

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>COSTA RICA</b>	2. DATE OF BIRTH			2a. AGE <b>60 Years</b>	3. SEX <b>Female</b>	3a. WEIGHT <b>Unk</b>	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
			<b>PRIVACY</b>					<b>17</b>	<b>MAY</b>	<b>2023</b>	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)  
**Fever [Pyrexia]**  
**Her stools have been softer than normal [Faeces soft]**  
**she has been tired [Fatigue]**  
**Diarrhoea [Diarrhoea]**

Case Description: This solicited case, reported by a consumer via a Patient Support Program (PSP), concerned a 60-year-old (at the time of initial report) female patient of an unknown origin.

Medical history included thyroid disease, around 2015 thyroid was removed

**(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) <b>#1 ) Abemaciclib (Abemaciclib) Tablet {Lot # D761191; Exp.Dt. OCT-2026}</b>		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) <b>#1 ) 150 mg, bid</b>	16. ROUTE(S) OF ADMINISTRATION <b>#1 ) Oral</b>	
17. INDICATION(S) FOR USE <b>#1 ) Breast cancer (Breast cancer)</b>		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) <b>#1 ) 17-MAY-2023 / MAR-2025</b>	19. THERAPY DURATION <b>#1 ) Unknown</b>	

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) <b>#1 ) ARIMIDEX (ANASTROZOLE) Unknown ; Unknown</b> <b>#2 ) VITAMINS NOS (VITAMINS NOS) Tablet ; Ongoing</b>		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)		
From/To Dates <b>2015 to Ongoing</b> <b>Unknown</b>	Type of History / Notes <b>Medical Condition</b> <b>Medical Condition</b>	Description <b>Thyroid disorder (Thyroid disorder)</b> <b>Goiter (Goitre)</b>

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER <b>Eli Lilly Interamerica Inc (AR Branch)</b> <b>Tronador 4890 - Piso 12</b> <b>Buenos Aires, Capital Federal CP: 1430 ARGENTINA</b> <b>Phone: 54 1145464000</b>		26. REMARKS
	24b. MFR CONTROL NO. <b>CR202305016968</b>	25b. NAME AND ADDRESS OF REPORTER <b>NAME AND ADDRESS WITHHELD.</b>  <b>NAME AND ADDRESS WITHHELD.</b>
24c. DATE RECEIVED BY MANUFACTURER <b>07-APR-2025</b>	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 <b>14-APR-2025</b>	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	

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

because she developed a goiter, Nov-2022 underwent surgery on her right breast, received chemotherapy (further details are not provided). Historical drug included coronavirus disease (covid-19) vaccine for an unknown indication which causes illnesses which was further explained as choking. Concomitant medications included centrum (as reported) and vitamins for an unknown indication.

The patient received abemaciclib (Verzenio) tablet, at 150 mg, twice daily, via oral route, for the treatment of breast cancer, beginning on 17-May-2023, also reported approximately in 23-May or 26-May-2023 (conflicting date). She also used anastrozole concomitantly for an unknown indication. On 17-May-2023, she experienced fever. She did not report diarrhea but since an unknown date, she had stools that had been softer than normal. Since an unknown date, she experienced tiredness and diarrhea (reported as since she started taking abemaciclib. As a corrective treatment she took loperamide for diarrhea and no corrective treatment was given for tiredness. Her treating physician decided to suspend abemaciclib for her Mar-2025 appointment (exact date is not provided). It was because her treating physician would be evaluating some issues affecting her, the doctor would be verifying her thyroid condition (medical history). For this reason, she would undergo hormonal tests on 22-Apr-2025 and have an appointment with a doctor on the 29-Apr-2025. Her treating physician advised her that she might need more medication for her thyroid. She was experiencing a loss of control with her pills (no further details provided). Information regarding corrective treatment for remaining events were not reported. Outcome of the events tired and diarrhea was recovering and for other events it was not resolved. The status of abemaciclib therapy was discontinued and restart status was not provided.

The initial reporting consumer did not provide an opinion on relatedness of the events with abemaciclib therapy.

Updated 23-Jan-2025: Additional information was received on 16-Jan-2025 from the initial reporter via PSP. Added one historical drug covid vaccine, one concomitant medication of vitamins, one treatment drug loperamide and two non-serious events of tiredness, diarrhea. Updated report type from spontaneous to solicited. Updated the narrative with new information.

Updated 27-Mar-2025: Additional information was received on 17-Mar-2025 from the initial reporter via PSP. Updated outcome of the events diarrhea and tired to recovering (previously not recovered). Narrative was updated accordingly.

Updated 13-Apr-2025: Additional information was received on 07-Apr-2025 from the initial reporter via PSP. Added five medical histories, batch number and expiry date of abemaciclib therapy, therapy stop date and one concomitant drug of anastrozole. Updated action taken from unknown to discontinued for abemaciclib therapy. Updated the date of birth from 31-May-1963 to 31-Mar-1963 and age 59 to 60 years-old. Narrative was updated accordingly.

**23. OTHER RELEVANT HISTORY continued**

From/To Dates	Type of History / Notes	Description
2022 to Unknown	Historical Drug	Covid Vaccine (COVID-19 VACCINES); Drug Indication: Drug use for unknown indication (Product used for unknown indication), Drug Reaction: Choking (Choking) Covid vaccine caused her to develop other illnesses, because 3 years ago.
2015 to Unknown	Procedure	Thyroidectomy (Thyroidectomy);
NOV-2022 to Unknown	Procedure	Breast operation (Breast operation);
Unknown	Procedure	Chemotherapy (Chemotherapy);