SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		71 Years	Female	65.00 kg		JUN	2025

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

Stomach pain [Abdominal pain upper]
Does not taste the food [Taste disorder]
Frequency of off-label dosing [Off label use]
Diarrhea [Diarrhoea]
Lack of appetite [Decreased appetite]
Nausea [Nausea]
Itching [Pruritus]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), concerned a 71-year-old female patient of **(Continued on Additional Information Page)**

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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 # 761191; Exp.Dt. OCT-2026}
(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)
#1) 150 mg, daily

16. ROUTE(S) OF ADMINISTRATION
#1) Oral

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)
#1) 11-JUN-2025 / 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) Pastille ; 2024 / Unknown
#2) CALCIUM (CALCIUM) Unknown ; Unknown
#3) VITAMIN D [COLECALCIFEROL] (COLECALCIFEROL) Unknown ; Unknown
#4) ENALAPRIL (ENALAPRIL) Unknown ; Unknown
#5) ROSUVASTATINE [ROSUVASTATIN] (ROSUVASTATINE [ROSUVAS
(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

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.
CR202507012960

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
11-JUL-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
16-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

unknown origin.

Medical history was not provided. Concomitant medications included, calcium for prophylaxis, colecalciferol for prophylaxis, enalapril for high blood pressure, ramotidine for heartburn, rosuvastatin for cholesterol and triglycerides

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice daily, via oral route, for the treatment of breast cancer, beginning on 11-Jun-2025, she also received anastrazol as concomitant medication for breast cancer on an unknown date of 2024. On 27-Jun-2025, after starting abemaciclib therapy, her symptoms began two weeks ago, she experienced diarrhea and treated with antidiarrheal therapy prescribed by her physician. She could not taste food and had lost her taste. She also had lack of appetite. She started to taken it one week, one day on, one day off, the second week, one every day, and the third week, one in the morning and one at night. She currently received 150 mg twice daily for two weeks abemaciclib therapy. She experienced discomfort because it gives her severe stomach pain when she went to the bathroom, and she had three to four bowel movements a day with a softer texture than normal, but with severe stomach pain. Itching began after undergoing chemotherapy, but now with this treatment, the same dermatitis-like symptoms had returned. On an unknown date of Jun-2025, she experienced moderate nausea and itching. No corrective treatment provided for other events and not provided for off label dosing. The outcome of events diarrhea, stomach pain, decreased appetite, taste disorder was not recovered, for events nausea, itching was recovering and for off label dosing was unknown. The status of abemaciclib therapy was ongoing. Follow-up would not be possible with both the reporter and HCP as no contact details were provided and consent to be contacted further was denied.

The reporting consumer did not provide relatedness with off label dosing and related the events with abemaciclib therapy.

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 # 761191; Exp.Dt. OCT-2026}; Regimen #2	150 mg, other (Every other day); Oral	Breast cancer (Breast cancer)	11-JUN-2025 / Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet {Lot # 761191; Exp.Dt. OCT-2026}; Regimen #3	150 mg, bid; Oral	Breast cancer (Breast cancer)	11-JUN-2025 / Ongoing; Unknown

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

#5) ROSUVASTATINE [ROSUVASTATIN] (ROSUVASTATINE [ROSUVASTATIN]) Unknown ; Unknown