# 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 | | 60 Years | Female | Unk | | | 2024 |

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

Weight loss [Weight decreased]
Very difficult for her to eat [Feeding disorder]
alkaline phosphatase dropped [Blood alkaline phosphatase decreased]
stomach pain [Abdominal pain upper]
feels sick [Illness]
cramps [Muscle spasms]
discomfort [Discomfort]
Tiredness/feeling tired [Fatigue]
Low hemoglobin [Haemoglobin decreased]
hematocrit dropped [Haematocrit decreased]

**(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 ) VITAMIN E [TOCOPHEROL] (TOCOPHEROL) Unknown

| 15. DAILY DOSE(S) | 16. ROUTE(S) OF ADMINISTRATION |
|---|---|
| #1 ) 150 mg, bid | #1 ) Oral |
| #2 ) At 10 am | #2 ) Oral |

17. INDICATION(S) FOR USE
#1 ) Breast cancer (Breast cancer)
#2 ) Skin sensitivity (Sensitive skin)

| 18. THERAPY DATES(from/to) | 19. THERAPY DURATION |
|---|---|
| #1 ) 24-SEP-2024 / Ongoing | #1 ) Unknown |
| #2 ) 2024 / Unknown | #2 ) Unknown |

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

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

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1 ) ARIMIDEX (ANASTROZOLE) Unknown ; Ongoing
#2 ) EUTIROX (LEVOTHYROXINE SODIUM) Unknown ; Ongoing
#3 ) CALCIUM (CALCIUM) Unknown ; 2024 / Ongoing

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 | Dental caries (Dental caries) |
| Unknown | Medical Condition | Thyroid disorder (Thyroid disorder) |

## 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.
**CR202409018676**

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

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

DATE OF THIS REPORT
02-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**

white blood cells low [White blood cell count decreased]
no longer hungry/Lack of appetite [Decreased appetite]
little dizziness [Dizziness]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) of a business partner, with additional information from initial reporter via PSP, concerned a 60-year-old female patient of unknown origin.

Medical history included pitted molars/two molars with cavities, radiotherapy, chemotherapy, an unspecified thyroid disorder, breast surgery with node removal, physiotherapy for the left arm, felt itchy when she became very hot, was planned to be treated with zoledronic acid monohydrate but an unspecified examination was performed that confirmed she did not have osteoporosis, hence was not treated with the same. Concomitant medication included calcium to strengthen her bones, levothyroxine sodium for an unspecified thyroid disorder,

The patient received abemaciclib (Verzenios) tablets, 150 mg, twice a day, via oral, for the treatment of breast cancer, beginning on 24-Sep-2024. As concomitant chemotherapy she received anastrozole for breast cancer, in addition to an unspecified medication. Additionally, she received tocopherol (vitamin E) for skin sensitivity; dosage, frequency, route of administration and start date were not provided. On an unknown date while on abemaciclib therapy, she experienced difficulty eating and weight loss from 58 to 55.3 kg (no reference range was provided). She only ate a few meals that included fruits, legumes, and vegetables but no sugar, juices, sodas, rice, beans, and meat because radiotherapy and chemotherapy affected her a lot. On an unknown date, she felt tired. On 02-Oct-2024, she received test results of her kidneys and liver and her hemoglobin was low at 12 (no units or reference range not provided), and she believed that these levels were fine for her age and that she was not anemic. On an unknown date, she was scheduled for a procedure where she was going to remove two of her molars because they were pitted as she had a black spot on the inside, which was present before taking abemaciclib therapy. She continued to lose weight as was previously at 56 Kg and on 01-Nov-2024, she weighed 54 Kg. On 01-Nov-2024, she had a blood test resulting in hemoglobin dropped to 10.5, alkaline phosphatase dropped to 43 (normal range 98 – 279), hematocrit dropped to 29.5 (normal range 37 – 47), platelets at 100,000 (normal range 4,000– 150,000), white blood cells were low at 3.6 (normal range 4 – 10) and creatinine was 0.89 (normal range 0.50 – 0.90). On an unknown date in 2024, she was no longer hungry/lack of appetite, has difficulty eating breakfast, and no longer tolerates eggs. Lack of appetite has worsened since taking calcium and vitamin E. On an unknown date, had stomach pain, experienced a little dizziness that passed after a while, felt sick, also got cramps not often and that she was not sent to the bathroom. During medical appointments she had been told not to take certain unspecified pills. On an unknown date after taking tocopherol, discomfort began. On an unknown date, she no longer felt tired. Information regarding corrective treatments was not provided. Outcome of tiredness was recovered; for weight loss, hemoglobin low, blood alkaline phosphatase decreased, hematocrit decreased, and white blood cell count low, appetite lost was not recovered; while for remaining events was unknown. Abemaciclib therapy was continued, and status of tocopherol was not provided. The business partner was responsible for follow-up, however, could not be attempted since reporting consumer did not authorize to be contacted nor her treating physician.

