

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 50 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					20	AUG	2025	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
Diarrhea [Diarrhoea]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) concerned a 50-year-old (at the time of initial report) female patient of an unknown origin.

Medical history and concomitant medications were not provided.

The patient received abemaciclib (Verzenio) tablet, 150mg, twice daily orally, for the treatment of breast cancer, beginning on 08-Aug-2025.

(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) 08-AUG-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)								
<div>23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)</div> <table border="1"> <thead> <tr> <th>From/To Dates</th> <th>Type of History / Notes</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td colspan="3">Unknown</td> </tr> </tbody> </table>			From/To Dates	Type of History / Notes	Description	Unknown		
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. CR202508024448	
24c. DATE RECEIVED BY MANUFACTURER 21-AUG-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 31-AUG-2025	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.

31-Aug-2025 20:46

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

On 20-Aug-2025, after starting abemaciclib therapy, she experienced diarrhea in the morning, her frequency was two bowel movements per morning. She received loperamide as corrective treatment for diarrhea. The outcome of the event was not resolved. Therapy status of abemaciclib was continued. Follow up is not possible because it is not possible to obtain further information because the patient, family member, or other non-healthcare professional does not agree to be contacted for future follow-up, nor does their treating physician.

The reporting consumer possibly related the event with abemaciclib therapy.