SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		57 Years	Female	Unk	09	NOV	2024

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

Intense dizziness that prevented him from performing his daily activities for approximately two weeks [Dizziness]
Stomach pain [Abdominal pain upper]
She has not been sleeping well in the last few days [Insomnia]
Stomach pain (indicates that it is in the pit of stomach and cramps)/cramps [Abdominal pain]
stomach upset [Abdominal discomfort]
Difficulty eating [Feeding disorder]
Weight loss [Weight decreased]
Difficulty focusing vision and moments with blurred vision (cannot see

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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)
#1) Abemaciclib (Abemaciclib) Tablet
#2) GRAVOL (DIMENHYDRINATE) Unknown
(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 150 mg, bid	#1) Oral
#2) UNK UNK, unknown	#2) Unknown

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)
#2) Drug use for unknown indication (Produ
(Continued on Additional Information Page)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 09-NOV-2024 / Ongoing	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) ANASTROZOLE (ANASTROZOLE) Tablet ; JUL-2024 / Unknown
#2) VITAMIN D [COLECALCIFEROL] (COLECALCIFEROL) Unknown ; JUL-2024 / Unknown
#3) CALCIUM (CALCIUM) Tablet ; JUL-2024 / Unknown
#4) TURMERIC [CURCUMA LONGA RHIZOME] (CURCUMA LONGA RHIZ
#5) PROTEIN (PROTEIN) 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	Gilbert's syndrome (Gilbert's syndrome) diagnosed when she was 15 years old
2014 to Unknown	Medical Condition	Fibromyalgia (Fibromyalgia) diagnosed 9 to 10 years ago

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.
CR202411008497

24c. DATE RECEIVED BY MANUFACTURER
30-MAY-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
05-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

well) [Vision blurred]
Cold sensation in her body [Feeling cold]
Low blood pressure [Blood pressure decreased]
Vertigo [Vertigo]
Headache [Headache]
Fatigue/ lot of tiredness [Fatigue]
Diarrhoea [Diarrhoea]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), concerns a 57-year-old (at the time of initial report) female patient of an unknown origin.

Medical history included gilbert's syndrome (diagnosed when she was 15 years old). At that time, she was taking some drinkable vitamins (unspecified), which gave her jaundice and resultant in hospitalization. Due to this syndrome, certain medicines caused her to become jaundiced, fibromyalgia since 2014 or 2015. She indicates that she used to take lirica but was no longer taking it. Now she received natural things like turmeric because she did not want to take any more medication, especially anastrozole because it caused her a lot of leg pain (prior to abemaciclib), started radiotherapy till Jul-2024 and that after this treatment she weighed 50 kg. Concomitant medications included colecalciferol, calcium, protein powder, curcuma longa rhizome for an unknown indication.

