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	PANAMA		PRIVACY		Unk	Female	Unk		MAR	2025

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

Ambulatory limitation/ Physician disability [Gait inability]
Visual impairment [Visual impairment]
Patient was in very delicate condition [Ill-defined disorder]

Case Description: This spontaneous case, reported by a consumer, via another manufacturer who contacted the company to report adverse events, concerned a female patient of an unknown age and origin.

Medical history and concomitant medications were not provided.

(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) Olumiant 4mg (Baricitinib) Tablet, 4 mg
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) UNK UNK, unknown

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

17. INDICATION(S) FOR USE
#1) Product used for unknown indication (P
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) 10-SEP-2024 / 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)

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 de Centroamerica, S.A.
Dario Merchant
Cl 74 Y Av 3b Sur San Fco
PANAMA
Phone: 507 430-1733

26. REMARKS

24b. MFR CONTROL NO.
PA202505008330

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

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

DATE OF THIS REPORT
18-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

The patient received baricitinib (Olumiant) film coated tablet, unknown dose and frequency, orally, for the treatment of unknown indication, beginning on 10-Sep-2024. On an unknown date in Mar-2025, while on baricitinib therapy, she experienced physical and ambulatory limitations. She also missed medication due to felt ill and had vision impairment. She spend entire month of Apr-2025, in a very delicate condition. The event of Unable to walk was considered to be serious by the reporter due to disability. Information regarding corrective treatment and outcome of events was not provided. Status of baricitinib therapy was discontinued. No additional follow-up will be attempted due to the information was received from another manufacturer, but if new information arrives, the manufacturer would be forward it.

The initial reporting consumer did not provide the relatedness assessment of the events with baricitinib 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) Olumiant 4mg (Baricitinib) Tablet, 4 mg; Regimen #1	UNK UNK, unknown; Oral	Product used for unknown indication (Product used for unknown indication)	10-SEP-2024 / Unknown; Unknown