

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 46 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET Day Month Year AUG 2024	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
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) Stomach pain / cramps [Abdominal pain upper] when she bends down and stands up quickly it makes her dizzy [Dizziness postural] when its too hot feels like she is going to break down (faint) [Feeling abnormal] blood pressure is very low [Hypotension] does not feel hungry in the afternoons [Decreased appetite] diarrhoea [Diarrhoea] Case Description: This solicited case, reported by a consumer via (Continued on Additional Information Page)							

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Abemaciclib (Abemaciclib) Tablet {Lot # D700887; 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) AUG-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) TAMOXI (TAMOXIFEN CITRATE) Unknown ; AUG-2024 / Ongoing #2) VITAMIN C [ASCORBIC ACID] (VITAMIN C [ASCORBIC ACID]) Unknown ; Unknown #3) B COMPLEX [VITAMIN B COMPLEX] (VITAMIN B COMPLEX) 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 Medical Condition Blood pressure high (Hypertension) she was diagnosed with this before the cancer Unknown Medical Condition Tumor enlargement (Neoplasm progression) from the time of the biopsy, up to the time it was removed, the tumor had grown by 2 cm	

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Eli Lilly de Centroamerica Edificio KPMG 2do Piso, San Rafael de Escazu, Boulevard Mutiplaza, Del Ctro Com.Boulevard San Jose de Costa Rica, COSTA RICA Phone: (506) 22087200-2208	26. REMARKS
24b. MFR CONTROL NO. CR202411011655	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 09-JAN-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 15-JAN-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

patient support program (PSP) of business partner, with additional information from initial reporter via PSP, concerned a 46-year-old female patient of unknown origin.

Medical history included feeling like vomiting after she had finished eating all her life, thus, she had to get rid of the taste of food after eating; high blood pressure diagnosed before the cancer; breast cancer tumor that from the time of a biopsy, up to the time it was removed, the tumor had grown by 2 cm; underwent quadrantectomy surgery to remove the breast cancer tumor on 17-Nov-2023; she was given red chemotherapy (as reported) that did not do anything but caused vomiting and diarrhea; also was given white chemotherapy (as reported) and 12 sessions of paclitaxel which went very badly as gave her neuropathy in her feet and hands which to date they were numb; and an allergy in her hands but had gone. Concomitant medications included ascorbic acid and vitamin B complex, both for unknown indications.

The patient received abemaciclib (Verzenio) tablets, 150 mg, two times a day, via oral, for the treatment of breast cancer, beginning in Aug-2024. Additionally, she received unspecified blood pressure pill, most probably for the treatment of high blood pressure; dosage, frequency, route of administration and start date were not provided. As concomitant chemotherapy she received tamoxifen for breast cancer. On an unknown date in Aug-2024, since she started taking abemaciclib therapy, she experienced stomach pain. On 21-Oct-2024, she went to consult with the physician about the symptom of stomach pain and was told that it would probably go away after four months, however, after taking loperamide as corrective treatment, no longer had it; she ate, and nothing happened to her. Later, she continued taking loperamide from time to time when any food caused her stomach pain. On an unknown date when she bent down and stood up quickly, it made her dizzy. When weather was very hot, she felt like was going to break down (faint). On an unknown date, she did not feel hungry in the afternoons but in the mornings, she did want to eat; experienced cramps that sent her to go to the toilet but when she went, she did not pass any stools and sometimes they were normal stools, nonetheless, when she ate cheese she got diarrhea. On an unknown date, she stopped taking unspecified blood pressure pill because her blood pressure was very low (values, units, and reference range were not provided); every day she measured her blood pressure and depending on how it was, took the pill or not, but it had been 94 over 90 (no units or reference range provided) so she had not taken the unspecified blood pressure pill. By 09-Jan-2025 her stomach pain and diarrhea improved and loperamide medication was discontinued. Outcome of blood pressure low was unknown, for stomach pain and diarrhea was recovering while for remaining events was not recovered. Information regarding further corrective treatments and status of unspecified blood pressure pill after discontinuation was not provided. Abemaciclib therapy was ongoing.

The reporting consumer did not provide the relatedness of the events with abemaciclib or unspecified blood pressure pill therapies.

Update 02-Dec-2024: Additional information was received on 26-Nov-2024 from the initial reporter via PSP of a business partner. Added further medical history; non-serious events of dizziness postural, feeling abnormal, decreased appetite, diarrhea and hypotension; ascorbic acid and vitamin B complex as concomitant medications, unspecified blood pressure pill as co-suspect and blood pressure measurement to lab data. Updated description as reported and to be coded and outcome of abdominal pain upper; and narrative accordingly with new information.

Update 14-Jan-2025: Additional information received on 09-Jan-2025 from the initial reporter via a PSP of a business partner. Added chemotherapy as medical history. Updated the outcome of the events stomach pain and diarrhea from not recovered to recovering. Updated narrative with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood pressure measurement		
		Very low.		
		No values, units or reference range provided.		
2		Blood pressure measurement		
		94 over 90		
		No units or reference range provided.		

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Numbness (Hypoaesthesia);

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
		in her feet and hands
Unknown	Medical Condition	Allergy (Hypersensitivity);
Unknown	Medical Condition	Nausea (Nausea); always feels like vomiting after she has finished eating. she indicates that he has been like this all his life, so he has to get rid of the taste of food after eating.
17-NOV-2023 to Unknown	Procedure	Breast operation (Breast operation); quadrantectomy surgery to remove the breast cancer tumour
Unknown	Procedure	Biopsy (Biopsy);
Unknown	Procedure	Chemotherapy (Chemotherapy); red and white
Unknown	Historical AR	Vomiting (Vomiting);
Unknown	Historical AR	Diarrhoea (Diarrhoea);
Unknown	Historical Drug	taxol (TAXOL); Drug Indication: Breast cancer (Breast cancer), Drug Reaction: Neuropathy (Neuropathy peripheral) neuropathy in her feet and hands