

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 66 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
		Day	Month	Year				Day	Month	Year	
			PRIVACY					21	MAR	2024	

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]
Allergic skin reaction due to interaction of radiotherapy with Verzenio [Drug interaction]
Allergic skin reaction due to interaction of radiotherapy with Verzenio [Dermatitis allergic]
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

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Abemaciclib (Abemaciclib) Tablet {Lot # B629171; Exp.Dt. OCT-2025} #2) ANASTROZOL (ANASTROZOL) Tablet		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) 150 mg, bid #2) UNK UNK, unknown	16. ROUTE(S) OF ADMINISTRATION #1) Oral #2) Oral	
17. INDICATION(S) FOR USE #1) Breast cancer (Breast cancer) #2) Breast cancer (Breast cancer)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 21-MAR-2024 / Ongoing #2) 2024 / Unknown	19. THERAPY DURATION #1) Unknown #2) 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 07-JUL-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT 14-JUL-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 2	

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**

[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/Skin itching [Pruritus]

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. Along with anastrozole (unknown manufacturer), at unknown dose and frequency, via oral route, for breast cancer, beginning in 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 21-Mar-2024, she developed an allergic skin reaction due to interaction of radiotherapy with abemaciclib therapy. As a corrective treatment for allergic skin reaction she took loratadine, and was recovering from the interaction between radiation therapy and abemaciclib therapy. She experienced skin itching but felt that it was recovering. 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. As of Jan-2025, she has had knee pain and was prescribed intravenous zoledronic acid monohydrate every six months for this symptom, as anastrozole was the drug which caused this bone problem. She was not hospitalised for these events. Information regarding corrective treatment for rest of the events was not provided. Outcome of the event skin discoloration was unknown, events pruritus, allergic skin reaction and interaction of radiotherapy with abemaciclib were recovering, while remaining events was not recovered. Abemaciclib therapy status was continued, whereas anastrozole therapy status was not provided. Follow up would not be requested as the reporting consumer declined to be contacted and to contact treating physician.

The reporting consumer related the event of pruritus, did not relate the event of diarrhea, allergic skin reaction and drug interaction to abemaciclib therapy, did not know the relatedness of events skin burning sensation and extremities burning sensation of, rash macular while did not provide a relatedness assessment between the remaining events and abemaciclib therapy. The reporting consumer related the event of knee pain with anastrozole, whereas did not provide relatedness for rest of the events with anastrozole 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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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.

Update 11-Jul-2025: Additional information was received from the initial reporting consumer via PSP through business partner on 07-Jul-2025. Added one co-suspect anastrozole, two treatment drugs for knee pain and allergic skin reaction, two non-serious events of allergic skin reaction and drug interaction. Upon review of information received on 01-Apr-2025, patient's age was corrected in patient's tab from 60 years to 66 years. Updated outcome for the event of pruritus from recovered to recovering, treatment received as yes for the event of knee pain, and 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)		
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);