

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH Day Month Year PRIVACY	2a. AGE 71 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET Day Month Year 06 JAN 2024	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION ☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) felt down [Depressed mood] did not want fluids [Thirst decreased] Itching [Pruritus] Redness [Erythema] Skin outbreak, in areas in the groin and waist [Rash] Dehydrated [Dehydration] Sciatic type pain, burning pain [Pain] numbness [Hypoaesthesia] severe pain in her left arm [Pain in extremity] burning sensation [Burning sensation] (Continued on Additional Information Page)							

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) 02-JAN-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)		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)		
From/To Dates Unknown	Type of History / Notes Medical Condition left side	Description Lymphedema (Lymphoedema)
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. CR202401007442	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 16-APR-2025	24d. REPORT SOURCE ☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 28-APR-2025	25a. REPORT TYPE ☒ INITIAL ☐ FOLLOWUP:	

28-Apr-2025 07:50

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

Diarrhea [Diarrhoea]
did not eat [Decreased appetite]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), concerned a 71-year-old (at the time of initial report) female patient of an unknown origin.

Medical history included left mastectomy and lymphedema in the arm on the same side and concomitant medications were not provided.

The patient received abemaciclib (Verzenio) tablet, 150 mg twice daily via oral route for the treatment of breast cancer, beginning on 02-Jan-2024. On 06-Jan-2024, she had moderate diarrhea, felt down, did not eat, did not want fluids and was somewhat dehydrated. She had not consulted with her treating physician, so she was advised to seek medical attention if she worsens. On 29-Mar-2024, she presented with sciatic type pain, described it as a burning pain and with an intensity of 5/10, as a corrective treatment she received unspecified analgesics without prescription. On 01-Oct-2024, she had skin outbreak in areas in the groin and waist, brown and sometimes turned reddish and sometimes itchy. In Mar-2025, she had severe pain in her left arm and associated with numbness and burning sensation to the touch. She went several times to the emergency room and treated with analgesics, the pain subsided for a while, but then continued with the same intensity. And despite various oral analgesics the pain persisted. She did not received any corrective treatment for remaining events. She might have oncologist appointment on 03-No-2024. Information regarding the corrective treatment was not provided. Outcome of the events was not resolved and abemaciclib therapy was continued.

The initial reporting consumer did not provide relatedness assessment of the events with abemaciclib therapy.

Update 21-Mar-2024: Information received from local affiliate on 20-Mar-2024. Business partner confirmed that permission to contact HCP was not granted hence follow up not possible with the HCP. No medically significant information received.

Update 04-Apr-2024: Information received from the initial reporter via business partner on 01-Apr-2024. Added one non-serious event of pain. Updated case and narrative accordingly with new information.

Update 21-May-2024: Information received from the initial reporter via business partner on 15-May-2024. No medically significant information received.

Update 30-Oct-2024: Additional information from the initial reporter via PSP was received on 25-Oct-2024. Added three non serious events of pruritus, rash and erythema. Updated narrative with new information.

Update 24-Apr-2025: Additional information received from the initial reporter via business partner on 16-Apr-2025. Added two medical history of mastectomy and lymphedema, three non-serious event of Numbness, Pain in arm and Burning sensation. Updated case and narrative accordingly with new information.