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		47 Years	Female	57.00 kg	16	OCT	2024	

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

When she ate her stomach was swelling [Abdominal distension]
Constipated [Constipation]
Burning in the soles of both feet/back has also been burning when she goes to bed at night/burning sensation in their back and feet worsened. [Burning sensation]
The patient awake due to severe headaches [Sleep disorder]
Forgetful [Memory impairment]
Heartburn [Dyspepsia]
Every time she took Verzenio she got a headache [Headache]
She was not very hungry [Decreased appetite]

(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) 16-OCT-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) ARIMIDEX (ANASTROZOLE) Capsule, 1 mg; Ongoing
#2) GOSERELINA (GOSERELINA) Unknown ; Ongoing
#3) INDOMETHACIN [INDOMETACIN SODIUM] (INDOMETACIN SODIU

(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	Appetite lost (Decreased appetite)
Unknown to Ongoing	Medical Condition	Listless (Listless)

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.
CR202410014447

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
04-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Moderate tiredness [Fatigue]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), with additional information from the initial reporter via PSP, concerned a 47-year-old (at time of initial report) female patient of unknown origin.

Medical history included not wanting to eat, feeling quite listless, weight loss, chemotherapy for breast cancer, memory loss, and surgery for left breast cancer. Concomitant medications included unspecified vitamins for unknown indications and indomethacin for pain.

The patient received abemaciclib (Verzenio) tablets, 150 mg every 12 hours, orally, starting on 16-Oct-2024, for the treatment of breast cancer. Concomitant chemotherapy included anastrozole, goserelin, and an unspecified breast cancer pill. On 16-Oct-2024, after starting abemaciclib therapy, she experienced heartburn and stomach swelling when she ate, she also experienced a headache every time she took abemaciclib. Due to severe headaches, she was awake, and that this had made her forgetful. On an unknown date, she experienced constipation and not being very hungry. On 12-Dec-2024, she experienced moderate tiredness, for which she did not consult a doctor, and did not take any other medication. By 22-Apr-2025, she continued to experience moderate tiredness occasionally. Additionally, she experienced severe worsening of burning sensation in the soles of both feet, on 01-Feb-2025 she has experienced moderate headaches and since approximately Feb-2025, she experienced worsening of burning sensation of back when she went to bed at night. As corrective treatment, the palliative care doctor prescribed unspecified cream that she applied twice a day to relieve the burning sensation in her back and feet. This unspecified ointment /cream numbs her skin like an anesthetic. Additionally, the palliative care doctor also prescribed unspecified capsule which she administered one capsule every day to relieve the burning sensation in her back and feet. Her burning sensation was less severe now. Due to chemotherapy and radiation therapy she forgets everything. She had finished the chemotherapy treatments about a year ago and the radiation treatments about six months ago. She would have oncology appointment on 23-Apr-2025. On an unknown date, she applied 2% lidocaine hydrochloride twice a day and Venlafaxine hydrochloride equivalent 75 mg capsules to relieve the burning effect on the back and feet. She would undergo a magnetic resonance imaging (MRI) to determine the cause of headaches and/or a CT scan for head on 28-May-2025 because she has severe headaches that was keeping her awake. She would undergo exam on 21-Jun-2025 to determine the cause of the burning sensation in her back and feet. Corrective treatment for the remaining events was not provided. Outcome of burning sensation was resolving, while other events were ongoing. Abemaciclib therapy status was ongoing.

The reporting consumer did not provide an opinion on relatedness between the events and abemaciclib therapy.

Updated 23-Oct-2024: This case was determined to be non-valid as there was no identifiable adverse event reported (Suspect drug started after AEs).

Update 05-Nov-2024: This case was originally determined to be non-valid. Additional information was received from the initial reporting consumer via PSP on 30-Oct-2024. Added five new non-serious events of swelling abdomen, constipation, heartburn, headache and decreased appetite. Updated narrative accordingly.

Update 30-Jan-2025: Additional information was received from the initial reporting consumer via PSP on 24-Jan-2025. Added one new non-serious event of tiredness. Narrative was updated with new information accordingly.

Update 28-Apr-2025: Additional information received on 22-Apr-2025 from the initial reporter via a PSP. Added one non-serious event of burning sensation, chemotherapy, breast cancer and memory loss as medical history, indomethacin as concomitant medication and an unspecified ointment as corrective treatment. Updated narrative with new information.

Update 16-May-2025: Additional information received on 09-May-2025 from the initial reporter via a PSP. Added two non serious event forgetfulness and sleep disorder, patient weight, medical history. Updated description as reported for the event of burning sensation from Burning in the soles of both feet/back has also been burning when she goes to bed at night to Burning in the soles of both feet/back has also been burning when she goes to bed at night/burning sensation in their back and feet worsened. Updated treatment information for event burning sensation and outcome of burning sensation from not recovered to recovering. Updated narrative with new information.

Update 21-May-2025: Additional information received on 09-May-2025 from the initial reporter via a PSP. Added two treatment drug of venlafaxine hydrochloride, lidocaine hydrochloride for event of burning sensation. Updated narrative with new information.

Update 03-Jun-2025: Additional information received on 26-May-2024 from the initial reporter via a PSP. Information regarding headache event was updated in narrative. No other changes were made to the case.

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

#3) INDOMETHACIN [INDOMETACIN SODIUM] (INDOMETACIN SODIUM) Unknown ; Ongoing

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Weight loss (Weight decreased);
Unknown	Procedure 12 white and 6 red	Chemotherapy (Chemotherapy);
Unknown	Medical Condition	Breast cancer (Breast cancer);
Unknown	Medical Condition	Memory loss (Amnesia);
06-MAY-2024 to Unknown	Procedure	Surgery (Surgery); Underwent surgery on her left breast for breast cancer.