# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

| 1. PATIENT INITIALS (first, last) | 1a. COUNTRY | 2. DATE OF BIRTH | | | 2a. AGE | 3. SEX | 3a. WEIGHT | 4-6 REACTION ONSET | | | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Day | Month | Year | | | | Day | Month | Year | |
| PRIVACY | COSTA RICA | | PRIVACY | | 75 Years | Female | Unk | 12 | DEC | 2024 | |

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

cold hands and feet and as symptom sometimes feels as if they are falling asleep (numbness of hands and feet) [Peripheral coldness]
constipation [Constipation]
Cough [Cough]
Patient administered Verzenio at the frequency of one tablet every other day and one tablet every 24 hours, No AE [Off label use]
felt like vomiting [Nausea]
diarrhoea / gastrointestinal problems [Diarrhoea]

Case Description: This solicited case, reported by a consumer via a **(Continued on Additional Information Page)**

- ☐ 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 {Lot # D761191; Exp.Dt. OCT-2026}
**(Continued on Additional Information Page)**

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)
#1 ) 150 mg, oth (Continued on Additional Information Page)

16. ROUTE(S) OF ADMINISTRATION
#1 ) Oral

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

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

18. THERAPY DATES(from/to)
#1 ) 12-DEC-2024 / Unknown

19. THERAPY DURATION
#1 ) Unknown

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

#1 ) ANASTROZOLE (ANASTROZOLE) Unknown ; Unknown
#2 ) ATENOLOL (ATENOLOL) Unknown ; Unknown
#3 ) METFORMIN (METFORMIN) Unknown ; Unknown
#4 ) LOVASTATIN (LOVASTATIN) Unknown ; Unknown
#5 ) HYDROCHLOROTHIAZIDE (HYDROCHLOROTHIAZIDE) Unknown ; Unknown
#6 ) EUTIROX (LEVOTHYROXINE SODIUM) 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 | Medical Condition | Blood pressure high (Hypertension) |
| Unknown | Medical Condition | Type 2 diabetes mellitus (Type 2 diabetes mellitus) |

## 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.
**CR202412016158**

24c. DATE RECEIVED BY MANUFACTURER
30-MAY-2025

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

DATE OF THIS REPORT
06-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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), with additional information from initial reporter and another consumer via PSP, concerned a 75-year-old female patient of an unknown origin.

Medical history included high blood pressure, type 2 diabetes, hypothyroidism, nerve problem, throat condition (unspecified) (15 or 20 years ago), numbness in her hands and feet since Nov-2023, and cancer surgery. Concomitant medication included atenolol and lovastatin for blood pressure, metformin for type 2 diabetes, hydrochlorothiazide to help with urination, levothyroxine sodium used for the throat, trifluoperazine used for nerves and vitamin B6 for unknown indication.

The patient received abemaciclib (Verzenio) tablets, 150 mg, every other day, orally, for the treatment of breast cancer, beginning on 12-Dec-2024. As concomitant chemotherapy she received anastrozole for breast cancer. In the following week on 19-Dec-2024, abemaciclib was administered at one tablet every 24 hours (off label dosing frequency). On an unknown date after starting abemaciclib therapy, she experienced constipation. On an unknown date in Dec-2024, at the beginning of abemaciclib therapy, she experienced diarrhea, but it improved, and she had had no gastrointestinal problems. In Dec-2024, since the last nutritional session, she felt cold hands and feet and sometimes felt as if they were falling asleep. In addition, when she traveled on the bus for examinations she felt like vomiting when was fasting. She continued to experience coldness in both feet and hands, along with numbness. After taking abemaciclib pill, both of her hands and feet become cold and remain that way all day and on subsequent days. On an unknown date, she coughs intermittently at various times, not as a constant symptom. On an unknown date, she started using abemaciclib, two pills a day of 150 mg each. On an unknown date, cough and the symptom of numbness of hands and feet improved very little, however, she continued the same with cold hands and feet since only improved when she exercised. As of 30-May-2025, she still experienced numbness in her hands and feet (medical history) but it was decreased. Information regarding corrective treatments was not provided. Outcome of constipation, diarrhea and nausea was recovered, for off label dosing frequency was unknown, for cough was recovering, while for the reaming event was not recovered. Abemaciclib therapy was ongoing at 150 twice daily.

