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	PANAMA		PRIVACY		65 Years	Female	Unk		Unk	

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

Other Serious Criteria: Medically Significant
the bottoms of my feet and my toes cracked open/skin condition has bothered her feet to the point that she can't do anything [Skin cracked]
all those wounds started to close, because they wouldn't close before [Wound healing delayed]
can't walk very well/couldn't walk, I couldn't put my feet down firmly/don't have strength in my legs to hold my body [Lower extremities weakness of]
a mass of blood [Bleeding]
legs shake [Tremor limb]

(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) Enbrel (ETANERCEPT) Solution for injection in pre-filled syringe
#2) Enbrel (ETANERCEPT (DEVICE CONSTITUENT)) Solution for injection in pre-filled syringe

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 50 mg, weekly	#1) Unknown
#2)	#2) Unknown

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

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
Pfizer S.A.
Laura Arce Mora
Avenida Escazú, Torre Lexus, piso 7. Escazú
San jose, COSTA RICA

26. REMARKS

24b. MFR CONTROL NO.
PV202500092100

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

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

DATE OF THIS REPORT
31-JUL-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

feet hurt [Painful feet]
fall [Fall]

Case Description: This is a spontaneous report and received from Consumer or other non HCPs, Program ID: 164974.

A 65-year-old female patient received etanercept (ENBREL), (Batch/Lot number: unknown) at 50 mg weekly. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: SKIN FISSURES (medically significant), outcome "recovered", described as "the bottoms of my feet and my toes cracked open/skin condition has bothered her feet to the point that she can't do anything"; IMPAIRED HEALING (medically significant), outcome "unknown", described as "all those wounds started to close, because they wouldn't close before"; MUSCULAR WEAKNESS (medically significant), outcome "unknown", described as "can't walk very well/couldn't walk, I couldn't put my feet down firmly/don't have strength in my legs to hold my body"; HAEMORRHAGE (medically significant), outcome "recovered", described as "a mass of blood"; TREMOR (non-serious), outcome "unknown", described as "legs shake"; PAIN IN EXTREMITY (non-serious), outcome "unknown", described as "feet hurt"; FALL (non-serious), outcome "unknown". The action taken for etanercept was unknown. Therapeutic measures were taken as a result of skin fissures, impaired healing, haemorrhage. Clinical course: The patient stated that she could not remain fasting for such a long time because she suffers from diabetes. the patient caretaker mentioned that "the patient couldn't walk very well, the skin condition had bothered her feet to the point that she couldn't do anything, she couldn't stand for long because her feet hurt". Additionally, the patient said "her legs shake, she had been in bed for a year and a month because the bottoms of her feet and her toes cracked open, they split, and she could not put her foot down firmly because it was a mass of blood. The doctor had been sending her medicine, taught her son how to clean her and everything, they sent her medications, and all those wounds started to close, because they wouldn't close before. She couldn't walk, She couldn't put her feet down firmly, but now the wounds have closed. She didn't have strength in her legs to hold her body, her legs shake, she couldn't steady herself, she walked slowly and they had to hold her because she fell, she walked just a little."

The information on the batch/lot number for etanercept will be requested and submitted if and when received.