

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 71 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 checked="" 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						06	JAN	2024	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
 Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
 Back pain [Back pain]
 Body ache [Pain]
 Arm pain [Pain in extremity]
 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]

(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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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.) <table border="1"> <thead> <tr> <th>From/To Dates</th> <th>Type of History / Notes</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>Unknown</td> <td>Medical Condition</td> <td>Lymphedema (Lymphoedema)</td> </tr> <tr> <td></td> <td>left side</td> <td></td> </tr> <tr> <td>Unknown</td> <td>Procedure</td> <td>Mastectomy (Mastectomy)</td> </tr> </tbody> </table>			From/To Dates	Type of History / Notes	Description	Unknown	Medical Condition	Lymphedema (Lymphoedema)		left side		Unknown	Procedure	Mastectomy (Mastectomy)
From/To Dates	Type of History / Notes	Description												
Unknown	Medical Condition	Lymphedema (Lymphoedema)												
	left side													
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	
24c. DATE RECEIVED BY MANUFACTURER 29-MAY-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 04-JUN-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	

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

NAME AND ADDRESS WITHHELD.

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

numbness [Hypoaesthesia]
severe pain in her left arm [Pain in extremity]
burning sensation [Burning sensation]
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. Since May-2025, she experienced severe pain in her back, arm and body due to which she was hospitalized and received morphine as corrective treatment. Additionally there was a change in her blood tests (but it was unspecified). Information regarding the corrective treatment for remaining events was not provided. Outcome of the events back pain, pain and pain in extremity was recovering and of remaining events was not resolved and abemaciclib therapy was continued.

The initial reporting consumer related pain, back pain and pain in extremity whereas did not provide relatedness assessment of the remaining 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.

Update 03-Jun-2025: Additional information received from the initial reporter via business partner on 29-May-2025. The case was upgraded from non-serious to serious due to addition of serious events of back pain, pain and pain in extremity. Added morphine as treatment medication. Updated the narrative and causality statement with new information.