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		60 Years	Female	Unk	25	MAR	2024

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

Worsened knee pain [Arthralgia]
A change in skin color/skin color is still white [Skin discolouration]
Burning in face [Skin burning sensation]
Burning in extremities/thermal sensation [Burning sensation]
Diarrhea [Diarrhoea]
She is eating very little / She is not tolerating food very well [Decreased appetite]
She has not been able to recover her palate, it is still bitter and when she eats salt or sugar she feels bitter [Dysgeusia]
Pruritus on arms and legs/Itching of extremities and face [Pruritus]

(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 {Lot # B629171; Exp.Dt. OCT-2025}

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) 21-MAR-2024 / Ongoing	#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) Unknown ; Unknown
#2) VITAMIN D3 (VITAMIN D3) Unknown ; Unknown
#3) EUTIROX (LEVOTHYROXINE SODIUM) Unknown ; Unknown
#4) VITAMIN B3 (VITAMIN B3) Unknown ; Unknown
#5) CALCIUM (CALCIUM) Unknown ; Unknown

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	Breast cancer (Breast cancer)
Unknown	Medical Condition	Knee pain (Arthralgia)

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.
CR202404004748

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

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

DATE OF THIS REPORT
11-APR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

Black/pink spots on her upper and lower extremities and on her face with widespread extent of lesion [Rash macular]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) received through a business partner, with additional information from the initial reporter via PSP through a business partner, concerned a 66-year-old (at the time of the report) caucasian female patient.

Medical history included a thyroidectomy on an unspecified date, in 2008; breast cancer; knee pain; and white chemotherapy which gave her diarrhea. Concomitant medications included levothyroxine sodium 100 mg, one pill per day for thyroidectomy, vitamin D3, vitamin B3 30 mg, calcium 500 mg for unknown indication, and radiotherapy since 21-Mar-2024.

The patient received abemaciclib (Verzenio) coated tablets, 150 mg, twice daily, orally, for the treatment of breast cancer, beginning on 21-Mar-2024. Concomitant endocrine therapy included anastrozole (Arimidex) for breast cancer. On an unknown date, while on abemaciclib therapy, her knee pain worsened. On 25-Mar-2024, she ate a pickle with chili and got diarrhea. On 26-Mar-2024, she started treatment with radiotherapies, she must undergo 25 radiotherapies. On 03-Apr-2024, she drank a soft drink, and it gave her diarrhea. She was very sensitive to certain things, as certain foods caused her diarrhea, if she did not eat them, she did not get diarrhea. For this reason, she was not tolerating food very well. When she ate something that caused her diarrhea, she only went to the bathroom once and then she did not get diarrhea, but before, when she ate something that hurt her, she would go to the bathroom immediately and it would come out, which did not even last 20 minutes in her stomach. On the other hand, she was eating very little. Also, she had not been able to recover her palate, as it continued to be bitter and when she ate salt or sugar, she felt bitter and could not tolerate it. Everything she ate, hurt her and caused diarrhea. With abemaciclib therapy, there were foods she did not tolerate like fatty food. The physician explained her that if she had diarrhea, she could not take abemaciclib and should stop taking it. In Mar-2024, she completed the radiation. After las appointment with nutritionist, she felt recovered from her stomach. On 22-Jun-2024, she had a CAT scan (details not provided). On 25-Jun-2024, she had an ultrasound (details not provided). On 17-Jul-2024, she would have two unknown tests. On 28-Jul-2024, she experienced pruritus in arms and legs. On 10-Oct-2024, she took abemaciclib with radiotherapy, she had black and pink spots on her upper and lower extremities as well as on her face and the extent of lesion was widespread. Her radiologist indicated that it was due to taking abemaciclib during radiation and it was a delayed reaction. It did not hurt, and there was no itching or discomfort, only a change in skin color. She also had burning sensation in extremities and face. She was not hospitalised for these events. Information regarding corrective treatments was not provided. Outcome of the event skin discoloration was unknown, event pruritus was resolved while remaining events was not recovered. Abemaciclib therapy status was continued. The business partner is responsible for follow-up per agreement as they are the MAH, therefore if they receive any additional information, they will forward it and case will be updated accordingly.

The reporting consumer did not relate the event of diarrhea to abemaciclib therapy, did not know the relatedness of events skin burning sensation and extremities burning sensation of, pruritus, rash macular while did not provide a relatedness assessment between the remaining events and abemaciclib therapy.

Update 02-Jul-2024: Information was received from the initial reporting consumer via a PSP on 26-Jun-2024. No medically significant information was received, and no further changes were made to the case.

Update 12-Aug-2024: Information was received from the initial reporting consumer via PSP through business partner on 07-Aug-2024. Added one non-serious adverse event of pruritus and two lab tests. Narrative was updated accordingly with new information.

Update 17-Feb-2025: Additional information was received from the initial reporting consumer via PSP through business partner on 12-Feb-2025. Added two events of rash macular and skin discoloration and onset date of pruritus. Updated narrative with new information.

Update 22-Mar-2025: Additional information was received from the initial reporting consumer via PSP through business partner on 18-Mar-2025. Added two events of skin burning sensation and extremities burning sensation of, outcome of event pruritus from not recovered to recovered, description as reported of pruritus from pruritus on arms and legs to pruritus on arms and legs/Itching of extremities and face. Updated narrative with new information.

Update 09-Apr-2025: Additional information was received from the initial reporting consumer via PSP through business partner on 01-Apr-2025. Added origin, height of the patient, event onset date of events extremities burning sensation of and burning sensation in face and skin discolouration. Updated as reported causality of events skin burning sensation and extremities burning sensation of, pruritus, rash macular from no to unknown, added. Description as reported of event LLT burning sensation of. Updated narrative with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	22-JUN-2024	Computerised tomogram		
		(no results, reference range nor units provided)		

Mfr. Control Number: CR202404004748

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
2	25-JUN-2024	Ultrasound scan (no results, reference range nor units provided)		

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2008 to Unknown	Procedure	Thyroidectomy (Thyroidectomy);
Unknown	Procedure	Chemotherapy (Chemotherapy);
Unknown	Historical AR During chemotherapy	Diarrhea (Diarrhoea);