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		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		53 Years	Female	Unk	20	OCT	2023

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

Inflammation of the right hand/Arthritis/Right hand pain/right hand had been swollen [Arthritis]
Pain in her right leg [Pain in extremity]
Fracture of lower limb/left big toe was swollen and purple [Foot fracture]
Upset stomach [Abdominal discomfort]
Stomach pain [Abdominal pain upper]
Back wear [Musculoskeletal discomfort]
Stomach discomfort [Abdominal discomfort]
Patient administered Verzenio daily instead of twice daily; No AE [Off label use]

(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 {Lot # D629171; Exp.Dt. OCT-2025}

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 150 mg, unknown

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) Unknown

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) ANASTROZOLE (ANASTROZOLE) Capsule ; Ongoing
#2) VITAMINS NOS (VITAMINS NOS) Unknown ; Ongoing

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
08-FEB-2023 to Unknown	Procedure	Mastectomy (Mastectomy)

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.
CR202311006306

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
03-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: CR202311006306

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: This solicited case, reported by consumer via a Patient Support Program (PSP), concerned a 53-years-old female patient of an unknown origin.

Medical history included on 08-Feb-2023, mastectomy was performed for left breast removal.

The patient received abemaciclib (Verzenio) coated tablet, 150 mg, at an unknown frequency, via orally for the treatment of breast cancer, beginning on an unknown date, she also received anastrozole 2.5 mg capsule, once a day, which was prescribed for seven years for the treatment of breast cancer and an unspecified drops (vitamins). On 20-Oct-2023, while on abemaciclib treatment, she had stomach pain, but that it resolved by taking the pill, and that she currently did not have this problem. She also felt stomach discomfort which was not frequent. Her dosing schedule was changed because of stomach discomfort from one capsule per day of 150 mg (off label use), which was taken at 11:00 am one hour before lunch to one capsule per day of 150 mg at 6:00 pm one hour before dinner. On an unknown date, her right hand had been swollen and that she had pain in it, which makes it impossible for her to work because the pain is so intense. Her oncologist told her that this swelling was not related to her area but to the orthopedic area. She had the same problem in past with her left hand and that she had an injection and it resolved, but that her right hand was currently affected. She also had a inflammation in a right hand and diagnosed with arthritis. The event arthritis were considered serious by the reporter due to disability reason. On an unknown date, she also had a back wear. On 30-Oct-2023, she stumbled on an exercise machine and injured her left big toe, she did not take it seriously because she was able to walk. On 31-Oct-2023, she went to the doctor because her left big toe was swollen and purple, the doctor indicated that she had a fracture and it was not just a blow, she was not given a cast because according to the doctor's orders it was not necessary, she was only given a bandage. On 31-Oct-2023, an ultrasound was performed on her right breast to rule out any sign of cancer in the right breast, because since the operation she had a small ball, in her results the doctor indicated that everything was fine. She had appointments on 07-Nov-2023 and 14-Nov-2023 for the change of bandages and on 21-Nov-2023, she had an x-ray exam for follow-up (result unspecified). She took acetaminophen and ibuprofen for pain from left breast surgery. On 10-Mar-2024, she had pain in her right leg that bothered her a lot. She would discuss the situation with her treating physician. She did not received any corrective treatment for upset stomach, arthritis, off label use and back wear. Information regarding corrective treatment for remaining events was not reported. Outcome of the event upset stomach was recovered while the outcome of the event off label use was unknown and outcome of the remaining events was not recovered. The status of abemaciclib therapy was ongoing with dose decreased.

The initial reporting consumer relate the events arthritis and upset stomach while did not relate the event back wear and did not provide an opinion on the relatedness of remaining events with abemaciclib therapy.

Update 19-Apr-2024: Additional information was received from an initial reporting consumer on 16-Apr-2024. Added one non-serious event pain in leg and start date of abemaciclib 150 mg. Updated narrative with new information.

Update 02-Jun-2025: Additional information was received from an initial reporting consumer on 28-May-2025. This case was upgraded from non-serious to serious upon addition of one serious event of arthritis. Added one concomitant drug, one new dosage regimen of abemaciclib therapy and four new non serious events of off label use, musculoskeletal discomfort, abdominal pain upper and abdominal discomfort. Update the action taken from no change to dose decreased. Updated the narrative accordingly.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	31-OCT-2023	Ultrasound breast Everything was fine. (unspecified ranges, units and values)		

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
#1) Abemaciclib (Abemaciclib) Tablet {Lot # D629171; Exp.Dt. OCT-2025}; Regimen #2	150 mg, daily; Oral	Breast cancer (Breast cancer)	20-OCT-2023 / Unknown; Unknown