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		Unk	Male	Unk	02	JUL	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 male patient of unknown age and 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 # **(Continued on Additional Information Page)**

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

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

17. INDICATION(S) FOR USE
#1) Drug use for unknown indication (Produ
#2) Unknown **(Continued on Additional Information Page)**

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

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

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
14-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: GT202507006186

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Concomitant medication was not provided.

The patient received ixekizumab (Taltz) via an pre-filled pen (Autoinjector), 80 mg at an unknown frequency, subcutaneously, for the treatment of an unknown indication, beginning on an unknown date. Information regarding the loading dose was not provided. On 02-Jul-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. Information regarding the corrective treatment, outcome of the event and status of ixekizumab therapy was not provided.

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 provide any opinion on relatedness assessment between the event and ixekizumab drug and suspect device.

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 # D764981CG; Exp.Dt. 30-JUL-2026}; Regimen #1	80 mg, unknown; Subcutaneous	Drug use for unknown indication (Product used for unknown indication)	Unknown; Unknown