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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	PANAMA		PRIVACY		40 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)

bruises were appearing on her skin, especially on her arms and in the belly area where ENBREL has been injected/ green bruises [Injection site bruising]
discomfort in the abdominal area [Abdominal discomfort]
due to gases [Gas]
anxiety crisis [Anxiety]
cramps in her hands and in the back of her calf leg [Cramps of extremities]

Case Description: This is a spontaneous report received from a Consumer

(Continued on Additional Information Page)

- ☐ 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 {Lot # LL4200; Exp.Dt. MAY-2027}
#2) Enbrel (ETANERCEPT (DEVICE CONSTITUENT)) Solution for injection **(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) 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.
PV202500097037

24c. DATE RECEIVED BY MANUFACTURER
13-AUG-2025

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

DATE OF THIS REPORT
15-AUG-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

or other non HCP and a Nurse, Program ID: 164974.

A 40-year-old female patient received etanercept (ENBREL), first regimen (Lot number: LL4200, Expiration Date: May2027) at 50 mg weekly and second regimen (Lot number: HK8929, Expiration Date: Jun2026) at 50 mg weekly. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: INJECTION SITE BRUISING (non-serious), outcome "unknown", described as "bruises were appearing on her skin, especially on her arms and in the belly area where ENBREL has been injected/ green bruises"; ABDOMINAL DISCOMFORT (non-serious), outcome "unknown", described as "discomfort in the abdominal area"; FLATULENCE (non-serious), outcome "unknown", described as "due to gases"; ANXIETY (non-serious), outcome "unknown", described as "anxiety crisis"; MUSCLE SPASMS (non-serious), outcome "not recovered", described as "cramps in her hands and in the back of her calf leg". Relevant laboratory tests and procedures are available in the appropriate section. The action taken for etanercept was unknown.

Additional information: The patient was feeling somewhat anxious and worried about the appearance of these bruises, and mentioned that she did not have an appointment with the rheumatologist until 30Sep2025. The patient commented that after a long time with the treatment, she had observed that her body had green bruises, that when she finished applying the Enbrel medication she felt discomfort in the abdominal area that went more to the left side. Additionally, she had an anxiety attack, where they did laboratories and X-rays and apparently it was due to gases. She felt that she was running out of breath, that it could be generated by anxiety or she did not know if it was because of the medication, also 2 months or more ago she was feeling cramps in her hands and in the back of her calf leg.

Amendment: This follow-up report is being submitted to amend previous information: event data (removed: Bruise).

Follow-up (13Aug2025) This is a spontaneous follow-up report received from a Consumer or other non HCP, Program ID: 164974. Updated Information: Patient data (lab data added), Product data (new lot number added), Events data (event details "Injection site bruising", new AE: Abdominal discomfort, anxiety, Flatulence and Muscle spasms added) and additional information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		X-ray	gases	

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) Enbrel (ETANERCEPT) Solution for injection in pre-filled syringe {Lot # HK8929; Exp.Dt. JUN-2026}; Regimen #2	50 mg, weekly; Unknown	Unknown	Unknown; Unknown
#2) Enbrel (ETANERCEPT (DEVICE CONSTITUENT)) Solution for injection in pre-filled syringe; Regimen #1	; Unknown	Unknown	Unknown; Unknown