

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>GUATEMALA</b>	2. DATE OF BIRTH			2a. AGE <b>65</b> Years	3. SEX <b>Female</b>	3a. WEIGHT <b>73.00</b> kg	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year		
		<b>PRIVACY</b>							<b>2024</b>		

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

Other Serious Criteria: Med sig  
Anemia [Anaemia]  
suspected liver damage/hepatic disorder [Liver injury]  
Abdominal pain/dolor abdominal [Abdominal pain]  
Leg pain/ leg pain [Pain in extremity]  
Swollen legs [Peripheral swelling]  
Waist pain/ Lower back pain [Back pain]  
The patient was prescribed one table of Verzenio 150 mg one day [Off label use]  
Joint pain [Arthralgia]

(Continued on Additional Information Page)

☐ PATIENT DIED  
☐ INVOLVED OR  
PROLONGED INPATIENT  
HOSPITALISATION  
☐ INVOLVED PERSISTENT  
OR SIGNIFICANT  
DISABILITY OR  
INCAPACITY  
☐ LIFE  
THREATENING

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1 ) Abemaciclib (Abemaciclib) Tablet {Lot # D700887; Exp.Dt. MAY-2026} (Continued on Additional Information Page)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input 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 female (Breast cancer female)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES(from/to) #1 ) 12-APR-2024 / 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 ) LETERO (LETROZOLE) Unknown ; Unknown #2 ) METFORMIN (METFORMIN) Unknown ; 2023 / Unknown #3 ) SITAGIL (SITAGLIPTIN PHOSPHATE) Unknown ; 2023 / Unknown #4 ) FELODIPINE (FELODIPINE) Unknown ; Unknown #5 ) RAMIPRIL (RAMIPRIL) 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
2023 to Unknown	Medical Condition	Type 2 diabetes mellitus (Type 2 diabetes mellitus)
Unknown	Medical Condition	Arterial hypertension (Hypertension)
	since before 2000	

## 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. <b>GT202408003217</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>26-AUG-2025</b>	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT <b>01-SEP-2025</b>	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 11	

01-Sep-2025 05:10

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

Pain as if it were the liver [Hepatic pain]  
felt pain in the pit of her stomach (stomach ache) [Abdominal pain upper]  
No taste of food [Food aversion]  
Vaginal bleeding [Vaginal haemorrhage]  
Diarrhea [Diarrhoea]  
Tiredness increased [Fatigue]  
Nausea [Nausea]  
presents hunger but does not pass food/for 2 months has not eaten food because the patient does not taste it (First episode)  
[Decreased appetite]  
Headache [Headache]  
Lack of appetite (second episode) [Decreased appetite]  
Weakness, some days she doesn't get out of bed [Asthenia]

Case Description: This solicited case reported by a consumer via Patient Support Program (PSP), concerned a 65-year female patient of an unknown origin.

Medical history included diabetes mellitus type two, arterial hypertension and fatigue. Concomitant medications included metformin, sitagliptin phosphate for diabetes mellitus type two, felodipine for blood pressure and ramipril for an unknown indication.

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice daily, via oral route, for the treatment of breast cancer female, beginning 12-Apr-2024 (or 12-Jul-2024, discrepant start date reported). She also received letrozole for breast cancer, concomitantly. On an unknown date in 2024, after starting abemaciclib therapy, she experienced moderate vaginal bleeding. Subsequently, she underwent uterine biopsy to determine treatment. On an unknown date in Jul-2024, after starting abemaciclib therapy, she experienced diarrhea, there were days when she had between five and six liquid depositions, while other days she only had one or two depositions, but always with a soft or liquid consistency. The first time she presented with liquid diarrhea, with a liquid aspect, as a corrective treatment, she took metronidazole. Her tiredness increased, had pain in her legs and joints and felt pain in the pit of her stomach (stomachache) and a pain as if it were her liver (pain), for which she had a test (unspecified) to evaluate how her liver was doing. On an unknown date in Jul-2024, she developed abdominal pain/dolor abdominal, and her physician suspected it as liver damage. A hepatic ultrasound was supposed to be performed on unspecified date in Jul-2024, but the results were not provided. She did not receive any corrective treatment for the events of liver damage and abdominal pain. Her next appointment with her doctor would be in Nov-2024. As she had diarrhoea and nausea, and presented hunger but did not pass food due to which one month ago her physician indicated to suspend one-week abemaciclib, and then in the appointment of 14-Nov-2024, the physician indicated to take abemaciclib one day one tablet and the other day she would take two tablets. She had diarrhea for approximately four months since she had been taking it abemaciclib and the nausea started about two and a half months ago and for two months she had not eaten food, because she did not taste the food (first episode) (decreased appetite), and this caused her to feel nauseous. On 02-Dec-2024, she had headache and lack of appetite (second episode). On an unknown date, she has no taste of food. She was given several medications for the nausea and diarrhea; she had some sachets of cholestyramine and Loperamide for the diarrhea. She was also given probiotics because she hardly ate. On an unknown date in Feb-2025, she had moderate weakness and some days she could not get out of bed. On an unknown date in Mar-2025, she was having moderate diarrhoea which was more than others. On an unknown date in May-2025, she was having severe anemia, lower back and leg pain, and swollen legs. On an unknown date in May-2025, her recent dose of abemaciclib therapy was discontinued. She had various medical appointments over the past year but did not receive an answer as to why she was experiencing vaginal bleeding. She received blood transfusion in emergency room for anemia. As of 07-Aug-2025, her anemia continued. The event of anemia was considered as serious by the company due to medically significant reason. On 21-Aug-2025, she restarted the abemaciclib treatment. There was also a surgery on uterus for an unknown reason due to which she would be admitted to the hospital on 09-Sep-2025 for preoperative care. Information regarding further corrective treatment was unknown. Outcome of the events of appetite lost (first episode), nausea, off label use, stomachache, liver damage and abdominal pain was unknown; while for the remaining events, it was not resolved. Status of abemaciclib therapy was restarted with unknown dose.

