

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>COSTA RICA</b>	2. DATE OF BIRTH			2a. AGE <b>73 Years</b>	3. SEX <b>Female</b>	3a. WEIGHT <b>Unk</b>	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	
			<b>PRIVACY</b>						<b>NOV</b>	<b>2024</b>	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)  
 Other Serious Criteria: Med sig  
 bronchial asthma [Asthma]  
 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]  
 (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 Unknown to Ongoing 2010 to Unknown	Type of History / Notes Medical Condition Medical Condition	Description Breast cancer (Breast cancer) Prediabetes (Glucose tolerance impaired) that since 2010 she has suffered from pre-diabetes, for which she takes medication, but she;does not remember the name.

## 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. <b>CR202501016624</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.  NAME AND ADDRESS WITHHELD.  NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>03-JUN-2025</b>	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 <b>09-JUN-2025</b>	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 3	

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

immediately has to go to the bathroom [Defaecation urgency]  
 drop in defenses / low immune system / immune system disorder [Decreased 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 / low hemoglobin [Haemoglobin decreased]  
 low platelets [Platelet count decreased]  
 diarrhea after breakfast [Diarrhoea]  
 bronchitis [Bronchitis]  
 flu virus or flu-like illness [Influenza like illness]

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. approximately 30 years ago, the patient had bronchial asthma. It lasted for 3 months until a doctor prescribed a 5-year treatment, and with natural medicines, she recovered. 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. As of 03-Jun-2025, her diarrhea has been improving, as it has decreased. She had been taking cassava starch (she says it's like flour) after breakfast. Sometimes she takes it with lemon. It helps support her stomach, as diarrhea affects her in the mornings after breakfast. She takes natural remedies to avoid taking medications. She has been recovering from the diarrhea. she has been recovering because her stomach upset/stomach pain has subsided. She has been taking flaxseed, chia seeds, green smoothies, oatmeal with pineapple, and oatmeal with apple. Therefore, the pain has greatly subsided. For decreased hemoglobin/ decreased platelets / immune system disorder, her complete blood count will be performed approximately in Jul-2025 (date not indicated) to validate his condition. On-18-May-2025 or

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

19-May-2025, she had a flu virus or flu-like symptoms. It started with a sore throat, but she did not have fever or body aches, but it quickly developed into bronchitis, causing her to cough, itchy throat, and she felt like she was going to burst from coughing so much. Also she felt like she was suffocating and drowning. On an unknown date, the doctor prescribed her medication for allergies, cough, and itchy throat, such as: Syrups (does not indicate which ones), Ventilar, Perebron, and Levinfar. For this reason, she was feeling better now because her bronchial tubes have opened and she coughs up phlegm. She was choking because she could not cough up the phlegm. Her doctor told her she had bronchial asthma, similar to bronchitis. approximately 30 years ago, the patient had bronchial asthma. It lasted for 3 months until a doctor prescribed a 5-year treatment, and with natural medicines, she recovered. She comments that the doctor also gave her recommendations such as being careful with temperature changes (for example, if it is very hot, do not drink anything cold, wait until it cools down to bathe). Her lungs have strengthened again. She had not been experiencing symptoms (bronchial asthma) until now, but assumes it was because her son had a cold. Her symptoms were not as severe as before. She hopes to feel better within 8 days and will wait a while for the medication she was currently taking so that she can come in for a complete blood count in July to be evaluated (hemoglobin, platelets, immune system), as she assumed that after the attack she experienced (bronchial asthma), her immune system was weakening. Also she was not experiencing any symptoms of nausea. The event of bronchial asthma was considered as serious by the company due to medically significant reason. Outcome of eye swelling, nausea and jawbone pain was recovered; for hoarseness, pain on the left side of face, cold, diarrhea, stomach upset, and stomach pain 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, bronchial asthma, bronchitis 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.

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.

Update 09-Jun-2025: Additional information was received on 03-Jun-2025 from the initial reporter via PSP of a business partner. This case is upgraded to serious upon addition of one serious event of bronchial asthma due to medically significant reason, two non-serious events of bronchitis, and flu-like illness, one medical history of bronchial asthma, three treatment drug for the event of bronchial asthma. Updated outcome for diarrhea, abdominal discomfort, and abdominal pain upper to recovering, nausea as recovered, 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		

09-Jun-2025 15:28

**ADDITIONAL INFORMATION****13. Lab Data**

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

**23. OTHER RELEVANT HISTORY continued**

From/To Dates	Type of History / Notes	Description
14-OCT-2023 to Unknown	Procedure	Cancer surgery (Cancer surgery); Left breast, October 14, 2023 she was operated on by the oncologist for breast cancer.
Unknown	Medical Condition	Corrective lens user (Corrective lens user);
15-DEC-2023 to 07-JUN-2024	Procedure	Chemotherapy (Chemotherapy); 4 red and 12 white chemotherapy, on December 15, 2023 she underwent her first red chemotherapy, a total of 4 red and 12 white chemotherapy, which ended on 07 or June 13, 2024
27-JUL-2024 to 21-AUG-2024	Procedure	Radiotherapy (Radiotherapy); 15 sessions, she also refers that she underwent 15 radiotherapies, which she started on July 27, 2024, her last radiotherapy was on August 21, 2024.
21-AUG-2024 to Ongoing	Historical AR	Cold (Nasopharyngitis); she finished the radiotherapy on August 21, 2024 she had a cold.
Unknown	Medical Condition	Bronchial asthma (Asthma); approximately 30 years ago, the patient had bronchial asthma. It lasted for 3 months until a doctor prescribed a 5-year treatment, and with natural medicines, she recovered