

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY GUATEMALA	2. DATE OF BIRTH			2a. AGE 65 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION ☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING
		Day	Month	Year				Day	Month	Year	
			PRIVACY					24	APR	2025	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
Cough [Cough]
vocal cord damage [Vocal cord disorder]
Skin rash [Rash]
Diarrhea 2 or 3 times a day [Diarrhoea]
Headache on occasion [Headache]
Physical exhaustion [Fatigue]
Taking 1 tablet of 150 mg every 24 hours [Off label use]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) from a business partner, with additional (Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Abemaciclib (Abemaciclib) Film-coated tablet #2) PANTECTA (PANTOPRAZOLE SODIUM SESQUIHYDRATE) (Continued on Additional Information Page)		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA
15. DAILY DOSE(S) #1) 150 mg, daily #2) 40 mg, daily	16. ROUTE(S) OF ADMINISTRATION #1) Oral #2) Oral	
17. INDICATION(S) FOR USE #1) Breast cancer (Breast cancer) #2) Gastric protector (Gastrointestinal disorder prophylaxis)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA
18. THERAPY DATES(from/to) #1) 24-APR-2025 / Unknown #2) 2020 / Ongoing	19. THERAPY DURATION #1) Unknown #2) Unknown	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) LETROZOLE (LETROZOLE) Unknown ; Unknown #2) PROCORALAN (IVABRADINE HYDROCHLORIDE) Unknown ; Unknown #3) EUTIROX (LEVOTHYROXINE SODIUM) Unknown ; Unknown #4) SELVIGON (PIPAZETATE HYDROCHLORIDE) Unknown ; Unknown #5) PREGABALIN (PREGABALIN) Unknown ; Unknown #6) BUDENA (BUDESONIDE) Unknown ; Unknown (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 to Ongoing	Medical Condition	Hypothyroidism (Hypothyroidism)
Unknown to Ongoing	Medical Condition	Arrhythmia (Arrhythmia)

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. GT202504024842	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 09-MAY-2025	24d. REPORT SOURCE ☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 20-MAY-2025	25a. REPORT TYPE ☒ INITIAL ☐ FOLLOWUP:	NAME AND ADDRESS WITHHELD.

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

information from another consumer via PSP of a business partner, concerned a 65-year-old female patient of unknown ethnicity.

Medical history included hypothyroidism, arrhythmia, insomnia, lung metastasis, diverticulosis and had unspecified chemotherapy treatment every three weeks and after each session the patient was convalescent. Concomitant medications included coderpina, respliquen, subimex (as reported), ivabradine hydrochloride, levothyroxine sodium, pipazetate hydrochloride, pregabalin, budesonide, ipratropium bromide, clonixin lysinate/pargerverine hydrochloride and loperamide; all for unknown indications.

The patient received pantoprazole sodium sesquihydrate (Pantecta), gastro-resistant tablets, 40 mg, daily, orally, as gastric protector beginning in 2020. She also received abemaciclib (Verzenio) film coated tablets, 150 mg, daily (off-label dosing frequency), via oral, for the treatment of breast cancer, beginning on 24-Apr-2025. As concomitant chemotherapy she received letrozole for breast cancer. On 04-May-2025, while on abemaciclib and pantoprazole sodium sesquihydrate therapies, she experienced moderate cough with vocal cord damage, headache on occasion and mild physical exhaustion. Unspecified corrective treatment was received for cough with vocal cord damage. On 05-May-2025, she experienced diarrhea two or three times a day and skin rash. As corrective treatment, she was taking sodium chloride for diarrhea. On an unknown date, abemaciclib dose was changed to 150 mg every 12 hours. Information regarding further corrective treatment was not provided. Outcome of off-label dosing frequency was recovered, for headache was recovering while for the remaining events was not recovered. Abemaciclib and pantoprazole sodium sesquihydrate therapies were ongoing. Follow-up could not be attempted since the reporter did not agree to be contacted and healthcare professional contact details were not provided.

The first reporting consumer did not provide an opinion of relatedness between the events and abemaciclib therapy either with pantoprazole sodium sesquihydrate therapy. The second reporting consumer did not relate cough with vocal cord damage to abemaciclib, did not provide relatedness assessment between off label dosing frequency and abemaciclib, while related the remaining events to abemaciclib therapy and did not provide an opinion of relatedness between the events and pantoprazole sodium sesquihydrate therapy.

Update 06-May-2025: This case was determined to be non valid due to no identifiable adverse event.

Update 07-May-2025: Additional information was received on 25-Apr-2025. Updated report type from spontaneous to post-marketing study. The case remained as non-valid due to no identifiable adverse event (off label use only).

Update 19-May-2025: Additional information was received on 09-May-2025 from the second reporter consumer via PSP of a business partner. This case was validated due to the addition of the following non-serious events: cough, vocal cord disorder, diarrhea, headache, fatigue and rash. Added second dosage regimen of abemaciclib and sodium chloride treatment. Updated outcome of off-label use to recovered. Upon review of previous information, the description to be coded of off-label use was updated to off label dosing frequency and start date was added; deleted concomitant therapies of codeine, amoxicillin trihydrate, and buprenorphine hydrochloride/naloxone hydrochloride as reported trade name was not available in world drug dictionary. Narrative was updated accordingly with new information.

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)	Ongoing; Unknown
#2) PANTECTA (PANTOPRAZOLE SODIUM SESQUIHYDRATE) Gastro-resistant tablet, 40 mg; Regimen #1	40 mg, daily; Oral	Gastric protector (Gastrointestinal disorder prophylaxis)	2020 / Ongoing; Unknown

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

#7) ATROVENT (IPRATROPIUM BROMIDE) Unknown ; Unknown

#8) SERTAL COMPUESTO [CLONIXIN LYSINATE;PARGEVERI (CLONIXIN LYSINATE, PARGEVERINE HYDROCHLORIDE) Unknown ; Unknown

#9) IMODIUM [LOPERAMIDE] (LOPERAMIDE) Unknown ; Unknown

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Insomnia (Insomnia);
Unknown to Ongoing	Medical Condition	Lung metastases (Metastases to lung);
Unknown to Ongoing	Medical Condition	Diverticulosis (Diverticulum intestinal); indicates that 5 days ago she finished antibiotics for diverticulitis
Unknown to Ongoing	Medical Condition	Convalescent (Convalescent);
Unknown to Ongoing	Procedure	Chemotherapy (Chemotherapy); chemotherapy treatment every three weeks