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		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)

Other Serious Criteria: med sig
Jaundice/Jaundice in skin and eyes [Jaundice]

Case Description: This spontaneous case, reported by a physician who contacted the company to report adverse events, concerned a 50-year-old (at the time of the initial report) female patient of an unknown origin.

Medical history and concomitant medications were not reported.

The patient received ixekizumab (Taltz) via a prefilled pen, 80 mg at an

(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) Taltz 80mg (Ixekizumab) Solution for injection in pre-filled pen, 80 mg {Lot # D689758AE; Exp.Dt. 16-DEC-2025}
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 80 mg, unknown

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

17. INDICATION(S) FOR USE
#1) Psoriasis (Psoriasis)

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

18. THERAPY DATES(from/to)
#1) DEC-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 Interamerica Inc (AR Branch)
Tronador 4890 - Piso 12
Buenos Aires, Capital Federal CP: 1430 ARGENTINA
Phone: 54 1145464000

26. REMARKS

24b. MFR CONTROL NO.
GT202504007005

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

24c. DATE RECEIVED BY MANUFACTURER
23-APR-2025

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

DATE OF THIS REPORT
04-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

Mfr. Control Number: GT202504007005

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

unknown frequency, via an unknown route of administration, for the treatment of psoriasis, beginning on unspecified date in Dec-2024. Information regarding loading dose was not provided. On Feb-2025, while on ixekizumab therapy, she experienced persistent elevation of liver tests, associated with abdominal pain, white stools, very yellow urine, and with negative hepatitis panel. After evaluation, jaundice was observed in skin and eyes, white stools and very yellow urine (Feb-2025). The event of jaundice was considered serious by the company due to medical significance. They suspended the use of the medication for one week, then resumed it and she presented symptoms again, so they decided to suspend the administration of the medication on 10-Apr-2025. She had normal liver tests, normal color stools, without any other symptoms. She was recovered from the event. Information regarding the corrective treatment and restart status of ixekizumab therapy were not reported.

The initial reporting physician did not provide the relatedness of the event with ixekizumab treatment.

Update 23-Apr-2025: Information was received from initial reporting physician on 11-Apr-2025. No medically significant information was provided; therefore, no other changes were made in the case.

Update 29-Apr-2025: Information was received from initial reporting physician on 23-Apr-2025. Added serious event of jaundice and subsumed all the other events with jaundice. Added stop date, batch number, unticked ongoing and updated action taken to drug discontinued. Updated 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) Taltz 80mg (Ixekizumab) Solution for injection in pre-filled pen, 80 mg {Lot # D689758AE; Exp.Dt. 16-DEC-2025}; Regimen #2	80 mg, unknown; Unknown	Psoriasis (Psoriasis)	Unknown / 10-APR-2025; Unknown