

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 75 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					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]
Numbness in hands and feet [Hypoaesthesia]
Low immune system [Decreased immune responsiveness]
felt like vomiting [Nausea]
diarrhoea / gastrointestinal problems [Diarrhoea]
Upset stomach/diarrhea (second episode) [Diarrhoea]
Patient administered Verzenio at the frequency of one tablet every other(Continued on Additional Information Page)

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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 06-JUN-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 17-JUN-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 3	NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

day and one tablet every 24 hours, No AE [Off label use]

Case Description: This solicited case, reported by a consumer via a 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. As of 06-Jun-2025 she experienced cold hands and feet, numbness of hands and feet, upset stomach/diarrhea (second episode) and low immune system. Information regarding corrective treatments was not provided. Outcome of constipation, diarrhea (first episode) and nausea was recovered, for off label dosing frequency, numbness in hand and feet, upset stomach/diarrhea (second episode), low immune system and cold hands and feet was unknown and for cough was recovering. Abemaciclib therapy was ongoing at 150 twice daily.

The initial reporting consumer did not know if the events peripheral coldness, numbness in hands and feet, low immune system and upset stomach/diarrhea (second episode) were related to abemaciclib therapy and while did not provide causal relationship between the remaining 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.

Update 16-Jun-2025: Additional information received on 06-Jun-2025 from the initial reporter via a PSP. Added event of numbness in hand and feet, upset stomach/diarrhea (second episode) and low immune system; changed outcome from not recovered to unknown and as reported causality from yes to unknown for the event of cold hands and 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.
16-Jun-2025: The company considered the events of numbness in extremities and low immune system not related to abemaciclib and the event of diarrhea (second episode) related to abemaciclib.

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
--	---	---------------------------	--

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 # 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
#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	Throat discomfort (Oropharyngeal discomfort); about 15 or 20 years ago
Unknown	Procedure	Cancer surgery (Cancer surgery); underwent surgery for some type of cancer
NOV-2023 to Ongoing	Medical Condition	Numbness in hand (Hypoaesthesia);
NOV-2023 to Ongoing	Medical Condition	Numbness in feet (Hypoaesthesia);