

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 59 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					02	APR	2025	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
Stomach pain [Abdominal pain upper]
Sweating [Hyperhidrosis]
blood pressure goes up [Blood pressure increased]
Red urine [Chromaturia]
Distended stomach [Gastric dilatation]
Toothache [Toothache]
Feeling like you were going to die [Anxiety]
Constipation [Constipation]
vomiting/ threw it away [Vomiting]
Diarrhea [Diarrhoea]

(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 checked="" type="checkbox"/> NO <input 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 type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 31-MAR-2025 / 04-JUN-2025	19. THERAPY DURATION #1) 2 months 5 days	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) ANASTROZOLE (ANASTROZOLE) Unknown ; Unknown #2) TAMOXIFEN (TAMOXIFEN) Unknown ; Unknown #3) TRAMADOL (TRAMADOL) Unknown ; Unknown #4) GABAPENTIN (GABAPENTIN) Unknown ; Unknown #5) ACETAMINOPHEN (ACETAMINOPHEN) Unknown ; Unknown #6) CLONAZEPAM (CLONAZEPAM) 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	Memory loss (Amnesia)
Unknown	Medical Condition	Low blood pressure (Hypotension)
	Low pressure	

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. CR202504015691	
24c. DATE RECEIVED BY MANUFACTURER 05-JUN-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 11-JUN-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 3	

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

NAME AND ADDRESS WITHHELD.

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

Lack of appetite [Decreased appetite]
 Feeling that stomach was burning [Dyspepsia]
 Rash on body [Rash]

Case Description: This solicited case, reported by a consumer via a Patient Support Program (PSP), concerned a 59-year-old (at the time of the initial report) female patient of an unknown origin.

Medical history included memory loss, low pressure, chemotherapies and radiotherapy. Concomitant medication included dimenhydrinate, hyoscine, clonazepam, acetaminophen, gabapentin and tramadol for the treatment of unknown indication.

The patient received abemaciclib (Verzenio) tablet, 150 mg twice daily via oral route for breast cancer, beginning on 31-Mar-2025. She took anastrozole for breast cancer and tamoxifen for unknown indication as concomitant medications. On 02-Apr-2025, she had diarrhea and almost threw it away, had vomiting. On an unknown date, abemaciclib made her sick because it caused diarrhea and stomach pain every day every time when she took it, when she got stomach pain she started sweating, one day she had to go to the emergency room because she got sick to her stomach from so much pain. Her blood pressure went up due to the pain that abemaciclib caused her since she started taking it. On an unknown date, she had constipation and lack of appetite. On 12-May-2025, she had a distended stomach, red urine, toothache, felt stomach was burning and felt like going to die, she had to go to the emergency room because she could not stand it. On 04-Jun-2025, she experienced rash on body. She went to the hospital and her treating physician prescribed discontinuation of abemaciclib of same day. She took loperamide for diarrhea and hydroxal to help her stomach and dextetoprofen trometamol, tramadol hydrochloride for toothache, however for remaining events treatment information was not provided. The outcome of the event vomiting was recovering whereas not recovered for remaining events. The status of abemaciclib therapy was discontinued. Follow-up was not possible as the reporter refused to be contacted and did not give permission to contact the treating physician.

The initial reporting consumer did not provide the relatedness of constipation and decreased appetite whereas related the remaining events with the abemaciclib therapy.

Update 04-May-2025: Additional information was received from the initial reporter via PSP conducted by business partner, on 28-Apr-2025. Added six concomitant drugs of dimenhydrinate, hyoscine, clonazepam, acetaminophen, gabapentin and tramadol, therapy start date of abemaciclib, and two non-serious events decreased appetite and constipation. Updated the outcome of the events diarrhea and vomiting from not recovered to recovering and narrative with new information

Update 21-May-2025: Additional information was received from the initial reporter via PSP conducted by business partner, on 13-May-2025. Added one treatment medication of dextetoprofen trometamol, tramadol hydrochloride, five non-serious events of dyspepsia, chromaturia, anxiety, toothache and gastric dilatation. Updated the outcome of the event diarrhea recovering to not recovered and narrative with new information.

Update 10-Jun-2025: Additional information was received from the initial reporter via PSP conducted by business partner, on 05-Jun-2025. Added stop date of abemaciclib, one non serious event of rash. Updated action taken with abemaciclib to drug discontinued and narrative with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood pressure measurement Positive increased (Value, unit and reference range was not provided)		

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

#7) HYOSCINE (HYOSCINE) Unknown ; Unknown

#8) GRAVOL (DIMENHYDRINATE) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Procedure	Chemotherapy (Chemotherapy);

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Procedure	Radiotherapy (Radiotherapy);