**CIOMS FORM**

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

| 1. PATIENT INITIALS (first, last) | 1a. COUNTRY | 2. DATE OF BIRTH | | | 2a. AGE | 3. SEX | 3a. WEIGHT | 4-6 REACTION ONSET | | | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Day | Month | Year | | | | Day | Month | Year | |
| PRIVACY | COSTA RICA | | PRIVACY | | 52 Years | Female | Unk | 08 | NOV | 2024 | |

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

Other Serious Criteria: medical significant
Tremor [Tremor]
Fall/impossible to move around [Fall]
Hitting the dorsal part of lower back and caused moderate pain [Back injury]
Stomach pain/inflammed stomach [Abdominal pain upper]
Moderate cough (Second episode) [Cough]
Does not support odors [Parosmia]
Moderate insomnia/ difficulty sleeping [Insomnia]
Migraine [Migraine]

**(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) Tablet

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 ) 08-NOV-2024 / 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 ) TAMOXIFEN (TAMOXIFEN) Unknown ; Unknown
#2 ) VITAMIN D NOS (VITAMIN D NOS) Unknown ; Unknown
#3 ) LEVOTHYROXINE (LEVOTHYROXINE) Unknown ; Unknown
#4 ) GEMFIBROZIL (GEMFIBROZIL) Unknown ; Unknown
#5 ) DOLO NEUROBION XR (CYANOCOBALAMIN, DICLOFENAC SODIUM
#6 ) ZAMEN (DEFLAZACORT) 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 | Hypothyroidism (Hypothyroidism) |
| Unknown | Historical Drug | |

**(Continued on Additional Information Page)**

## 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.
**CR202412000214**

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

24c. DATE RECEIVED BY MANUFACTURER
22-APR-2025

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

DATE OF THIS REPORT
28-APR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

## ADDITIONAL INFORMATION

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

Hoarse or aching voices [Dysphonia]
Increased appetite [Increased appetite]
Cough caused by the nausea (First episode) [Cough]
Nausea [Nausea]
Vomiting [Vomiting]
Diarrhea [Diarrhoea]
Weakness [Asthenia]
Headache [Headache]
Tiredness [Fatigue]
Itchy neck and skin [Pruritus]

Case Description: This solicited case reported by a consumer via a patient support program (PSP) and business partner, with additional information from the initial reporter, concerned a 52-years-old (at the time of initial report) female patient of an unknown origin.

Medical history included hypothyroidism. Historical drug included dimenhydrinate for nausea and caused sleepy. Concomitant medications included levothyroxine for the treatment of hypothyroidism, gemfibrozil for the treatment of triglycerides, cyanocobalamin/diclofenac sodium/pyridoxine hydrochloride/thiamine hydrochloride and deflazacort and vitamin D NOS for the treatment of unknown indication and unspecified allergy pill.

