CIOMS FORM

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	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
PRIVACY	COSTA RICA		PRIVACY		46 Years	Female	Unk		NOV	2023	

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

Prolactin level of 274.81 ng/ml [Blood prolactin increased]
Breast discharge [Breast discharge]
Stomach heaviness/discomfort in the stomach [Abdominal discomfort]
Stomach pain [Abdominal pain upper]
Bloating/Swollen belly [Abdominal distension]
Dizziness [Dizziness]
Diarrhea/stools as watery [Diarrhoea]
Nausea [Nausea]

Case Description: This solicited case, reported by a consumer via **(Continued on Additional Information Page)**

- ☐ 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) Unknown

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

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 23-NOV-2023 / Ongoing	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

#1) TAMOXIFEN (TAMOXIFEN) Capsule ; Unknown
#2) ESCITALOPRAM (ESCITALOPRAM) Unknown ; Unknown
#3) TAFIL [TADALAFIL] (TADALAFIL) Unknown ; Unknown
#4) MAGNESIUM (MAGNESIUM) Unknown ; Unknown
#5) OMEGA 3 [FISH OIL] (FISH OIL) Unknown ; Unknown
#6) VITAMIN C [ASCORBIC ACID] (VITAMIN C [ASCORBIC ACID]) 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 to Ongoing	Medical Condition	Anxiety disorder (Anxiety disorder)
	anxiety and panic disorder for more than 20 years	
Unknown to Ongoing	Medical Condition	Panic disorder (Panic disorder)
	anxiety and panic disorder for more than 20 years	

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.
CR202402010554

24c. DATE RECEIVED BY MANUFACTURER
02-JUN-2025

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

DATE OF THIS REPORT
09-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

patient support program (PSP) from a business partner, with additional information from the initial reporter via PSP of a business partner, concerned a 46-year-old (at the time of initial report) female patient of unknown origin.

Medical history included anxiety disorder and panic disorder for more than 20 years; qualifying as a diabetic with glucose value at 200 and hemoglobin A1c at 5.6 (units and reference range were not provided) about a year ago, it was managed by diet, exercise and fasting; and 10 kg of weight loss. Concomitant medication included escitalopram as an anti-depressant for anxiety and panic disorder; tadalafil, magnesium, fish oil, ascorbic acid and bacillus clausii used for unknown indications.

The patient received abemaciclib (Verzenio) tablets, 150 mg, twice daily, orally, for the treatment of breast cancer, beginning on 23-Nov-2023. Concomitantly, she received tamoxifen to lower estrogen level. On 23-Nov-2023, after taking first dose of abemaciclib therapy in the morning, she experienced diarrhea every day. On an unknown date in Nov-2023, she noticed breast discharge, on the same she was operated on (unspecified reason). Reportedly, from Nov-2023 to mid-Jan-2024, she went to bathroom seven times a day. Her stools were watery. On an unknown date, while on abemaciclib therapy, she had stomach pain and bloating and suspected it might be related to her colon. On an unknown date in Jan-2024, while on abemaciclib therapy, she experienced a four-day episode of dizziness that led her to visit the hospital. She was referred to an otorhinolaryngologist, but due to the wait time, she paid for a private ear, nose, and throat (ENT) who prescribed famotidine and levosulpiride as a corrective treatment and she took the same for a week. On 31-Jan-2024, she again experienced dizziness and took the same corrective treatment. Reportedly, it was believed that dizziness was related to her ears, but everything was fine with it moreover, when another bout of dizziness was sensed a single dose of famotidine alleviates it. On an unknown date, since starting treatment with abemaciclib, she experienced nausea, stomach heaviness and a desire to vomit that made her fasting challenging. Reportedly, she had varying levels of nausea and was described as nervous. On 13-Feb-2024, while on abemaciclib therapy, she underwent an immunology laboratory test, and the results showed a prolactin level of 274.81 ng/ml. On 14-Feb-2024, a glucose curved showed fasting at 85 and 112 two hours later, moreover she never took any medication for sugar control. As of 15-Feb-2024, she was going to bathroom four or five times a day. On an unknown date, diarrhea continued but was bearable because she did not stray far from places where there was a bathroom nearby, and if she had to go somewhere where there was no bathroom, she did not even go and did not leave her house. Information regarding corrective treatment of the remaining events were not provided. She had not recovered from the events. Abemaciclib therapy was ongoing. Follow-up could not be attempted since the reporter did not agree to be contacted nor to treating physician.

The reporting consumer related diarrhea to abemaciclib while did not provide relatedness assessment between the remaining events and abemaciclib therapy.

Update 24-Feb-2024: Additional information was received from the initial reporting consumer via business partner and PSP on 15-Feb-2024. Added six non-serious events of dizziness, nausea, stomach heaviness, diarrhea, stomach pain, and bloating, five concomitant medications, three medical history, and two treatment medications of the event dizziness. Updated the corresponding field and narrative accordingly.

Update 06-Jun-2025: Additional information was received on 02-Jun-2025 from the initial reporter via PSP of a business partner. Updated causality of diarrhea from not reported to yes and narrative accordingly with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood prolactin Positive High	274.81 ng/mL	

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

#7) ENTEROGERMINA [BACILLUS CLAUSII] (BACILLUS CLAUSII) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Fasting (Fasting);
2023 to Ongoing	Medical Condition	Diabetic (Diabetes mellitus); tests to check for diabetes,including a glucose curve.values were at 200,hemoglobin A1c was 5.6.

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ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2023 to Unknown	Medical Condition	Weight loss (Weight decreased);