

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>GUATEMALA</b>	2. DATE OF BIRTH			2a. AGE <b>61</b> Years	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>12</b>	<b>OCT</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)  
 takes 150 mg every 24 hours. [Inappropriate schedule of product administration]  
 Reflux [Gastroesophageal reflux disease]  
 Upset stomach [Abdominal discomfort]  
 Decay [Depressed mood]  
 Inflammation of the liver [Hepatitis]  
 Anemia [Anaemia]  
 Tiredness/a little tired [Fatigue]  
 Nausea/nauseous [Nausea]  
 Lack of appetite [Decreased appetite]

(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
(Continued on Additional Information Page)		
15. DAILY DOSE(S) #1 ) 150 mg, daily	16. ROUTE(S) OF ADMINISTRATION #1 ) Oral	21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
17. INDICATION(S) FOR USE #1 ) Breast cancer (Breast cancer)		
18. THERAPY DATES(from/to) #1 ) 10-OCT-2024 / Unknown	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 ) FULVESTRANT (FULVESTRANT) Unknown ; Unknown #2 ) AROMASIN (EXEMESTANE) Unknown ; Unknown #3 ) VALSARTAN (VALSARTAN) Unknown ; Unknown #4 ) CALCIUM (CALCIUM) Unknown ; Unknown #5 ) ENSURE [ASCORBIC ACID;BIOTIN;CALCIUM CARBONAT (ASCOR #6 ) ESOMEPRAZOLE (ESOMEPRAZOLE) 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
Unknown	Medical Condition	Hypertension (Hypertension)
Unknown	Medical Condition	Gastritis (Gastritis)

## 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>GT202410013637</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.  NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>20-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>01-JUL-2025</b>	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 3	

01-Jul-2025 06:53

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

Case Description: This solicited case, reported by a consumer from a business partner via a patient support program (PSP), with additional information from the initial reporter, concerned a 61-year-old (at the time of initial report) female patient of an unknown origin.

The medical history included hypertension, gastritis, back pain, and lack of appetite. Concomitant medication included tramadol hydrochloride, esomeprazole, calcium, valsartan, and ascorbic acid, biotin, calcium carbonate, calcium pantothenate, carbohydrates nos, copper sulfate, cyanocobalamin, ergocalciferol, fats nos, ferrous sulfate, folic acid, linoleic acid, magnesium chloride, manganese chloride, nicotinamide, phytomenadione, potassium chloride, potassium citrate, potassium iodide, protein, pyridoxine hydrochloride, retinol palmitate, riboflavin, sodium polymetaphosphate, thiamine hydrochloride, tocopheryl acetate, zinc sulfate, all for the treatment of an unknown indication.

The patient received abemaciclib (Verzenio) tablets, 150mg, orally twice daily, for the treatment of breast cancer, beginning on 10-Oct-2024. She received exemestane and fulvestrant, as concomitant chemotherapy. On an unspecified date, while on abemaciclib therapy, she felt a little tired and sometimes in the morning, she got nauseous. On 13-Oct-2024, she did not ate dinner and had reflux, then she ate first before taking medication and recovered from the event. She also experienced lack of appetite and upset stomach. On 14-Oct-2024, she had a scintigraphy (no result, unit, baseline value, and reference range were provided). On 25-Feb-2025 she had liver inflammation and on an unknown date she experienced anemia, due to this events, abemaciclib therapy was suspended and on 27-Mar-2025 she resumed therapy as the liver tests came back normal. She restarted treatment with dosage 150 mg every 24 hours in May-2025 but experienced adverse effects such as nausea, decay (depressed mood) but no vomiting, fatigue that prevented her from getting out of bed. An unspecified treatment was administered for anemia and she recovered from the event, she was recovering from the liver inflammation, and had not recovered from the remaining events. Information regarding further corrective treatments was not provided. Abemaciclib therapy continued with no changes.

The reporting consumer did not provide an opinion on the relationship between the events and the the abemaciclib therapy.

Update 05-Nov-2024: Additional information was received from the initial reporter via PSP on 30-Oct-2024. Added two non-serious events of appetite lost and upset stomach. Updated narrative with the new information.

Update 01-Apr-2025: Additional information was received from the reporting consumer on 27-Mar-2025. Added the non-serious events of inflammation of the liver and anemia. Updated case and narrative with new information, no further changes were made to the case.

Update 06-May-2025: Information was received on 30-Apr-2025. No new medically significant information was received. Hence, no changes were made to the case.

Update 30-Jun-2025: Additional information was received from the reporting consumer via PSP on 20-Jun-2025. Added one dosage regimen slider and non-serious events of Inappropriate schedule of drug administration and depressed mood. Updated case and narrative with new information.

**13. Lab Data**

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	14-OCT-2024	Radioisotope scan		
(no result, unit, baseline value and reference range were provided)				

**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
#1 ) Abemaciclib (Abemaciclib) Tablet; Regimen #2	150 mg, daily; Oral	Breast cancer (Breast cancer)	MAY-2025 / Ongoing; Unknown

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

#5 ) ENSURE [ASCORBIC ACID;BIOTIN;CALCIUM CARBONAT (ASCORBIC ACID, BIOTIN, CALCIUM CARBONATE, CALCIUM PANTOTHENATE, CARBOHYDRATES NOS, COPPER SULFATE, CYANOCOBALAMIN, ERGOCALCIFEROL, FATS NOS, FERROUS SULFATE, FOLIC ACID, LINOLEIC ACID, MAGNESIUM CHLORIDE, MANGANESE CHLORIDE, NICOTINAMIDE, PHYTMENADIONE, POTASSIUM CHLORIDE, POTASSIUM CITRATE, POTASSIUM IODIDE, PROTEIN, PYRIDOXINE HYDROCHLORIDE, RETINOL PALMITATE, RIBOFLAVIN, SODIUM POLYMETAPHOSPHATE, THIAMINE HYDROCHLORIDE, TOCOPHERYL ACETATE, ZINC SULFATE) Unknown ; Unknown

ADDITIONAL INFORMATION

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

#7 ) TRAMACET [TRAMADOL HYDROCHLORIDE] (TRAMADOL HYDROCHLORIDE) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition	Back pain (Back pain);
Unknown	Medical Condition	Decreased appetite (Decreased appetite);