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)

Other Serious Criteria: med sig
Jaundice/Jaundice in skin and eyes [Jaundice]
Urea nitrogen was 21.30 [Blood urea increased]
Total cholesterol was 507 [Blood cholesterol]
Triglycerides was 302 [Blood triglycerides increased]
LDH was 227 [Blood lactate dehydrogenase increased]
HbA1C was 13.70 [Glycosylated haemoglobin increased]
Pre-prandial glucose was 409 [Blood glucose increased]
Urine abnormal [Urine analysis abnormal]
Moderate hepatic steatosis [Hepatic steatosis]

(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) Taltz 80mg (Ixekizumab) Solution for injection in pre-filled pen, 80 mg {Lot # D689758AE; Exp.Dt. 06-DEC-2025}
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 160 mg, single (two doses of 80 mg)

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
29-APR-2025

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

DATE OF THIS REPORT
09-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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. Investigation before initiation of ixekizumab therapy showed creatinine was 0.69 (units and reference range was not provided), urea nitrogen was 13.10 (units and reference range was not provided), uric acid was 5.4 (units and reference range was not provided), total cholesterol was 58 (units and reference range was not provided), triglycerides was 158 (units and reference range was not provided), High density lipoprotein) cholesterol was 49.7, Low density lipoprotein (LDL), cholesterol was 84, aspartate aminotransferase (ASAT) was 21 (units and reference range was not provided), Alanine aminotransferase (ALAT) was 27 (units and reference range was not provided), Lactate dehydrogenase (LDH) was 194 (units and reference range was not provided), HbA1c was 9 (units and reference range was not provided), pre-prandial glucose was 180 (units and reference range was not provided).

The patient received ixekizumab (Taltz) via a prefilled pen, 160 mg (two doses of 80 mg), followed by 80 mg, every two weeks (from week 2 to week 12), subcutaneously, for the treatment of psoriasis, beginning on unspecified date in Dec-2024. On an unknown date, investigation post starting the ixekizumab therapy, creatinine was 1.09 (units and reference range was not provided), urea nitrogen was 21.30 (units and reference range was not provided), uric acid was 4.9 (units and reference range was not provided), total bilirubin was 8.89 (units and reference range was not provided), indirect bilirubin was 1.97 (units and reference range was not provided), direct bilirubin was 6.92 (units and reference range was not provided), total cholesterol was 507 (units and reference range was not provided), triglycerides was 302 (units and reference range was not provided), ASAT was 136 (units and reference range was not provided), ALAT was 234 (units and reference range was not provided), LDH was 227 (units and reference range was not provided), HbA1c was 13.70 (units and reference range was not provided), pre-prandial glucose was 409 (units and reference range was not provided), Hepatitis B surface antigen was negative, Hepatitis B E antigen was negative, Hepatitis B E antibody was negative, Hepatitis B IgM core antibody was negative, Hepatitis B total core antibody was negative, Hepatitis A IgM was negative, Hepatitis C (antibody) was negative. Urine: color: amber, Appearance: cloudy, density: 1.033, pH: 5.00, leukocytes was 25/uL (reference range was not provided), nitrites was negative, protein was 25mg/dl (reference range was not provided), urine glucose was 1000 mg/dl, ketone bodies was 5mg/dl (reference range was not provided), urobilinogen was 1mg/dL (reference range was not provided), bilirubin was 3mg/dl, erythrocytes was 25/uL (reference range was not provided), white blood cells was 9,590 (units and reference range was not provided), red blood cell counts was 4.66, hemoglobin was 13.20 (units and reference range was not provided), hematocrit was 39.30 (reference range was not provided), mean corpuscular volume was 84.30 (units and reference range was not provided), platelet count was 222,000 (units and reference range was not provided), lymphocytes was 22% (reference range was not provided), monocytes was 6% (reference range was not provided), neutrophils was 69% (reference range was not provided), eosinophils was 1.30% (reference range was not provided) and sedimentation rate: 2.00 (reference range was not provided). On an unknown date in Dec-2024, since starting the 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 of the signs and symptoms which included jaundice and acholia, jaundice was confirmed 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. In addition on 31-Mar-2025, conventional abdominal ultrasound showed moderate hepatic steatosis and there were no other abnormalities observed. 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 of jaundice and for the remaining events outcome was not reported. Information regarding the corrective treatment and restart status of ixekizumab therapy were not reported.

The initial reporting physician related the event of jaundice, while did not provide the relatedness assessment for the remaining events 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.

Update 07-May-2025: Additional information was received from initial reporting physician on 29-Apr-2025. Added dosing details of ixekizumab therapy, relatedness assessment of the event jaundice (Yes), eight non-serious events of blood urea increased, blood cholesterol, blood triglycerides, blood lactate dehydrogenase, glycosylated haemoglobin, blood glucose increased, urine abnormal and hepatic steatosis, lab test details before starting and post receiving the ixekizumab therapy. Updated onset date of event jaundice to Dec-2024. Updated case and narrative as per the new information received.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Alanine aminotransferase		

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
		234 (units and reference range was not provided)		
2		Aspartate aminotransferase 136 (units and reference range was not provided)		
3		Bilirubin conjugated increased 6.92 (units and reference range was not provided)		
4		Blood bilirubin 8.89 (units and reference range was not provided)		
5		Blood bilirubin 3 mg/dL	mg/dL	
6		Blood bilirubin unconjugated increased 1.97 (units and reference range was not provided)		
7		Blood cholesterol 507 (units and reference range was not provided)		
8		Blood creatinine 1.09 (units and reference range was not provided)		
9		Blood glucose 409 (units and reference range was not provided)		
10		Blood ketone body 5 mg/dL	mg/dL	
11		Blood lactate dehydrogenase 227 (units and reference range was not provided)		
12		Blood triglycerides 302 (units and reference range was not provided)		
13		Blood urea increased 4.9 (units and reference range was not provided)		
14		Glucose urine 1000 mg/dL	mg/dL	
15		Glycosylated haemoglobin		

Mfr. Control Number: GT202504007005

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
		13.70		
16		Investigation Color: amber, appearance: cloudy, density: 1.033, pH: 5.00		
17		Protein urine 25 mg/dl	mg/dL	
18		Red blood cell count 25/uL	25 /uL	
19	31-MAR-2025	Ultrasound abdomen Conventional abdominal ultrasound showed moderate hepatic steatosis		
20		Urobilinogen urine 1 mg/dL		
21		White blood cell count 25 uL	uL	

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. 06-DEC-2025}; Regimen #2	80 mg, other (every two weeks); Unknown	Psoriasis (Psoriasis)	Unknown / 10-APR-2025; Unknown