The patient received abemaciclib (Verzenio) tablets, 150mg twice daily via orally for treatment of breast cancer beginning on 09-Nov-2024. On an unknown date, she received dimenhydrinate at an unknown dose and frequency, via an unknown route for an unknown indication. She also received anastrozole as a concomitant medication for an unknown indication. On 09-Nov-2024, one the same day of starting abemaciclib therapy, she experienced diarrhea. and vertigo. On 10-Nov-2024, she took the treatment at the same time, went to the gym, but experienced cramps/stomach pain (pit of her stomach and cramps), and stomach upset. She took paracetamol, tramadol hydrochloride and a glucose, sodium chloride serum for diarrhea as corrective treatment. On an unknown date in Nov-2024, she experienced headache which she believed was due to sleeping unwell in the last few days. On 11-Nov-2024, she had four bouts of diarrhoea. As a corrective treatment, she took two tablets of loperamide and then for each diarrhea one tablet until it stops. On an unknown date in Nov-2024, the initial weeks of taking abemaciclib drug were very strong due to an intense dizziness, which prevented her from performing her daily activities for approximately two weeks. During this period, she felt that her blood pressure remained very low and she sometimes had experienced a cold sensation in her body. She had identified dimenhydrinate as an upset stomach pill. In those initial weeks, she also had difficulty eating, which caused her to lose weight, reaching 50 kg. Subsequently, she managed to recover to her initial weight and currently weighs 53 kg. On an unknown date, she had experienced a lot of tiredness and insomnia, so she decided to supplement with potassium and magnesium together as it helped her to slightly manage these symptoms. On 14-Dec-2024, she had no new episodes of diarrhea. As of 16-Dec-2024, she no longer had pain in the pit of her stomach but continued to have headache, but had not taken medication to treat it. Instead, he applied essential oil to his head or smells lavender. On 09-Dec-2024 (approximately), she has noticed difficulty focusing her vision and moments with blurred vision (could not see well). In Jan-2025, she had fully recovered from diarrhea and vertigo. The event of dizziness was considered as serious by the reporter due to disability reason. Information regarding the corrective treatment for remaining events was not provided. Outcome of the events of fatigue, feeling cold, abdominal discomfort was unknown, insomnia was resolving, weight loss, diarrhea, vertigo and difficulty eating was resolved whereas remaining events were not resolved. The status of abemaciclib treatment was ongoing while that dimenhydrinate was unknown.

The initial reporting consumer related diarrhea and vertigo whereas did not provide relatedness assessment between the remaining events and abemaciclib treatment. The initial reporting consumer related the event of upset stomach while did not provide the relatedness assessment of remaining events with dimenhydrinate.

Update 21-Nov-2024: Additional information was received from the initial reporting consumer via PSP on 14-Nov-2024. Added treatment medications paracetamol, tramadol hydrochloride and a glucose, sodium chloride; one new non-serious event of stomach upset. Updated description as reported stomach pain (she indicates that it is in the pit of her stomach and cramps)/cramps; event onset date from Nov-2024 to 10-Nov-2024 for event abdominal cramps, and diarrhea; abemaciclib start date from 08-Nov-2024 to 09-nov-2024. Narrative was updated with new information accordingly.

Update 19-Dec-2024: Additional information was received on 16-Dec-2024 from initial reporting consumer via the PSP. This case was upgraded to serious due to one serious event of dizziness due to disability. Added non-serious events of blood pressure decreased, feeling cold, vision blurred, weight decreased, feeding disorder, and fatigue, one co-suspect medication, event stop date of diarrhea and treatment medications. Updated outcome of event insomnia as resolving from not resolved, abdominal pain as resolved from not resolved, abdominal discomfort as not resolved from unknown and diarrhea as resolved from not resolved, and narrative with new information.

Update 03-Jun-2025: Additional information was received from initial reporter via PSP on 30-May-2025. Added one non-serious event of vertigo. Updated the event stop date of diarrhea from 14-Dec-2024 to Jan-2025 and its causality as reported from no to yes. Updated the narrative and causality statement with new information.

Mfr. Control Number: CR202411008497

ADDITIONAL INFORMATION

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
#2) GRAVOL (DIMENHYDRINATE) Unknown; Regimen #1	UNK UNK, unknown; Unknown	Drug use for unknown indication (Product used for unknown indication)	Unknown; Unknown

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

#4) TURMERIC [CURCUMA LONGA RHIZOME] (CURCUMA LONGA RHIZOME) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition Due to drinkable vitamins (unspecified)	Jaundice (Jaundice);
Unknown	Medical Condition she finished it in July 2024 and that after this treatment she weighed 50 kg.	Radiotherapy (Radiotherapy);
Unknown	Historical Drug	lirica (LIRICA); Drug Indication: Fibromyalgia (Fibromyalgia), Drug Reaction: No adverse drug effect (No adverse event)
Unknown	Historical Drug Prior to Verzenio.	Anastrozole (ANASTROZOLE); Drug Indication: Fibromyalgia (Fibromyalgia), Drug Reaction: Leg pain (Pain in extremity)