

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH Day Month Year PRIVACY	2a. AGE 69 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET Day Month Year NOV 2024	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) bronchomoniasis [Respiratory monilliasis] Influenza [Influenza] Inflammation in the liver [Hepatitis] Inflammation of the gallbladder [Cholecystitis] Pain on the right side [Pain] stomach hurts/is like cramps [Abdominal pain upper] Diarrhoea [Diarrhoea] Case Description: This solicited case, reported by a consumer via a patient support program (PSP), concerned a 69-year-old (at the time of (Continued on Additional Information Page)							

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Abemaciclib (Abemaciclib) Tablet	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) 13-NOV-2024 / Ongoing	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) ENALAPRIL (ENALAPRIL) Unknown ; Unknown #2) CONTROLIP [FENOFIBRATE] (FENOFIBRATE) Unknown ; Unknown #3) FAMOTIDINE (FAMOTIDINE) Unknown, 90 mg; Unknown #4) GEMFIBROZIL (GEMFIBROZIL) Unknown ; Unknown #5) GLIBENCLAMIDE (GLIBENCLAMIDE) Unknown ; Unknown #6) METFORMIN (METFORMIN) 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 2007 to Ongoing Medical Condition Type 2 diabetes mellitus (Type 2 diabetes mellitus) Unknown to Ongoing Medical Condition Eyeglasses wearer (Corrective lens user)		

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. CR202412000125	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.	
24c. DATE RECEIVED BY MANUFACTURER 21-MAY-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 27-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

27-May-2025 09:15

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

initial report) female patient of an unknown origin.

Medical history included type 2 diabetes, high pressure, high triglycerides, asthma, vision abnormal and eyeglasses wearer. Concomitant medications included enalapril for blood pressure, fenofibrate for triglycerides, and famotidine, gemfibrozil, glibenclamide, metformin, loratadine, beclometasone, salbutamol, disodium fumarate, calcium, ascorbic acid; all for unknown indication.

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice daily via oral route of administration, for the treatment of breast cancer, beginning on 13-Nov-2024. On an unknown date in Nov-2024, three days after starting abemaciclib therapy, she had diarrhea. She took serum and was given medication for the diarrhea (unspecified). Sometimes, if she ate cheese, custard, milk or meat, her stomach hurts like cramps and got diarrhea. On an unknown date, she was hospitalized for 22 days due to severe liver and gallbladder inflammation. She was treated for nine days for the gallbladder and liver inflammation, and for the remaining days in hospital she was treated for moderate influenza that caused bronchomoniasis. She was released from hospital on an unknown date in May-2025. On an unknown date, she had mild pain on her right side, pain was not below the rib. Information regarding further corrective treatment was not provided. Outcome of the event diarrhea was resolved, not recovered for pain, unknown for abdominal pain upper whereas recovering for remaining events. Therapy status of abemaciclib was continued.

The reporting consumer did not provide an opinion on relatedness assessment of the events diarrhea and abdominal pain upper whereas did not relate the remaining events with abemaciclib therapy.

Update 27-May-2025: Additional information was received from the initial reporter via PSP on 21-May-2025. This case was upgraded to serious due to addition of four serious events cholecystitis, hepatitis, influenza and respiratory moniliasis with criteria of hospitalization. Added two medical histories and one non serious event of pain. Updated the narrative with new information.

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

- #7) LORATADINE (LORATADINE) Unknown, 10 mg; Unknown
- #8) BECLOMETHASONE [BECLOMETASONE] (BECLOMETHASONE [BECLOMETASONE]) Unknown ; Unknown
- #9) SALBUTAMOL (SALBUTAMOL) Unknown ; Unknown
- #10) FUMARATE DISODIUM (DISODIUM FUMARATE) Unknown ; Unknown
- #11) CALCIUM (CALCIUM) Unknown ; Unknown
- #12) VITAMIN C [ASCORBIC ACID] (VITAMIN C [ASCORBIC ACID]) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Vision abnormal (Visual impairment);
Unknown	Medical Condition	Blood pressure increased (Blood pressure increased);
Unknown	Medical Condition	Triglycerides high (Blood triglycerides increased);
Unknown	Medical Condition	Asthmatic (Asthma);