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		68 Years	Male	Unk	15	APR	2025	

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

Hives around the anus, itchy and painful [Urticaria]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) from a business partner, concerned a 68-year-old male patient of unknown ethnicity.

Medical history and concomitant medications were not provided.

(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) Baricitinib (Baricitinib) Film-coated tablet

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 4 mg, daily	#1) Oral

17. INDICATION(S) FOR USE
#1) Rheumatoid arthritis (Rheumatoid arthritis)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 20-MAR-2025 / Unknown	#1) Unknown

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

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

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 Interamerica Inc (AR Branch)
Tronador 4890 - Piso 12
Buenos Aires, Capital Federal CP: 1430 ARGENTINA
Phone: 54 1145464000

26. REMARKS

24b. MFR CONTROL NO.
GT202505007606

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

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

DATE OF THIS REPORT
15-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 tablets, 4 mg daily, via oral, for the treatment of rheumatoid arthritis, beginning on 20-Mar-2025. On 15-Apr-2025, after starting baricitinib therapy, he experienced hives around the anus, itchy and painful for which clostebol acetate/neomycin sulfate cream was applied to the area as corrective treatment, but without positive results, hence, he would go to the dermatologist. Outcome of the event was not recovered. Information regarding baricitinib therapy status was not provided. Follow-up could not be attempted since the reporter did not agree to be contacted and healthcare professional contact details were not provided.

The reporting consumer related the event to baricitinib therapy.

Update 14-May-2025: Initial information received on 06-May-2025 and additional information received on 07-May-2025 were processed at the same time.