

# 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>Unk</b>	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>Unk</b>	<b>Unk</b>		

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

Case Description: This spontaneous case, reported by a physician who contacted the company via a business partner, concerned a female patient of unknown age and origin.

Medical history and concomitant medications were not provided.

(Continued on Additional Information Page)

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1 ) Verzenio (Abemaciclib) Tablet  (Continued on Additional Information Page)		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1 ) UNK UNK, unknown	16. ROUTE(S) OF ADMINISTRATION #1 ) Oral	
17. INDICATION(S) FOR USE #1 ) Drug use for unknown indication (Produ  (Continued on Additional Information Page)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES(from/to) #1 ) 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)		
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>CR202506025230</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>25-JUN-2025</b>	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	
DATE OF THIS REPORT <b>01-JUL-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	



ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient received abemaciclib (Verzenio) tablets, at unknown dose and frequency via oral route of administration for an unknown indication, beginning on an unknown date. On an unknown date, while on abemaciclib therapy, she experienced gastrointestinal (as reported) and diarrhea. Information regarding corrective treatment and outcome of the events were not provided. The status of abemaciclib therapy was not provided. Follow up was not possible as the reporter declined to be contacted.

The reporting physician related the events with abemaciclib therapy.

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 ) Verzenio (Abemaciclib) Tablet; Regimen #1	UNK UNK, unknown; Oral	Drug use for unknown indication (Product used for unknown indication)	Unknown; Unknown