

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 70 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					02	FEB	2024	

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
Pain in left lower limb redness in the same with local heat/Deep venous thrombosis in left lower limb/leg and foot were very swollen/left leg thrombosis [Deep vein thrombosis]
feels like a lump/balls were due to thrombosis [Mass]
excess uric acid [Blood uric acid increased]
blood in the stool [Haematochezia]
Altered renal blood tests/kidneys were altered [Renal function test abnormal]
Pain in joints, such as joints of arms, knees, elbows when she bends, and

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Abemaciclib (Abemaciclib) Tablet #2) ANASTROZOLE (ANASTROZOLE) Unknown <div align="right">(Continued on Additional Information Page)</div>		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 #2) UNK UNK, unknown	16. ROUTE(S) OF ADMINISTRATION #1) Oral #2) Unknown	
17. INDICATION(S) FOR USE #1) Breast cancer (Breast cancer) #2) Drug use for unknown indication (Produ) <div align="right">(Continued on Additional Information Page)</div>		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) 20-JAN-2024 / Ongoing #2) Unknown	19. THERAPY DURATION #1) Unknown #2) Unknown	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) CLEXANE (ENOXAPARIN SODIUM) Unknown ; SEP-2024 / Ongoing #2) VITAMIN D3 (VITAMIN D3) Unknown ; Unknown #3) IONIC CALCIUM (CALCIUM CHLORIDE, TRACE ELEMENTS NOS) 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 to Ongoing Medical Condition Breast cancer (Breast cancer) Unknown Medical Condition Diverticular disease (Diverticulum)		

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. CR202402002094	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 11-JUN-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 17-JUN-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

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

also the shoulders [Arthralgia]

Diarrhea [Diarrhoea]

Tiredness [Fatigue]

Nausea [Nausea]

Case Description: This solicited case reported by a consumer via a patient support program (PSP), concerned a 70-year-old (at the time of initial report) female patient of an unknown origin.

Medical history included diverticula and diarrhea with anastrozole, allergies since she was a child and was asthmatic, but for years. She had not flown with asthmatic crisis to the hospital for eight years and breast cancer. Concomitant medication included Vitamin D3, ionic calcium (calcium chloride/trace elements NOS) and enoxaparin sodium, all used for unknown indication.

The patient received abemaciclib (Verzenios) tablet, 150 mg, twice a day, via oral route, for the treatment of breast cancer, beginning on 20-Jan-2024. On an unknown date, she also received anastrozole (unknown manufacturer), at unknown dose and frequency, via unknown route of administration, for treatment of an unknown indication beginning on an unknown date. On an unspecified date, while on anastrozole in combination with abemaciclib therapy, she had experienced diarrhea. Prior to therapy she used to go bathroom only once but after therapy she went to bathroom twice; had little more loosely, although it was indicated as not a lot of diarrhea. Her oncologist had suggested taking loperamide as corrective treatment if she experienced diarrhea. On 30-Jan-2024, she had taken one dose of loperamide because she was going out and did not want to have problems with diarrhea outside her home. On same day, she went to the bathroom twice but indicated that she did not have diarrhea. On 02-Feb-2024, she experienced pain in left lower limb, redness in the same, with local heat and went several times to the emergency unit of her locality. She started with the thrombosis discomfort, she had thrombosis in her left leg, but in Aug-2024, she had swollen left leg and felt like a lump. She got some lumps, before the ankle, about 20 centimetres above the ankle on one side of the leg and thought they were insect bites because they itched inside and burned her, and as she was allergic to everything, she thought they were bites. On 08-Aug-2024, she went to the hospital where she was examined and prescribed the antibiotic cephalexin every 6 hours, she took it for a few days, but she did not see results, because it was not bites that she had, but the balls were due to thrombosis. She assumed that abemaciclib caused a thrombosis in her left leg. On 14-Aug-2024, a week later, she presented herself to the emergency area because she could not tolerate it and was given a unspecified stronger antibiotic, for the supposed insect bite because she had a ball in that area. On 10-Sep-2024, she underwent an ultrasound and a deep vein thrombosis was found in her left lower limb. She already been allergic to a mosquito or wasp sting, she imagined that it was an insect bite in 12-Sep-2024. The event of deep vein thrombosis in the left lower limb was considered as serious by the company due to medically significant reason. On 12-Sep-2024, she went to an appointment with the internal medicine doctor, she had an ultrasound done on 13-Sep-2024, the ultrasound physician discovered the thrombosis in the left leg and the physician prescribed anticoagulants enoxaparin injections, she had to take twice as she took them in her stomach because that was where it hurt less. On 19-Sep-2024, her leg and foot were very swollen and reportedly, severe deep vein thrombosis continued to be red hot and painful. On 30-Sep-2024, she had an appointment with the oncologist so that she could verify if she continued taking abemaciclib or not, because it was affecting her. Since her appointment on 08-Aug-2024 to the present, she had swelling in her left leg. She was currently (at the time of reporting) in the hospital for two days, she did not have a date, a colonoscopy would be performed because some blood tests showed that her kidneys were altered, excess uric acid and blood in the stool, for this reason colonoscopy was scheduled on 27-Sep-2024, where reason for the altered tests would be verified and to see how she was inside, for this reason she had not been taking abemaciclib for two days. As per information received on 23-Oct-2024, she also had nausea, tiredness, severe diarrhea and pain in her joints, such as in the joints of arms, knees, elbows when he bends, and also in her shoulders. She currently had the thrombosis under control with the help of the anticoagulant, but her left leg foot did not swell much and the balls were always there, about 20 centimeters above the ankle, where she presented the swelling, as if from the calf downwards it swelled. She had her next appointment with the oncologist on 11-Nov-2024. Information regarding corrective treatment of the remaining event was not provided. The outcome of the event mass was unknown, diarrhea and deep vein thrombosis was recovered in Feb-2024, and remaining events was not resolved. Status of abemaciclib therapy was ongoing and status of anastrozole was not provided.

