SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	PANAMA		PRIVACY		62 Years	Female	Unk	12	JUN	2025

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

Aphthous ulcers in the roof of the mouth [Aphthous ulcer]
Taking 150 milligrams once a day for one week [Off label use]
Fall down the stairs [Fall]
Mild fatigue [Fatigue]
Diarrhea [Diarrhoea]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), concerned a 62-year-old female patient of an unknown ethnicity.

(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) Film-coated tablet
(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) 12-JUN-2025 / 19-JUN-2025

19. THERAPY DURATION
#1) 8 days

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

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 & Company
Dario Merchant
Cl 74 Y Av 3b Sur San Fco
PANAMA
Phone: 507 430-1733

26. REMARKS

24b. MFR CONTROL NO.
PA202506019183

24c. DATE RECEIVED BY MANUFACTURER
19-AUG-2025

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

DATE OF THIS REPORT
28-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Medical history and concomitant medications were not provided.

The patient received abemaciclib (Verzenio) tablet, at 150 mg dose, daily, orally for the indication of breast cancer beginning on 12-Jun-2025. Since 12-Jun-2025, she was administering abemaciclib 150 mg once a day for one week (Off label use) and discontinued this regimen on 19-Jun-2025. On 20-Jun-2025, she started administering full dose of abemaciclib which was 150 mg every 12 hours (twice daily). On 08-Jul-2025, while on abemaciclib therapy, she experienced mild fatigue that had already been resolved. On 23-Jul-2025, she had profuse diarrhea all night after eating a meal with a lot of oil at dinner and had aphthous ulcers in the roof of the mouth that bothers her. On 25-Jul-2025, she felt much better and did not had any more bowel movements in the morning. On 18-Aug-2025, she fell down the stairs because she slipped due to this event she received medical attention and boot placement. No corrective treatment was reported for the events aphthous ulcers in the roof of the mouth, diarrhea, fatigue and off label use. The outcome for the event diarrhea and fall was recovering and the outcome of the remaining events were recovered. The status of abemaciclib was ongoing with 150 mg twice daily regimen. Follow-up was not possible with reporter and treating physician as reporter did not agree to be contacted for future follow-up.

The initial reporting consumer assessed the relatedness of events diarrhea, aphthous ulcers in the roof of the mouth, fatigue as related to abemaciclib and assessed as not related for the event off label use with abemaciclib therapy.

Update 23-Jun-2025: This case was determined to be non-valid as there was no identifiable valid event; it was reported that the doctor started her on a reduced dose: taking 150 mg once a day for one week and then, she should begin taking 150 mg twice a day. As of 18-Jun-2025, abemaciclib was ongoing at daily dose. On 20-Jun-2025, she would start abemaciclib at twice daily dose. Follow-up could not be attempted since the reporter did not agree to be contacted nor treating physician.

Update 28-Jun-2025: Additional information received on 23-Jun-2025 from initial consumer. Added stopped date for 150 mg once a day dose. Updated outcome of event from recovering to recovered. On 19-Jun-2025, the patient stopped off label dosing of abemaciclib 150 mg once a day dose. She started receiving abemaciclib 150mg twice a day on 20-Jun-2025. The patient continued abemaciclib 150mg twice a day dose. The case remain non-valid as there was no identifiable adverse event. Follow up was not possible as consent to contact denied by the initial reporter and healthcare professional (HCP).

Update 23-Jul-2025: This case was initially determined to be non-valid due to no identifiable valid adverse event; however additional medically significant information received from the initial reporter on 18-Jul-2025 via PSP which contained valid non-serious adverse event of fatigue. Added event of fatigue. Updated report type from non-valid to valid and narrative amended accordingly.

Update 30-Jul-2025: Additional information received from initial reporter on 24-Jul-2025. Added non-serious events of diarrhea and aphthous ulcers in the roof of the mouth and updated the narrative accordingly.

Update 26-Aug-2025: Additional information was received from the initial reporting consumer via a PSP on 19-Aug-2025. Added one non-serious event of fall. Updated the outcome of the event aphthous ulcer from not recovered to recovered, narrative and relevant fields.

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) Film-coated tablet; Regimen #2	150 mg, bid; Oral	Breast cancer (Breast cancer)	20-JUN-2025 / Ongoing; Unknown