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		44 Years	Female	Unk	05	MAR	2025

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

Patient took Verzenio 150mg once daily for breast cancer instead of twice daily, No AE [Inappropriate schedule of product administration]
Stomach pain [Abdominal pain upper]
feeling of fullness in the stomach [Abdominal distension]
Dizziness [Dizziness]

Case Description: This solicited case, reported by a consumer via Patient Support Program (PSP), concerned a 44-year-old, female patient of an unknown origin.

(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 # D763191; Exp.Dt. OCT-2026}

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 150 mg, bid	#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)	19. THERAPY DURATION
#1) 28-FEB-2025 / Unknown	#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) Unknown ; Unknown
#2) GOSERELIN (GOSERELIN) Unknown ; Unknown
#3) VITAMIN D3 (VITAMIN D3) Unknown ; Unknown
#4) AMLODIPINE (AMLODIPINE) Tablet ; Unknown
#5) IRBESARTAN (IRBESARTAN) Tablet ; Unknown
#6) CALCIUM (CALCIUM) 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
Unknown	Medical Condition	Blood pressure high (Hypertension)

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.
CR202503008663

24c. DATE RECEIVED BY MANUFACTURER
08-APR-2025

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

DATE OF THIS REPORT
14-APR-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: CR202503008663

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Medical history included High blood pressure, and concomitant medications included Vitamin D3, Ionic calcium, Irbersatan 20 mg, Amlodipin 5 mg, for unknown indication.

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice daily, orally for treatment of Breast Cancer, beginning on 28-Feb-2025. She also received anastrazole and goserelin as concomitant medications. Since 05-Mar-2025, while on abemaciclib therapy, she had a feeling of fullness in the stomach. She was stable and was waiting for an appointment with her treating physician. On 07-Mar-2025, her abemaciclib frequency was changed to once a day (Inappropriate schedule of drug administration). On 07-Mar-2025, when she started taking 150 mg once daily, she experienced dizziness and stomach pain. The doctor instructed her to take the pill after lunch, she started doing so in Apr-2025, and those symptoms were now occasional. Information regarding corrective treatment was not provided. Outcome of event of stomach fullness was recovered; events of dizziness and stomach pain were recovering and remaining event outcome was not provided. Status of abemaciclib therapy was continued at 150mg once a day.

The reporting consumer did not provide relatedness of events with abemaciclib therapy.

Update 12-Mar-2025: This case was determined to be non-valid as there was no valid identifiable adverse event reported.

Update: 15-Mar-2025: This case was initially determined to be non-valid due to no identifiable adverse event. Additional information received from initial reporter 10-Mar-2025 with a valid event. Added one dosage regimen to abemaciclib therapy, one non-serious event of stomach fullness. Upon review of the information receive on 07-Mar-2025, updated event onset date of Inappropriate schedule of drug administration. Updated narrative accordingly.

Update 20-Mar-2025: Additional information was received from the initial reporter on 14-Mar-2025 and another information received from the initial reporter via PSP on 17-Mar-2025. Added one new dosage regimen of 250 mg. Subsumed new description as reported under event Inappropriate schedule of drug administration. Updated narrative accordingly.

Update 20-Mar-2025: Information received on 14-Mar-2025 and 17-Mar-2025 were combined and processed together.

Update 14-Apr-2025: Additional information was received from the initial reporter on 08-Apr-2025 via PSP. Checked ongoing checkbox for abemaciclib 150 mg dose. Updated outcome of event of Stomach fullness to recovered. Added two non-serious events of dizziness and stomach pain. Updated narrative accordingly.

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 # D763191; Exp.Dt. OCT-2026}; Regimen #2	150 mg, daily; Oral	Breast cancer (Breast cancer)	07-MAR-2025 / Ongoing; Unknown