

# 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>64</b> Years	3. SEX <b>Female</b>	3a. WEIGHT <b>126.00</b> kg	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>24</b>	<b>MAY</b>	<b>2025</b>		

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)  
Colic/ cramps [Abdominal pain]  
Lower back pain [Back pain]  
Chills [Chills]  
tiredness [Fatigue]  
Diarrhea [Diarrhoea]

Case Description: This solicited case, reported by a consumer via a business partner who was contacted by the company via patient support program (PSP) to report adverse events, concerned a 64-year-old female patient of an unknown origin.

(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
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 ) 24-MAY-2025 / 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 ) LETROZOL (LETROZOL) Unknown ; Unknown #2 ) OMEGA 3 [FISH OIL] (FISH OIL) Unknown ; Unknown #3 ) CALCIUM (CALCIUM) Unknown ; Unknown #4 ) ZINC (ZINC) Unknown ; Unknown #5 ) MAGNESIUM (MAGNESIUM) Unknown ; Unknown #6 ) ESOMEPRAZOLE (ESOMEPRAZOLE) 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		

## 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>GT202506005781</b>	
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>10-JUN-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

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

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

Medical history was not provided. Concomitant medications included esomeprazole, magnesium, zinc, calcium, fish oil all for unknown indication.

The patient received abemaciclib (Verzenio) tablet, 150 mg twice daily, orally, for the treatment of breast cancer beginning on 24-May-2025. She was taking letrozole concomitantly. On 24-May-2025, since she started taking abemaciclib, she had mild cramps/colic and moderate tiredness but no diarrhea. On 26-May-2025, she went to eat at a restaurant, then she had mild diarrhea. Since that day, she had sporadic diarrhea therefore, she took loperamide when she had diarrhea as corrective treatment. Since 26-May-2025, she also experienced mild chills. On 30-May-2025, she experienced lower back pain. She did not receive corrective treatment for rest of the events. The outcome of all the events was not recovered. The therapy status of abemaciclib was ongoing.

The reporting consumer related the events of diarrhea, tiredness, and cramps with abemaciclib therapy while did not know the relatedness of the events of lower back pain and chills with abemaciclib therapy.

Lilly Analysis Statement: 09-Jun-2025: The company considered the events of chills and lowback pain as unrelated to abemaciclib.