

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 67 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)
Other Serious Criteria: Medically Significant stroke in eye [Ocular stroke]
hemorrhage in my eye [Ocular hemorrhage]

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

A 67-year-old female patient received etanercept (ENBREL), (Lot number: NF5711, Expiration Date: Apr2026) at 50 mg. The patient's relevant medical history and concomitant medications were not reported.

(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 pen {Lot # NF5711; Exp.Dt. APR-2026} #2) Enbrel (ETANERCEPT (DEVICE CONSTITUENT)) Solution for injection in pre-filled pen		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 #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) 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. PV202500060528	
24c. DATE RECEIVED BY MANUFACTURER 19-MAY-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 21-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

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

The following information was reported: OCULAR STROKE (medically significant), outcome "unknown", described as "stroke in eye"; EYE HAEMORRHAGE (medically significant), outcome "unknown", described as "hemorrhage in my eye". The action taken for etanercept was unknown. Therapeutic measures were taken as a result of ocular stroke.

Clinical course: Patient indicated: "I use the injections of the drug Enbrel, but I had a stroke in my eye and they had to operate on me. I have a long time to put on the Enbrel and this happened to me a fortnight ago." Take into account that the patient told the ophthalmologist who is treating her, that she was injecting Enbrel, and what the doctor told her was that this could have been the cause of the stroke. The patient is confused because she does not know whether or not to apply Enbrel, the patient is redirected to the family doctor.