

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>PANAMA</b>	2. DATE OF BIRTH			2a. AGE <b>69</b> Years	3. SEX <b>Male</b>	3a. WEIGHT <b>Unk</b>	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	
		<b>PRIVACY</b>						<b>Unk</b>			

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  
 Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)  
 injected a little of the medication and the rest was discarded, he did not inject the full dose [Incomplete dose administered]  
 at the time of injecting he became nervous when he felt the needle punch [Fear of needles]  
  
 Case Description: This is a spontaneous report received from a Consumer or other non HCP, Program ID: 164974.  
  
 A 69-year-old male patient received etanercept (ENBREL), (Batch/Lot number: unknown) at 50 mg.  
  
 (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 #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 type="checkbox"/> NA
15. DAILY DOSE(S) #1 ) 50 mg #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 type="checkbox"/> NA
18. THERAPY DATES(from/to) #1 ) Unknown #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. <b>PV202500039530</b>		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>09-MAY-2025</b>	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 <b>09-MAY-2025</b>	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1		

09-May-2025 09:23

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**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: INCORRECT DOSE ADMINISTERED (non-serious), outcome "unknown", described as "injected a little of the medication and the rest was discarded, he did not inject the full dose"; FEAR OF INJECTION (non-serious), outcome "unknown", described as "at the time of injecting he became nervous when he felt the needle punch". The action taken for etanercept was unknown.

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

Follow-up (09May2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.