

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY PANAMA	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	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	Female	Unk	29	APR	2025	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
she felt discomfort after applying the medication [Discomfort]

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

An adult female patient (not pregnant) received etanercept (ENBREL), (Batch/Lot number: unknown).

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Enbrel (ETANERCEPT) Unknown		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) UNK	16. ROUTE(S) OF ADMINISTRATION #1) Unknown	
17. INDICATION(S) FOR USE #1) Unknown		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) Unknown	19. THERAPY DURATION #1) 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. 202500092958	
24c. DATE RECEIVED BY MANUFACTURER 29-APR-2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	
DATE OF THIS REPORT 02-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	
		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.

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: DISCOMFORT (non-serious) with onset 29Apr2025, outcome "unknown", described as "she felt discomfort after applying the medication". The action taken for etanercept was unknown.

No follow-up attempts are possible. Batch/lot number is not provided, and it cannot be obtained.