

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 73 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						NOV	2024	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
Felt bone in her lower jaw was going to fall apart because it hurt [Pain in jaw]
little hoarse [Dysphonia]
Pain on the left side of face [Facial pain]
Swelling in one eye, described as slightly bumpy [Eye swelling]
stomach discomfort / Stomach upset [Abdominal discomfort]
stomach loosens but not directly diarrhea [Gastrointestinal disorder]
stomach hurts and twists / stomach pain [Abdominal pain upper]
immediately has to go to the bathroom [Defaecation urgency]
drop in defenses / low immune system / immune system disorder [Decreased
(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}		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) 09-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) ANASTROZOLE (ANASTROZOLE) Unknown ; 07-AUG-2024 / 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 to Ongoing	Medical Condition	Breast cancer (Breast cancer)
2010 to Unknown	Medical Condition	Prediabetes (Glucose tolerance impaired)

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. CR202501016624	
24c. DATE RECEIVED BY MANUFACTURER 05-MAY-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 14-MAY-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 2	

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

14-May-2025 10:40

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

immune responsiveness]
stomach becomes tender [Abdominal tenderness]
Cold/ severe cold with following symptoms: a lot of coughing, discomfort in throat like a pain, hurt like the left side of head, productive cough, fever and moderate general malaise. [Nasopharyngitis]
Nausea [Nausea]
headaches [Headache]
go to the bathroom 1 to 3 times, but sometimes up to 4 times in a row [Frequent bowel movements]
drop in hemoglobin / lowhemoglobin [Haemoglobin decreased]
low platelets [Platelet count decreased]
diarrhea after breakfast [Diarrhoea]

Case Description: This solicited case, reported by a consumer via patient support program (PSP) of a business partner, with additional information from the initial reporter via PSP of a business partner, concerned a 73-year-old female patient of unknown origin.

Medical history included pre-diabetes since 2010, breast cancer and using glasses for years to see properly, left breast cancer operation on 14-Oct-2023; underwent her first red chemotherapy on 15-Dec-2023, completing a total of 4 red and 12 white chemotherapy sessions, which ended on 07-Jun-2024 or 13-Jun-2024; also received 15 sessions of radiotherapy starting on 27-Jul-2024, with the last session on 21-Aug-2024; had a cold when she finished the radiotherapy. Historical medication included an unspecified medication for pre-diabetes. Concomitant medications were not provided.

The patient received abemaciclib (Verzenio) tablets, 150 mg, twice daily, orally, for the treatment of breast cancer, beginning on 09-Nov-2024. As concomitant chemotherapy she received anastrozole for breast cancer. During previous radiotherapy and chemotherapy treatments, she did very well, but abemaciclib was hitting her hard, as it caused many side effects. In Nov-2024, during the first month of abemaciclib therapy, she experienced nausea and headaches. Since that time, she had also been suffering from rhinitis or a cold, which were initially worse but gradually improved. On an unspecified date in Dec-2024, about a month and a half into treatment, she developed a cold accompanied by pain on the left side of her head and face, along with swelling in one eye, described as slightly bumpy. The swelling gradually went away, but she continued to experience a lot of coughing, throat discomfort including pain and mild hoarseness. She took unspecified syrups for cough, which worked very well for her. On an unknown date, she felt something very strange as the bone in her lower jaw was going to fall apart because it hurt. However, the pain gradually went away. Furthermore, her nausea became moderate to severe, in the morning hours. In addition, she came down with a severe cold with productive cough, fever and moderate general malaise. On an unknown date, she went to receive medical attention, and chest x-rays were taken with normal result and hematocrit in which leukocytes are normal (no units, baseline value and reference range were provided). Her doctor referred that it (cold) was viral. She was resting, the cold symptoms had lasted several weeks, including cough. On 09-Jan-2025, two months after taking abemaciclib therapy, blood tests were performed resulting in a drop in hemoglobin (no values, units or reference provided) for which she took unspecified things to raise the hemoglobin as corrective treatment. As of 03-Feb-2025, improvement in cold was noted with no medication, only rest and good hydration. As of 06-Mar-2025, she was doing well, being stable. On an unknown date in the morning after breakfast, she experienced stomach discomfort, her stomach loosened, she felt like it hurt and twisted, she immediately had to go to the bathroom one to three times, but sometimes up to four times in a row, however, these were not directly diarrhea. As corrective treatment, she took some unspecified natural remedies, which helped to calm stomach discomfort. She used to experience a lot of nausea, but then it was going away. On 27-Mar-2025, she had the blood test again and noticed that the hemoglobin continued to be low at 10 when she had always managed it at 14; defenses were dropped at 3.2 or 3000.2, and in relation to platelets, she had managed them at 300 or more but had them at 150 (no units or reference range provided for neither lab tests). Even when she received chemotherapy prior to abemaciclib, her hemoglobin level had not dropped as much as it did with abemaciclib therapy. On her physician's recommendation, since the immune system was very low, she should take care of herself so that she did not pass on any virus and had to walk with a mask and carry alcohol gel to clean their hands. On an unknown date, the low hemoglobin level continued, there were times when her hemoglobin level was normal, but sometimes it dropped and she must be careful; the low hemoglobin and platelet levels persisted although they were less. When she took abemaciclib dose in the morning, she had to wait 30 minutes to have something to eat, because it was when her stomach became tender. There were situations in which she only experienced diarrhea after breakfast, which caused her to go to the bathroom three to four times, other times, it was less common. Occasionally, she experienced an upset stomach or stomach pain, since it did not happen all the time. On an unknown date, she still had an immune system disorder, although it was slightly less severe than last time because it was then higher. As of 05-May-2025, she continued to use abemaciclib, but when went out, did not eat because she only took liquids (saline solution). Information regarding further corrective treatments was not provided. Outcome of eye swelling and jawbone pain was recovered; for hoarseness, pain on the left side of face, cold, nausea and headache was recovering; for gastrointestinal disorder, defecation urgency, frequent bowel movements and abdominal tenderness was unknown; while for the remaining events was not recovered. Abemaciclib therapy was ongoing despite experiencing side effects. However, if her immune system dropped too low, abemaciclib treatment would have to be discontinued.