The initial reporting consumer considered the event peripheral coldness as related to abemaciclib therapy, while did not provide causal relationship between rest of the events and abemaciclib therapy. The second reporting consumer did not provide relatedness assessment between any event and abemaciclib therapy.

Update 24-Jan-2025: Additional information received on 21-Jan-2025 from the initial reporter via PSP of a business partner. Added non-serious events of diarrhea, peripheral coldness and nausea. Updated narrative with new information.

Update 12-Mar-2025: Additional information received from the initial reporter via PSP on 07-Mar-2025. Added medical history of cancer surgery, indications of all concomitant medications except anastrozole and vitamin B6, additional dosage regimen for abemaciclib (150 mg, bid (2 pills a day)), batch number of dosage regimen 150 mg every other day, onset date of diarrhea and non-serious event of cough. Updated medical history from diabetes to type 2 diabetes, outcome of events constipation, diarrhea and nausea to recovered, causality of event peripheral coldness from not reported to related, and updated narrative with new information.

Update 12-May-2025: Additional information was received on 05-May-2025 from another consumer via PSP of a business partner. Updated outcome of cough to recovering and description reported for peripheral coldness. Upon internal review of previous information, the event of inappropriate schedule of product administration was updated to off label dosing frequency. Narrative was updated accordingly with new information.

Update 05-Jun-2025: Additional information was received on 30-May-2025 from initial reporting consumer via PSP conducted by a business partner. Added two medical histories of numbness in hand and numbness in feet. Updated narrative with new information.

Lilly Analysis Statement: 05-Jun-2025: The company considered the events of nausea and diarrhea related to the abemaciclib. The company considered the event of peripheral coldness unrelated to the abemaciclib.

**14-19. SUSPECT DRUG(S) continued**

| 14. SUSPECT DRUG(S) (include generic name) | 15. DAILY DOSE(S);<br>16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to);<br>19. THERAPY DURATION |
|---|---|---|---|
| #1 ) Abemaciclib (Abemaciclib) Tablet {Lot # D761191; Exp.Dt. OCT-2026}; Regimen #1 | 150 mg, other (One tablet every other day); Oral | Breast cancer (Breast cancer) | 12-DEC-2024 / Unknown; Unknown |
| #1 ) Abemaciclib (Abemaciclib) Tablet; Regimen #2 | 150 mg, daily (One tablet every 24 hours); Oral | Breast cancer (Breast cancer) | 19-DEC-2024 / Unknown; Unknown |

Mfr. Control Number: CR202412016158

## ADDITIONAL INFORMATION

**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 # D78502; Exp.Dt. OCT-2026}; Regimen #3 | 150 mg, bid (2 pills a day); Oral | Breast cancer (Breast cancer) | Ongoing; Unknown |

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

#7 ) VITAMIN B6 (VITAMIN B6) Unknown ; Unknown

#8 ) TRIFLUOPERAZINA [TRIFLUOPERAZINE] (TRIFLUOPERAZINA [TRIFLUOPERAZINE]) Tablet ; Unknown

**23. OTHER RELEVANT HISTORY continued**

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| Unknown | Medical Condition | Hypothyroidism (Hypothyroidism); |
| Unknown | Medical Condition | Nerve damage (Nerve injury); |
| Unknown | Medical Condition<br>about 15 or 20 years ago | Throat discomfort (Oropharyngeal discomfort); |
| Unknown | Procedure<br>underwent surgery for some type of cancer | Cancer surgery (Cancer surgery); |
| NOV-2023 to Ongoing | Medical Condition | Numbness in hand (Hypoaesthesia); |
| NOV-2023 to Ongoing | Medical Condition | Numbness in feet (Hypoaesthesia); |