

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

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|--|---------------------------------|------------------|-------|------|-------------------------------|-------------------------|----------------------------------|--------------------|-------------|--|--|
| 1. PATIENT INITIALS (first, last) PRIVACY | 1a. COUNTRY GUATEMALA | 2. DATE OF BIRTH | | | 2a. AGE 48 Years | 3. SEX Female | 3a. WEIGHT 87.00 kg | 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 | | | | | | JAN | 2025 | | |

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
Breast discomfort from surgery [Post procedural discomfort]
Celiac syndrome [Coeliac disease]
Joint pain [Arthralgia]
Swollen abdomen [Abdominal distension]
Diarrhoea/Liquid stool [Diarrhoea]
Nausea [Nausea]

Case Description: This solicited case, reported by a consumer via a Patient Support Program (PSP), concerned a 48-year-old (at the time of initial report) female patient of an unknown origin.

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

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| 14. SUSPECT DRUG(S) (include generic name) #1) Abemaciclib (Abemaciclib) Tablet {Lot # D724277; Exp.Dt. MAY-2026} | | 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) 02-DEC-2024 / Ongoing | 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) LETROZOLE (LETROZOLE) Unknown ; Unknown #2) ENTEROGERMINA [BACILLUS SUBTILIS] (BACILLUS SUBTILIS) #3) ESOMEPRAZOLE (ESOMEPRAZOLE) 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 |
| 04-NOV-2024 to 04-NOV-2024 | Procedure | Mastectomy (Mastectomy) |
| 24-NOV-2024 to 24-NOV-2024 | Procedure | Ovarian surgery (Ovarian operation) |

IV. MANUFACTURER INFORMATION

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| 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. GT202502002202 | 25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD. |
| 24c. DATE RECEIVED BY MANUFACTURER 01-AUG-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 11-AUG-2025 | 25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 2 | |

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

Medical history included completion of chemotherapy cycles in Sep-2024, had left breast resection on 04-Nov-2024 and ovarian resection on 24-Nov-2024.

The patient received abemaciclib (Verzenio) tablet, 150mg, twice a day, orally for the treatment of breast cancer beginning on 02-Dec-2024 or 03-Dec-2024 (discrepant therapy start date reported). She also received letrozole for breast cancer and enterogermina for intestinal flora and esomeprazole concomitantly. On an unknown date in Jan-2025, after starting abemaciclib therapy, she had several episodes of diarrhea with mild intensity between 3 and 6 and liquid stools and nausea especially with smells of certain foods such as eggs. She also had breast discomfort from left breast resection surgery done on 04-Nov-2024. She took loperamide as a corrective treatment of diarrhea after which the consistency of the stools was now more solid and she was only having two stools a day. She continues to present episodes of diarrhea. She indicates that they were after breakfast. On an unknown date, she sometimes had a swollen abdomen with mild intensity and wakes up with the joint pain on some days with moderate intensity. On 24-Jul-2025, she was diagnosed with celiac syndrome with moderate intensity. No treatment was given for celiac syndrome, joint pain and swollen abdomen. Information regarding corrective treatment of the remaining events was not reported. Outcome of the events was not resolved. The therapy status of abemaciclib was ongoing.

The reporting consumer did not relate the events of diarrhea, celiac syndrome, joint pain and swollen abdomen while did not provide an opinion on relatedness assessment between the events and abemaciclib therapy.

Update 11-Mar-2024: Additional information was received from initial reporting consumer via PSP on 06-MAR-2025: Added one concomitant medication (esomeprazole). Updated the narrative with new information.

Update 08-Aug-2025: Additional information was received from initial reporting consumer via PSP on 01-Aug-2025: Added height and weight, three non-serious events of celiac syndrome, joint pain and swollen abdomen. Updated outcome of the event diarrhea from recovering to not recovered. Updated the narrative with new information.

Lilly Analysis Statement: 11-Aug-2025: The company considered the events of diarrhea and nausea related to the Abemaciclib

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

#2) ENTEROGERMINA [BACILLUS SUBTILIS] (BACILLUS SUBTILIS) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

| From/To Dates | Type of History / Notes | Description |
|---------------------|-------------------------|------------------------------|
| Unknown to SEP-2024 | Procedure | Chemotherapy (Chemotherapy); |