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	GUATEMALA		PRIVACY		27 Years	Female	Unk		MAY	2025

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

She gets sick a lot, with different things [Ill-defined disorder]

Case Description: This solicited case, reported by a consumer via Patient Support Program (PSP) who contacted the company to report adverse events, concerned a 27-years-old (at the time of initial report) female patient of an unknown origin.

Medical history and concomitant medications were not provided.

The patient received ixekizumab (Taltz) via a unknown formulation, 80mg,

(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) Ixekizumab (Ixekizumab) Solution for injection

15. DAILY DOSE(S)
#1) 80 mg, monthly (1/M)

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

17. INDICATION(S) FOR USE
#1) psoriatic arthritis (Psoriatic arthropathy)

18. THERAPY DATES(from/to)
#1) 05-APR-2025 / Unknown

19. THERAPY DURATION
#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.
GT202507009860

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

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

once monthly, subcutaneously for the treatment of psoriatic arthritis, beginning on 05-APR-2025. Information regarding loading dose was not provided. On an unknown date in May-2025, while on ixekizumab drug, she gets sick a lot, with different things. Information regarding corrective treatment was not provided. The outcome of the event was resolving. The status of ixekizumab therapy was not provided. Follow up could not be attempted since the reporter refused to provide more information and physician contact details were not provided.

The initial reporting consumer related the event and ixekizumab therapy.

Lilly Analysis Statement: 11-Jul-2025: The company considered the unlisted event of Ill-defined disorder unrelated to the ixekizumab drug.