The reporting consumer not related weight loss, difficulty eating and related appetite lost to abemaciclib therapy while did not provide relatedness assessment between remaining events and abemaciclib therapy; related unspecified symptoms to tocopherol but did not relate these unspecified symptoms to abemaciclib because she has noticed that after taking the tocopherol, the discomfort began after a while.

Update 13-Oct-2024: Additional information was received by the initial reporting consumer via PSP on 04-Oct-2024. Added three medical histories of urticaria thermal and dental caries. Added the lab test result of hemoglobin. Added concomitant medication of anastrozole. Added two non-serious event terms of fatigue and hemoglobin low. Updated coding of concomitant medication of Vitamin E (tocopherol). Updated the narrative with new information.

Update 11-Nov-2024: Additional information was received on 05-Nov-2024 from the initial reporter via PSP of a business partner. Added oral route of administration of abemaciclib, further weight and hemoglobin lab tests results; platelet count and creatinine lab tests; non-serious events of blood alkaline phosphatase NOS decreased, hematocrit decreased, and white blood cell count low along with their lab tests, decreased appetite, abdominal pain upper, dizziness, illness, muscle spasms and discomfort. Updated outcome of weight loss to not recovered, outcome of fatigue to recovered, tocopherol as suspect drug, and narrative accordingly with new information.

Update 02-Jun-2025: Additional information received from initial reporting consumer on 26-May-2025 and 27-May-2025. Causality of event lack of appetite is updated from no to yes. Updated narrative accordingly with new information.

**13. Lab Data**

| # | Date | Test / Assessment / Notes | Results | Normal High / Low |
|---|---|---|---|---|
| 1 | 01-NOV-2024 | Blood alkaline phosphatase<br><br>Dropped<br>No units provided. | 43 | 279<br>98 |

Mfr. Control Number: CR202409018676

## ADDITIONAL INFORMATION

**13. Lab Data**

| # | Date | Test / Assessment / Notes | Results | Normal High / Low |
|---|---|---|---|---|
| 2 | 01-NOV-2024 | Blood creatinine<br>Within range<br>No units provided. | 0.89 | 0.9<br>0.5 |
| 3 | 01-NOV-2024 | Haematocrit<br>Dropped<br>No units provided. | 29.5 | 47<br>37 |
| 4 | 02-OCT-2024 | Haemoglobin<br>Low (no units, baseline value and reference range were provided) | 12 | |
| 5 | 01-NOV-2024 | Haemoglobin<br>Dropped<br>No units or reference range provided. | 10.4 | |
| 6 | 01-NOV-2024 | Platelet count<br>Within range<br>No units provided. | 100000 | 150000<br>4000 |
| 7 | | Weight<br>(no reference range was provided) | 56 kg | |
| 8 | | Weight<br>(no reference range was provided) | 58 kg | |
| 9 | | Weight<br>(no reference range was provided) | 55.3 kg | |
| 10 | 01-NOV-2024 | Weight<br>(no reference range was provided) | 54 kg | |
| 11 | 01-NOV-2024 | White blood cell count<br>Low<br>No units provided. | 3.6 | 10<br>4 |

**23. OTHER RELEVANT HISTORY continued**

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| Unknown | Medical Condition | Urticaria heat (Urticaria thermal); |
| Unknown | Procedure<br>November 2023 (tumor) and December 2023 (ganglions). | Surgery (Surgery); |
| 2024 to Unknown | Procedure<br>Reported as 4 red and 12 white chemotherapies. | Chemotherapy (Chemotherapy); |

## ADDITIONAL INFORMATION

**23. OTHER RELEVANT HISTORY continued**

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| Unknown | Procedure<br>Reported as 15 radiotherapy for 15 days. | Radiotherapy (Radiotherapy); |
| Unknown | Procedure<br>Exercises for left arm. | Physiotherapy (Physiotherapy); |
| 2024 to 09-SEP-2024 | Procedure | Chemotherapy (Chemotherapy); |