

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY GUATEMALA	2. DATE OF BIRTH			2a. AGE 65 Years	3. SEX Female	3a. WEIGHT 74.00 kg	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION ☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING
		Day	Month	Year			Day	Month	Year		
		PRIVACY					15	MAY	2025		

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
 Feels very sleepy / Lots of sleep [Somnolence]
 Stomach pain [Abdominal pain upper]
 Decay [Depressed mood]
 Pain in toe due to neuropathy [Neuralgia]
 Lack of appetite / No appetite [Decreased appetite]
 Diarrhea/had 5 bowel movements in one day and other days 1 or 2 bowel movements/liquid and abundant [Diarrhoea]
 Lethargic/a feeling of heaviness in the body [Lethargy]
 Feeling weak [Asthenia]

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Abemaciclib (Abemaciclib) Tablet {Lot # D795083; Exp.Dt. MAY-2027}		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ 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? ☐ YES ☐ NO ☒ NA
18. THERAPY DATES(from/to) #1) 15-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) ANASTROZOL (ANASTROZOL) Pillules ; Unknown #2) BENICAR (OLMESARTAN MEDOXOMIL) Pillules ; 2005 / Unknown #3) ESOMEPRAZOLE (ESOMEPRAZOLE) Pillules ; 2025 / Unknown #4) ODICA (PREGABALIN) Pillules ; Unknown #5) NUCLEO CMP (CYTIDINE MONOPHOSPHATE DISODIUM, URIDINE) (Continued on Additional Information Page)								
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">From/To Dates</td> <td style="width: 33%;">Type of History / Notes</td> <td style="width: 33%;">Description</td> </tr> <tr> <td>2021 to Ongoing</td> <td>Medical Condition</td> <td>Neuropathy (Neuropathy peripheral)</td> </tr> </table>			From/To Dates	Type of History / Notes	Description	2021 to Ongoing	Medical Condition	Neuropathy (Neuropathy peripheral)
From/To Dates	Type of History / Notes	Description						
2021 to Ongoing	Medical Condition	Neuropathy (Neuropathy peripheral)						

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. GT202507019938	
24c. DATE RECEIVED BY MANUFACTURER 29-JUL-2025	24d. REPORT SOURCE ☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:	
DATE OF THIS REPORT 04-AUG-2025	25a. REPORT TYPE ☐ INITIAL ☒ FOLLOWUP: 2	

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

NAME AND ADDRESS WITHHELD.

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

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) conducted by a business partner, concerned a 65-year-old female patient of an unknown origin.

Medical history included neuropathy. Concomitant medications included Olmesartan medoxomil for arterial hypertension, esomeprazole for gastric pain and pregabalin, cytidine monophosphate disodium/uridine triphosphate trisodium, both for neuropathy.

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice daily, orally for the treatment of breast cancer, beginning on 15-May-2025. She also received anastrozol for breast cancer, as concomitant chemotherapy. On 15-May-2025 since starting abemaciclib therapy, she experienced diarrhea but not every day. After taking the medication, when she ate, some days she has three to four consecutive episodes of diarrhea. Her diarrhea increased. Some days she has had five bowel movements in one day and other days one or two bowel movements but were always liquid and abundant in consistency. She had moderate weakness/feeling weak, and moderate diarrhea. She had not received treatment and then had stomach pain. Somedays she had no appetite and felt very sleepy, and lethargic, some days more than others. She did not feel like getting up and just wanted to sleep. She also experienced decay/depressed mood. On 17-Jul-2025, she felt pain in her toe, which she believed was due to neuropathy (medical history). She had another appointment on 13-Aug-2025. All of her events, except lethargic, were mild, diarrhea was moderate and required no corrective treatment. Information regarding corrective treatment for event lethargic was not provided. The outcome of the events was not recovered. The status of abemaciclib therapy was ongoing.

The initial reporting consumer did not relate the event neuropathic pain, did not provide the relatedness for the event of lethargic, while related the remaining events with abemaciclib therapy.

Update 30-Jul-2025: Additional information was received from the initial reporter on 25-Jul-2025. Added start date of medical history as 2021, and event frequency for the event of lethargy. Updated outcome of event lethargy from unknown to not recovered and description as reported to Lethargic/a feeling of heaviness in the body and narrative with new information.

Update 04-Aug-2025: Both additional information was received from the initial reporter via PSP on 29-Jul-2025 and 30-Jul-2025 were processed together. Update the event verbatim for diarrhea from diarrhea to diarrhea/had 5 bowel movements in one day and other days 1 or 2 bowel movements/liquid and abundant updated the frequency from mild to moderate. Added one non serious event of feeling weak. Updated narrative with new information.

Lilly Analysis Statement: 24-Jul-2025: The company considered the event of lethargy related to the abemaciclib.

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

#5) NUCLEO CMP (CYTIDINE MONOPHOSPHATE DISODIUM, URIDINE TRIPHOSPHATE TRISODIUM) Pillules ; 2005 / Unknown