarrhoea). On 20-Dec-2024, she experienced generalized joint pain, it happened when she laid down and got up, she would get a lot of pain that would go away with mobility. She did not receive corrective treatment for the event of generalized joint pain. On 20-Jan-2025, she had swelling in the right cheek. She felt a discomfort until 21-Jan-2025 dawned with this condition. She did not receive any medical care or medication. She was now better. Information regarding corrective treatment for the remaining events was not provided. Outcome of the events of dengue fever and anemia was not recovered, unknown for sickness whereas for remaining events it was resolving. The status of abemaciclib therapy was ongoing.

The initial reporting consumer related the event diarrhea whereas did not provide the relatedness assessment of the remaining events with abemaciclib therapy.

Edit 22-Feb-2024: Upon internal case review received on 07-Feb-2024. Removed follow-up not possible information from narrative and no other changes were made in the case.

Update 17-May-2024: Additional information was received from initial reporting consumer via PSP of business partner on 14-May-2024. Added one new dosage regimen of abemaciclib 150 mg (D669613), treatment drugs loperamide hydrochloride. Updated causality as reported from no to yes for event diarrhea, event outcome from not recovered to recovering. Narrative was updated with new information accordingly.

Update 13-Jun-2024: Additional information was received from initial reporting consumer via PSP of business partner on 07-Jun-2024. Added one lab test, three non-serious events sickness, anaemia, and dengue. Updated narrative with new information.

Update 20-Jan-2025: Additional information was received from reporting consumer via PSP on 14-Jan-2025. Added one new non-serious event of generalized joint pain. Updated narrative accordingly.

Update 27-Jan-2025: Additional information was received from reporting consumer via PSP on 21-Jan-2025. Added one new non-serious event of swelling face. Updated narrative accordingly.

Update 21-Mar-2025: Additional information was received from reporting consumer via PSP on 17-Mar-2025. Updated outcome of events diarrhea and anemia to not recovered from recovering and remaining events from not recovered to recovering narrative accordingly.

ADDITIONAL INFORMATION

13. Lab Data

| # | Date | Test / Assessment / Notes | Results | Normal High / Low |
|---|------|---|---------|-------------------|
| 1 | | Platelet count Positive Platelets were low(value, unit, and reference range were not provided). | | |
| 2 | | Weight Positive losing weight (value, unit, and reference range were not provided). | | |

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 {Lot # D669613; Exp.Dt. APR-2026}; Regimen #2 | 150 mg, bid; Oral | Breast cancer (Breast cancer) | 06-FEB-2024 / Ongoing; Unknown |