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		48 Years	Female	Unk		MAR	2025

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

Leg pain [Pain in extremity]
Infection [Infection]

Case Description: This solicited case, reported by a consumer via a business partner via a patient support program (PSP), concerned a 48-year-old female patient of unknown origin.

Medical history and concomitant medications were not provided.

The patient received ixekizumab (Taltz) via an unspecified disposable

(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) Ankylosing spondylitis (Ankylosing spondylitis)

18. THERAPY DATES(from/to)
#1) 10-MAR-2025 / 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.
GT202504006996

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

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

DATE OF THIS REPORT
09-APR-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

device, 80 mg monthly, subcutaneously, for the treatment of ankylosing spondylitis, beginning on 10-Mar-2025. On an unknown date in Mar-2025, while on ixekizumab treatment, she had a lot of leg pain and as a corrective treatment she took unspecified medication for the pain, then a week later she had an infection, as a corrective treatment she took unspecified antibiotic. Her doctor advised that she should not take the injection until April. Outcome of the event were not recovered. Status of ixekizumab therapy was drug discontinued, and it was unknown whether it would be restarted or not. Follow up was not possible as the case was received through a manufacturer, follow-up was not pursued. If the manufacturer received any additional information about this case, they would forward it and case would be updated accordingly.

The initial reporting consumer did not provide the relatedness assessment between the events with ixekizumab therapy.