The reporting consumer related the events of deep vein thrombosis leg and diarrhoea while did not provide an opinion on relatedness assessment of the remaining events with abemaciclib therapy. The reporting consumer related the event diarrhea while did not provide the relatedness for remaining events with anastrozole therapy.

Update 25-Sep-2024: Additional information was received from an initial reporting consumer via a PSP on 19-Sep-2024. This case was upgraded to serious by adding one serious event of deep vein thrombosis leg. Added one concomitant therapy as enoxaparin sodium. Updated narrative with new information accordingly.

Update 01-Oct-2024: Additional information was received from an initial reporting consumer via a PSP on 26-Sep-2024. Added three non serious events of mass, blood uric acid increased, blood in stool, added additional medical history allergy, asthmatic and a lab data for blood uric acid. Updated the ARC (as reported causality) for the event deep vein thrombosis from No to Yes and narrative with new information.

Update 28-Oct-2024: Additional information was received from initially reporting consumer on 23-Oct-2024 via PSP. Added one treatment medication of enoxaparin and three non-serious events of fatigue, nausea and joint pain. Updated correspondence fields and narrative with new information.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Update 17-Jun-2025: Additional information was received from initially reporting consumer via PSP on 11-Jun-2025. Added one medical history of breast cancer, one non-serious event of renal function test abnormal, severity for events of diarrhea and deep vein thrombosis, end date of event diarrhea as Feb-2024. Updated start date, as reported verbatim and outcome of event deep vein thrombosis. Updated outcome of event diarrhea from not recovered to recovered and as reported causality from not provided to related. Updated narrative with new information.

Lilly Analysis Statement: 17-Jun-2025: The company considered the events of nausea and fatigue as related to abemaciclib.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	10-SEP-2024	Blood uric acid Positive excess (values, units and reference range were not provided)		
2	10-SEP-2024	Ultrasound scan Positive deep vein thrombosis in the left lower limb		

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
#2) ANASTROZOLE (ANASTROZOLE) Unknown; Regimen #1	UNK UNK, unknown; Unknown	Drug use for unknown indication (Product used for unknown indication)	Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition since she was a child	Allergy (Hypersensitivity);
Unknown	Medical Condition	Asthmatic (Asthma);
Unknown	Historical Drug	Anastrozole (ANASTROZOLE); Drug Indication: Drug use for unknown indication (Product used for unknown indication), Drug Reaction: Diarrhea (Diarrhoea)