The initial reporting consumer did not know the relatedness of the events of abdominal pain and liver damage, related the events of low back pain, leg pain and swelling of legs, did not relate the event of anemia, vaginal bleeding while did not provide the relatedness of the remaining events with abemaciclib therapy. The secondary reporting consumer did not provide the relatedness of the events with abemaciclib therapy.

Update 26-Aug-2024: Additional information was received from the initial reporting consumer via PSP on 19-Aug-2024. Added weight of patient 73.48 kg and height 148 cm as her demographics; start dates of concomitant drugs of metformin and sitagliptin phosphate and two new non-serious events of abdominal pain and liver damage. Updated indication of suspect drug from breast cancer to breast cancer female and narrative with new information. Complete information present in all documents which were received on 19-Aug-2024, was processed together.

Update 19-Sep-2024: Additional information was received on 17-Sep-2024. No medically significant information was received, and no significant changes were made to the case.

Update 26-Nov-2024: Additional information was received from the secondary reporting consumer via PSP on 19-Nov-2024. Added

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

an additional reporter consumer, an additional dosage regimen or abemaciclib 150 mg daily, two treatment medications for diarrhoea loperamide, cholestyramine and three non-serious events of nausea, appetite lost and off label use. Updated the action taken form unknown to drug discontinued and the narrative with new information.

Update 12-Feb-2025: Additional information was received from the initial reporting consumer via PSP on 05-Feb-2025. Added three non-serious events of headache, food aversion and appetite lost (second episode). Updated narrative with relevant information.

Update 05-Mar-2025: Additional information was received from the initial reporting consumer via PSP on 05-Feb-2025. Updated therapy start date of abemaciclib from 12-Jul-2024 to 12-Apr-2024 (conflicting therapy start date reported), and narrative with relevant information.

Update 10-Apr-2025: Additional information was received from the initial reporter via PSP on 06-May-2025. Added one non-serious event on asthenia and severity and frequency for the event of diarrhea. Updated corresponding fields and narrative with new information.

Update 21-May-2025: Additional information was received from the initial reporter via PSP on 12-May-2025 and 13-May-2025 were processed together. Added two non-serious event on anemia and diarrhea. Updated corresponding fields and narrative with new information.

Update 21-Jun-2025: Additional information was received from the initial reporter via PSP on 16-Jun-2025 and 17-JUN-2025 were processed together. Added new dosage regimen of abemaciclib with batch details, non-serious events of low back pain and swelling of legs. Episode of leg pain subsumed under previously reported event of leg pain. Updated causality as reported for event anemia from related to not related, Updated causality as reported for event leg pain from not provided to related. Updated narrative with new information.

Update 26-Jun-2025: Additional information was received from the initial reporter via PSP on 17-Jun-2025 and 18-Jun-2025. Added therapy stop date for abemaciclib. Updated action taken of abemaciclib from ongoing to discontinued in narrative. Updated corresponding fields and narrative with new information.

Update 15-Jul-2025: Additional information was received from the initial reporter via PSP on 09-Jul-2025. Added one non-serious event vaginal bleeding. Updated corresponding fields and narrative with new information.

Update 14-Aug-2025: Additional information was received on 07-Aug-2025 from the initial consumer reporter via PSP. The case upgraded to serious upon updating the non-serious event of anemia as serious with seriousness criteria of medically significant. Added corrective treatment for anemia. Updated narrative with new information.

Update 30-Aug-2025: Additional information was received on 26-Aug-2025 from the initial consumer reporter via PSP. Added one new dosage regimen of abemaciclib therapy. Details regarding the surgery on uterus was mentioned in narrative. Updated narrative with new information.

Lilly Analysis Statement: 21-Jun-2025: the company considered the event of diarrhoea, fatigue, nausea, decreased appetite, headache, and anemia related to the abemaciclib.

**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; Regimen #2	150 mg, daily; Oral	Breast cancer female (Breast cancer female)	14-NOV-2024 / Unknown; Unknown
#1 ) Abemaciclib (Abemaciclib) Tablet {Lot # D785022; Exp.Dt. OCT-2026}; Regimen #3	150 mg, daily; Oral	Breast cancer female (Breast cancer female)	Unknown / MAY-2025; Unknown
#1 ) Abemaciclib (Abemaciclib) Tablet; Regimen #4	UNK UNK, unknown; Unknown	Breast cancer female (Breast cancer female)	21-AUG-2025 / Unknown; Unknown

**23. OTHER RELEVANT HISTORY continued**

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Fatigue (Fatigue);