

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>COSTA RICA</b>	2. DATE OF BIRTH			2a. AGE <b>57 Years</b>	3. SEX <b>Female</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)  
got colds very frequently/been sick approximately 8 times this year [Cold]  
always had very low defenses [Immune system disorder]

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

A 57-year-old female patient received etanercept (ENBREL), (Batch/Lot number: unknown) at 50 mg weekly (50 mg, weekly (on tuesdays)).

(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, weekly (on Tuesdays) #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>202500062854</b>	
24c. DATE RECEIVED BY MANUFACTURER <b>08-JUN-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>08-JUN-2025</b>	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	
		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.

08-Jun-2025 04:19

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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: NASOPHARYNGITIS (non-serious), outcome "unknown", described as "got colds very frequently/been sick approximately 8 times this year"; IMMUNE SYSTEM DISORDER (non-serious), outcome "unknown", described as "always had very low defenses". 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 (08Jun2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.