

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 53 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 checked="" type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
		Day	Month	Year				Day	Month	Year	
			PRIVACY					20	OCT	2023	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
 Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
 Inflammation of the right hand/Arthritis/Right hand pain/right hand had been swollen [Arthritis]
 Pain in her right leg [Pain in extremity]
 Fracture of lower limb/left big toe was swollen and purple [Foot fracture]
 Upset stomach [Abdominal discomfort]
 Stomach pain [Abdominal pain upper]
 Dental problems [Tooth disorder]
 Lost lower teeth [Tooth loss]
 Body generating a lot of tartar [Tooth deposit]
 Back wear [Musculoskeletal discomfort]

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Abemaciclib (Abemaciclib) Tablet {Lot # D629171; Exp.Dt. OCT-2025} (Continued on Additional Information Page)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) 150 mg, unknown	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 type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) Unknown	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) ANASTROZOLE (ANASTROZOLE) Capsule ; Ongoing #2) VITAMINS NOS (VITAMINS NOS) Unknown ; Ongoing		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates Type of History / Notes Description 08-FEB-2023 to 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. CR202311006306	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 21-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 24-JUL-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	

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

Stomach discomfort [Abdominal discomfort]

Patient administered Verzenio daily instead of twice daily; No AE [Off label use]

Case Description: This solicited case, reported by consumer via a Patient Support Program (PSP), with additional information from the reporting consumer, concerned a 53-years-old female patient of an unknown origin.

Medical history included on 08-Feb-2023, mastectomy was performed for left breast removal. Concomitant medications included unspecified vitamins for unknown reason.

The patient received abemaciclib (Verzenio) coated tablet, 150 mg, at an unknown frequency, orally for the treatment of breast cancer, beginning on an unknown date, she also received as concomitant chemotherapy, anastrozole 2.5 mg capsule, once a day, which was prescribed for seven years for the treatment of breast cancer. On 20-Oct-2023, while on abemaciclib treatment, she experienced stomach pain, but that it resolved by taking the pill in the evening, and that she currently did not have this problem. She also experienced stomach discomfort which was not frequent. Her dosing schedule was changed because of stomach discomfort from one capsule per day of 150 mg (off label use), which was taken at 11:00 am one hour before lunch to one capsule per day of 150 mg at 6:00 pm one hour before dinner. On an unknown date, her right hand had been swollen and that she had pain in it, which makes it impossible for her to work because the pain is so intense. Her oncologist told her that this swelling was not related to her area but to the orthopedic area. She had the same problem in past with her left hand and that she had an injection and it resolved, but that her right hand was currently affected. She also had a inflammation in a right hand and diagnosed with arthritis. The event arthritis was considered serious by the reporter due to disability reason. On an unknown date, she also had a back wear. On 30-Oct-2023, she stumbled on an exercise machine and injured her left big toe, she did not take it seriously because she was able to walk. On 31-Oct-2023, she went to the doctor because her left big toe was swollen and purple, the doctor indicated that she had a fracture and it was not just a blow, she was not given a cast because according to the doctor's orders it was not necessary, she was only given a bandage. On 31-Oct-2023, an ultrasound was performed on her right breast to rule out any sign of cancer, because since the operation she had a small ball, in her results the doctor indicated that everything was fine. She had appointments on 07-Nov-2023 and 14-Nov-2023 for the change of bandages and on 21-Nov-2023, she had an x-ray exam for follow-up (result unspecified). She took acetaminophen and ibuprofen for pain from left breast surgery. On 10-Mar-2024, she had pain in her right leg that bothered her a lot. She would discuss the situation with her treating physician. On an unknown date, she experienced unspecified dental problems and, since 2024, she had lost her lower teeth due to her body generating a lot of tartar and to poor hygiene. As corrective treatment she underwent tooth extraction and tartar removal. On an unknown date, she recovered from the abdominal discomfort and abdominal pain upper. She had not recovered from the arthritis, pain in extremity, foot fracture, tooth loss, back wear, abdominal discomfort (2nd episode). The outcome of the remaining events was not reported. She did not received any corrective treatment for upset stomach, arthritis, off label use and back wear. Information regarding corrective treatment for remaining events was not reported. Abemaciclib therapy was ongoing with dose decreased.

The reporting consumer related the events arthritis and upset stomach (1st episode) while did not relate the events of loss of teeth and back wear, and did not provide an opinion on the relatedness between the remaining events and abemaciclib therapy.

Update 19-Apr-2024: Additional information was received from an initial reporting consumer on 16-Apr-2024. Added one non-serious event pain in leg and start date of abemaciclib 150 mg. Updated narrative with new information.

Update 02-Jun-2025: Additional information was received from an initial reporting consumer on 28-May-2025. This case was upgraded from non-serious to serious upon addition of one serious event of arthritis. Added one concomitant drug, one new dosage regimen of abemaciclib therapy and four new non serious events of off label use, musculoskeletal discomfort, abdominal pain upper and abdominal discomfort. Update the action taken from no change to dose decreased. Updated the narrative accordingly.

Update 24-Jul-2025: Additional information was received from reporting consumer via PSP on 21-Jul-2025. Added three non-serious events of dental problems, tooth deposit and loss of teeth. Also added details of pain in hand and swelling (arthritis). Updated narrative accordingly.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	31-OCT-2023	Ultrasound breast	Everything was fine. (unspecified ranges, units and values)	
2	21-NOV-2023	X-ray	No results provided	

ADDITIONAL INFORMATION			
14-19. SUSPECT DRUG(S) continued			
14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Abemaciclib (Abemaciclib) Tablet {Lot # D629171; Exp.Dt. OCT-2025}; Regimen #2	150 mg, daily; Oral	Breast cancer (Breast cancer)	20-OCT-2023 / Ongoing; Unknown