The patient received abemaciclib (Verzenio) tablet, 150mg, twice daily, orally, for the treatment of breast cancer, beginning on 08-Nov-2024 and 14-Nov-2024 (conflicting dates), in combination with tamoxifen concomitantly. Since 08-Nov-2024, she has been nauseous. As a corrective treatment for nausea, she received metoclopramide on 27-Nov-2024 and did not feel so bad. On 18-Nov-2024, she wanted to go to the supermarket, driving, for a SueroX but had to call the ambulance. Her head was hurting, and her hands were shaking. She also felt weakness. The event of tremor was considered as serious by the reporter due to medically significant reason. Her blood pressure was 129 and her blood sugar was 94. As a corrective treatment, she was given intravenous (IV) fluids and other unspecified things. Then she returned home and fell asleep. She could not stand smells, any smell but especially shampoo. On 20-Nov-2024, she experienced diarrhea and took unspecified serum as corrective treatment. On 26-Nov-2024, she vomited dinner. She had already brushed and then vomited. She received SueroX and went to sleep. She had been very hungry. She had a lot of stomach pain, that it was like gastritis, or she did not know but that it was a pain like from so many pills. She received bromide when her stomach was very inflamed, and she took 1 pill and a lot of water. She no longer had that pain. She also took famotidine (1 every day before going to sleep), because she had felt a lot of pain, which made her go to the bathroom. She went to the bathroom normally, the first two times and the third time it was diarrhea, so she took 2 loperamide and if she got another diarrhea, she took another loperamide but no more, because she did not get diarrhea anymore. She experienced having too much headache and her body was very broken down, she felt weak, she fell and could not drive. On 26-Nov-2024, she felt sick again, but she was not driving, her niece was. Sometimes she got headaches and sometimes she did not. She has had the pain for about 3 days. On 04-Dec-2024, she fell from her own height entering her home, hitting the dorsal part of her lower back, which caused moderate pain and made it impossible for her to move around but did not require hospitalization. The events of fall and back injury were considered as serious by the reporter due to disability reasons. As a corrective treatment, she went to receive medical attention and was given treatment (not specified). Since an unknown date, she was very tired and had a cough caused by the nausea. As of 10-Jan-2025, she continued with nausea and diarrhea. She did not receive vitamin D drops, and did not know if she would continue taking it or not. On an unknown date, her doctor ordered x-rays, which showed no injury. Since 10-Dec-2024, after starting abemaciclib therapy, she was having moderate insomnia and had trouble sleeping. On an unknown date, while on abemaciclib therapy, she experienced itching on her neck and skin. On 04-Feb-2025, she had a medical visit, where she was given an unspecified allergy pill and was instructed to take one every day, but she only took a pill on the nights she experienced itching. On 10-Feb-2025, while on abemaciclib therapy, she experienced migraine. On an unknown date, she recovered from diarrhea, and cough, and only experienced nausea when she smelled perfume. On 25-Feb-2025, she had moderate cough without being sick with the flu or something similar. She had felt recovered from her cough for two months, only occasionally experiencing very hoarse or aching voices. However, she commented that the cough only occurred when she felt nauseous. When she was next to a person who was heavily perfumed (that was, someone who smells strongly of a certain scent), it caused nausea. However, since she did not vomit, that was when the cough occurred, or when she brushed her teeth and felt nauseous, she still got a cough. Information regarding corrective treatment of the remaining events was not provided. The outcome of the events of vomiting, stomach pain, diarrhea, cough (first and second episodes), parosmia, and nausea was recovered, the outcome of fall and back injury was recovering while the outcome of event hoarseness was unknown and for the remaining events was not recovered. Status of abemaciclib therapy was ongoing.

The initial reporting consumer did not provide relatedness of the events of insomnia, hoarseness, back injury, tiredness, cough (first episode), migraine, and itchy skin, did not relate the events of parosmia, fall, increased appetite and tremor, while related the remaining events with abemaciclib therapy.

Update 05-Dec-2024: Upon review of information received on 28-Nov-2024, updated ranking for the event of headache based on listedness. Additional information was received from initial reporting consumer via PSP on 30-Nov-2024. Added event onset date for the event of diarrhea. Updated narrative with new information received.

Update 11-Dec-2024: Additional information was received from initial reporting consumer via PSP on 07-Dec-2024. Added two

## ADDITIONAL INFORMATION

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

concomitant medications of deflazacort and cyanocobalamin/ diclofenac sodium/pyridoxine hydrochloride/thiamine hydrochloride and two serious events of fall and back injury with seriousness criteria of disability. Updated causality statement and narrative with new information.

Update 14-Jan-2025: Additional information was received from the initial consumer reporter on 10-Jan-2025, via a PSP. Added: two non-serious events tiredness and cough. Updated onset date of event nausea, weakness and outcome of diarrhea from recovered to not recovered. Updated narrative accordingly with new information.

Update 27-Jan-2025: Additional information was received from the initial reporter on 21-Jan-2025. Updated outcome of the events of fall and back injury from not recovered to recovering. Updated narrative with new information.

Update 31-Jan-2025: Additional information was received from the initial reporting consumer on 28-Jan-2025 via a PSP. Added a non-serious event of insomnia. Updated narrative with new information.

Update 13-Feb-2025: Additional information was received from the reporting consumer on 10-Feb-2025 via a PSP. Added: the non-serious events of migraine and itchy skin. Updated: the outcome of the following non-serious events from not recovered to recovered: diarrhea, cough, parosmia, and nausea; and narrative accordingly.

Update 27-Mar-2025: Additional information was received from initial reporting consumer via PSP on 24-Mar-2025. Added one non-serious event of cough. Updated the narrative accordingly.

Update 28-Apr-2025: Additional information was received from initial reporting consumer via PSP and business partner on 22-Apr-2025. Added one new non-serious event of hoarseness. Updated the outcome of event moderate cough (second episode) from not recovered to recovered. Ticked the concomitant therapy administered box. Updated the narrative with new information.

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

#5 ) DOLO NEUROBION XR (CYANOCOBALAMIN, DICLOFENAC SODIUM, PYRIDOXINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE)  Unknown ; Unknown

**23. OTHER RELEVANT HISTORY  continued**

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| Unknown | Historical Drug | Gravol (GRAVOL); Drug Indication: Nausea (Nausea), Drug Reaction: Sleepy (Somnolence) |