

# 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>65 Years</b>	3. SEX <b>Female</b>	3a. WEIGHT <b>66.00 kg</b>	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
			<b>PRIVACY</b>						<b>FEB</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)  
**Other Serious Criteria: Med sig  
Thrombosis [Thrombosis]**

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), with additional information from the initial reporter, concerned a 65-year-old female patient of an unknown origin.

Medical history included breast cancer diagnosed in Mar-2023. Concomitant medications included unspecified blood pressure pills.

(Continued on Additional Information Page)

☐ PATIENT DIED  
☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION  
☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY  
☐ LIFE THREATENING

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) <b>#1 ) Abemaciclib (Abemaciclib) Tablet</b>		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) <b>#1 ) 150 mg, bid</b>	16. ROUTE(S) OF ADMINISTRATION <b>#1 ) Oral</b>	
17. INDICATION(S) FOR USE <b>#1 ) Breast cancer (Breast cancer)</b>		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES(from/to) <b>#1 ) 01-JUN-2024 / MAR-2025</b>	19. THERAPY DURATION <b>#1 ) Unknown</b>	

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)		
From/To Dates <b>MAR-2023 to Ongoing</b>	Type of History / Notes <b>Medical Condition</b>	Description <b>Breast cancer (Breast cancer)</b>

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER <b>Eli Lilly Interamerica Inc (AR Branch) Tronador 4890 - Piso 12 Buenos Aires, Capital Federal CP: 1430 ARGENTINA Phone: 54 1145464000</b>		26. REMARKS
	24b. MFR CONTROL NO. <b>CR202507006579</b>	
24c. DATE RECEIVED BY MANUFACTURER <b>29-JUL-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>04-AUG-2025</b>	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	
		25b. NAME AND ADDRESS OF REPORTER <b>NAME AND ADDRESS WITHHELD.</b>
		<b>NAME AND ADDRESS WITHHELD.</b>

04-Aug-2025 17:24

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

The patient received abemaciclib (Verzenio) tablet, 150 mg at twice daily via oral route, for breast cancer, beginning on 01-Jun-2024. Information regarding concomitant chemotherapy was not provided. On an unspecified date at the end of Feb-2025, six or seven months after starting abemaciclib therapy, she experienced moderate thrombosis. As a corrective treatment she took apixaban, which would be taken until Sep-2025. The event of thrombosis was considered as serious by the reporter due to medically significant reason. Abemaciclib therapy was discontinued on an unknown date in Mar-2025. On an unknown date, she recovered from the event after discontinuation, and she had not resumed abemaciclib therapy again.

The reporting consumer related the event with abemaciclib therapy.

Update 21-Jul-2025: Information was received on 16-Jul-2025. No medically significant information was received. No changes were made to the case.

Update 01-Aug-2025: Additional information was received from the initial reporter in response to a medical questionnaire via PSP on 29-Jul-2025. Added apixaban as treatment medication. Updated onset date of the event of thrombosis, the outcome of the event of thrombosis from recovering to recovered and narrative with the new information.