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		
		Day	Month	Year				Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		48 Years	Male	Unk	25	JUN	2025

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

Patient did not administer complete dose of Taltz 80 mg due to device issue;No AE [Incorrect dose administered]

Case Description: This spontaneous case, reported by a consumer who contacted the company to report adverse event, concerned a 48-year-old male patient of unknown origin.

Medical history was not provided.

(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 # D764981CG; Exp.Dt. 30-JUL-2026}
#2) Taltz Autoinjector (Taltz Autoinjector) Pen, Disposable {Lot # D764981CG}

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 80 mg, monthly (1/M)	#1) Subcutaneous
#2)	#2) Unknown

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 28-MAR-2025 / Unknown	#1) Unknown
#2) Unknown	#2) 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.
GT202507006186

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

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

DATE OF THIS REPORT
16-JUL-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

Concomitant medication was not provided.

The patient received ixekizumab (Taltz) via a pre-filled pen (Autoinjector), 80 mg, monthly, subcutaneously, for the treatment of psoriasis, beginning on 28-Mar-2025. Information regarding the loading dose was not provided. On 25-Jun-2025, while on ixekizumab therapy, when pressed the injection button, heard two clicks, injection button got stuck, waited few seconds to saw if medication was administering, felt the needle, and administered a small amount of medication and when it was removed medication spilled out and another amount of medication remained in it (Incomplete dose administered) (Batch number: D764981CG). No corrective treatment was required. The outcome of the event was resolved. Ixekizumab therapy status was continued.

The operator of the device was the patient and his training status was not provided. The general model duration of use was not provided and the suspect device duration of use was single use device. The action taken with the suspect device was not provided and its return status was not provided.

The reporting consumer did not relate the event with ixekizumab drug and its suspect ixekizumab device.

Update 16-Jul-2025: Additional information was received from the initial reporting consumer on 08-Jul-2025. Added date of birth of patient, indication of use, start date, and frequency of suspect ixekizumab drug and added event onset date. Updated the treatment received of the event from unknown to no, outcome of the event from unknown to resolved and as reported causality if the event from not reported to no and narrative with new information.