The reporting consumer did not provide a causal relationship between jawbone pain, abdominal tenderness and diarrhea with abemaciclib; while related the remaining events to abemaciclib therapy.

Update 30-Jan-2025: Both the information received on 21-Jan-2025 and 27-Jan-2025 was processed together.

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

Update 08-Feb-2025: Additional information received by initial reporting consumer via PSP on 03-Feb-2025. Added two lab tests of chest x ray and hematocrit and three non-serious event terms of viral infection, pyrexia and malaise. The narrative was updated with new information.

Update 11-Mar-2025: Additional information was received on 06-Mar-2025 from the initial reporter via PSP of a business partner. Updated outcome of nausea, facial pain, headache and hoarseness; all to recovering. Upon internal review of previous information, it was deleted viral infection and rhinitis events, and it was merged the events of oropharyngeal pain, fever and malaise into nasopharyngitis as they were symptoms. Narrative was updated accordingly with new information.

Update 21-Apr-2025: Additional information was received on 10-Apr-2025 from the initial reporter via PSP of a business partner. Added corrective lens use as medical history; non-serious events of abdominal discomfort, gastrointestinal disorder, abdominal pain upper, defecation urgency, frequent bowel movements, hemoglobin decreased, decreased immune responsiveness and platelet count decreased; and their respective lab tests. Updated start date of abemaciclib therapy, dosage of anastrozole, and narrative accordingly with new information.

Update 12-May-2025: Additional information was received on 05-May-2025 from the initial reporter via PSP of a business partner. Added non-serious events of abdominal tenderness and diarrhea. Updated description reported for abdominal pain upper, outcome of decreased immune responsiveness to recovering and narrative accordingly with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Chest X-ray		
		Normal		
2		Haematocrit		
		Leukocytes are normal		
3		Haemoglobin	14	
		No units or reference provided		
4	09-JAN-2025	Haemoglobin		
		drop in hemoglobin		
		No values, units or reference provided		
5	27-MAR-2025	Haemoglobin	10	
		continued to be low		
		No units or reference provided		
6	27-MAR-2025	Immunology test	3.2	
		alternate result: 3000.2		
		drop in defenses		
		low immune system		
		No units or reference provided		
7		Platelet count	300	
		No units or reference provided		
8	27-MAR-2025	Platelet count	150	

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
No units or reference provided				

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
14-OCT-2023 to Unknown	Procedure Left breast	Cancer surgery (Cancer surgery);
Unknown	Medical Condition	Corrective lens user (Corrective lens user);
15-DEC-2023 to 07-JUN-2024	Procedure 4 red and 12 white chemotherapy	Chemotherapy (Chemotherapy);
27-JUL-2024 to 21-AUG-2024	Procedure 15 sessions	Radiotherapy (Radiotherapy);
21-AUG-2024 to Ongoing	Historical AR	Cold (Nasopharyngitis);