

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 47 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					16	OCT	2024	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
When she ate her stomach was swelling [Abdominal distension]
Constipated [Constipation]
Burning in the soles of both feet/back has also been burning when she goes to bed at night [Burning sensation]
Heartburn [Dyspepsia]
Every time she took Verzenio she got a headache [Headache]
She was not very hungry [Decreased appetite]
Moderate tiredness [Fatigue]

Case Description: This solicited case, reported by a consumer via a (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) 16-OCT-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) #1) ARIMIDEX (ANASTROZOLE) Capsule, 1 mg; Ongoing #2) GOSERELINA (GOSERELINA) Unknown ; Ongoing #3) INDOMETHACIN [INDOMETACIN SODIUM] (INDOMETACIN SODIU (Continued on Additional Information Page)		
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 Appetite lost (Decreased appetite) Unknown to Ongoing Medical Condition Listless (Listless)		

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. CR202410014447	
24c. DATE RECEIVED BY MANUFACTURER 22-APR-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 30-APR-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	
		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

patient support program (PSP), with additional information from the initial reporter via PSP, concerned a 47-year-old (at time of initial report) female patient of unknown origin.

Medical history included not wanting to eat, feeling quite listless, weight loss, chemotherapy for breast cancer and memory loss. Concomitant medications included unspecified vitamins for unknown indications and indomethacin for pain.

The patient received abemaciclib (Verzenio) tablets, 150 mg every 12 hours, orally, starting on 16-Oct-2024, for the treatment of breast cancer. Concomitant chemotherapy included anastrozole, goserelin, and an unspecified breast cancer pill. On 16-Oct-2024, after starting abemaciclib therapy, she experienced heartburn and stomach swelling when she ate, she also experienced a headache every time she took abemaciclib. On an unknown date, she experienced constipation and not being very hungry. On 12-Dec-2024, she experienced moderate tiredness, for which she did not consult a doctor, and did not take any other medication. By 22-Apr-2025, she continued to experience moderate tiredness occasionally. Additionally, she experienced severe burning in the soles of both feet and since approximately Feb-2025, her back had also been burning when she went to bed at night. As corrective treatment for burning soles she had applied an unspecified ointment that numbs her skin like an anesthetic. She would have oncology appointment on 23-Apr-2025. All the events were ongoing. Corrective treatment for the remaining events was not provided. Abemaciclib therapy status was ongoing.

The reporting consumer did not provide an opinion on relatedness between the events and abemaciclib therapy.

Updated 23-Oct-2024: This case was determined to be non-valid as there was no identifiable adverse event reported (Suspect drug started after AEs).

Update 05-Nov-2024: This case was originally determined to be non-valid. Additional information was received from the initial reporting consumer via PSP on 30-Oct-2024. Added five new non-serious events of swelling abdomen, constipation, heartburn, headache and decreased appetite. Updated narrative accordingly.

Update 30-Jan-2025: Additional information was received from the initial reporting consumer via PSP on 24-Jan-2025. Added one new non-serious event of tiredness. Narrative was updated with new information accordingly.

Update 28-Apr-2025: Additional information received on 22-Apr-2025 from the initial reporter via a PSP. Added one non-serious event of burning sensation, chemotherapy, breast cancer and memory loss as medical history, indomethacin as concomitant medication and an unspecified ointment as corrective treatment. Updated narrative with new information.

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#3) INDOMETHACIN [INDOMETACIN SODIUM] (INDOMETACIN SODIUM) Unknown ; Ongoing

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Weight loss (Weight decreased);
Unknown	Procedure 12 white and 6 red	Chemotherapy (Chemotherapy);
Unknown	Medical Condition	Breast cancer (Breast cancer);
Unknown	Medical Condition	Memory loss (Amnesia);