**CIOMS FORM**

# 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 | | | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Day | Month | Year | | | | Day | Month | Year | |
| PRIVACY | GUATEMALA | | PRIVACY | | 65 Years | Female | Unk | 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]
Taking 1 tablet of 150 mg every 24 hours [Off label use]
Skin rash [Rash]
Diarrhea 2 or 3 times a day [Diarrhoea]
Headache on occasion [Headache]
Physical exhaustion [Fatigue]

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)**

- ☐ 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
#2 ) PANTECTA (PANTOPRAZOLE SODIUM SESQUIHYDRATE) **(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, daily | #1 ) Oral |
| #2 ) 40 mg, daily | #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) | 19. THERAPY DURATION |
|---|---|
| #1 ) 24-APR-2025 / Unknown | #1 ) Unknown |
| #2 ) 2020 / Ongoing | #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**

24c. DATE RECEIVED BY MANUFACTURER
22-MAY-2025

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

DATE OF THIS REPORT
27-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
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## 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/pargeverine hydrochloride; 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. On 06-May-2025, her diarrhoea increased to 6 to 8 per day (intensity moderate) by taking 4 tablets over the course improved between 2 to 4 diarrhoeas. 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.

Update 26-May-2025: Additional information received on 22-May-2025 via a PSP. Added the intensity as moderate for the event diarrhoea and updated loperamide from concomitant medication to treatment drug for diarrhea. Updated the narrative 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

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## 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 |