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		50 Years	Female	Unk		FEB	2025

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

Liver problems [Liver disorder]
Yellow skin [Yellow skin]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), concerned a 50-year-old (at time of initial report) female patient of unknown origin.

Medical history and concomitant medications were not provided.

The patient received ixekizumab (Taltz) injections via an unspecified

(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) Psoriasis (Psoriasis)

18. THERAPY DATES(from/to)
#1) 05-DEC-2024 / 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.
GT202505014230

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

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

DATE OF THIS REPORT
25-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

disposable device, 80 mg, every 30 days, subcutaneously, for the treatment of psoriasis, starting on 05-Dec-2024. Information on loading dose was not provided. On an unknown date, in Feb-2025, while on ixekizumab therapy, the medication did not do any good to her as she experienced liver problems and yellow skin due to which her ixekizumab therapy was discontinued by her doctor. Information regarding corrective treatment was not provided. Outcome of the events was not recovered. It was unknown when or if ixekizumab therapy would be re-started. Follow-up would not be possible since reporting consumer declined consent for further contact.

The initial reporting consumer related the events with ixekizumab therapy.

Update 23-May-2025: Additional information was received from initial reporting consumer via a PSP on 16-May-2025. Added one non-serious event of yellow skin and partial start date as Feb-2025 of event liver disorder. Updated outcome of event liver disorder from recovering to not recovered and its as reported causality from not related to related (Yes). Narrative was updated with new information accordingly.