

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY PANAMA	2. DATE OF BIRTH			2a. AGE 38 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
		Day	Month	Year				Day	Month	Year	
			PRIVACY					Unk			

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
 swelling in her knees [Knee swelling]
 normally, it should have been two injections, but to avoid running out, she tried to use only one [Intentional misuse by dose change]
 what had been flaring up were joint pains [Clinical flare reaction]

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

A 38-year-old female patient received etanercept (ENBREL), since 2012 (ongoing) (Lot number: LE3059, Expiration Date: Oct2026) at 50 mg weekly.
 (Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Enbrel (ETANERCEPT) Solution for injection in pre-filled syringe {Lot # LE3059; Exp.Dt. OCT-2026} #2) Enbrel (ETANERCEPT (DEVICE CONSTITUENT)) Solution for injection in pre-filled syringe		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) 50 mg, weekly #2)	16. ROUTE(S) OF ADMINISTRATION #1) Unknown #2) Unknown	
17. INDICATION(S) FOR USE #1) Unknown #2) Unknown		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 2012 / Ongoing #2) Unknown	19. THERAPY DURATION #1) 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. PV202500102098		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 20-AUG-2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous		NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 25-AUG-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:		

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: INTENTIONAL PRODUCT MISUSE (non-serious), outcome "unknown", described as "normally, it should have been two injections, but to avoid running out, she tried to use only one"; CONDITION AGGRAVATED (non-serious), outcome "unknown", described as "what had been flaring up were joint pains"; JOINT SWELLING (non-serious), outcome "unknown", described as "swelling in her knees". The action taken for etanercept was dosage not changed.

Additional information: The patient reported she administered the Enbrel herself. Her doctor was a private consultant, and during the last appointment, he gave her a prescription that would last until the following month. On 19Aug2025 she administered one of the injections; normally, it should have been two, but to avoid running out, she tried to use only one, since she was quite stable. What had been flaring up, her doctor had already warned her, was joint pains. Recently, she experienced swelling in her knees, something that hadn't happened before. For the time being, she would not be able to visit the doctor because she didn't have the financial resources to pay for the consultation. When she was without medication, she didn't inject herself; she bought topical creams, like betamethasone, just to avoid breaking out and to prevent lesions on her body.