SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	PANAMA	19	JUL	1962	62 Years	Female	Unk		Unk	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

Other Serious Criteria: Medically Significant
she is more advanced, she is in a wheelchair [Disease progression]
currently having a crisis (referring to pain) [Pain]
so sometimes she cannot walk [Gait inability]

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

A 62-year-old female patient received etanercept (ENBREL), (Batch/Lot number: unknown) at 50 mg (50 mg, every 8 days (one dose)).

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

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? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)
#1) 50 mg, every 8 days (one dose)
#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? ☐ YES ☐ NO ☐ 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	Relevant Med History inherited	Arthritis (Arthritis)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Pfizer Inc
Head Drug Safety Surveillance
Pfizer, Inc. 66 Hudson Boulevard East
New York, New York 10001 UNITED STATES
Phone: 212 733 5544

26. REMARKS

24b. MFR CONTROL NO.
PV202500020524

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
07-JUL-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
21-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history included: "arthritis" (unspecified if ongoing), notes: inherited. The patient's concomitant medications were not reported. The following information was reported: DISEASE PROGRESSION (medically significant), outcome "not recovered", described as "she is more advanced, she is in a wheelchair"; PAIN (non-serious), outcome "unknown", described as "currently having a crisis (referring to pain)"; GAIT INABILITY (non-serious), outcome "unknown", described as "so sometimes she cannot walk". The action taken for etanercept was unknown.
No follow-up attempts are possible. Batch/lot number is not provided, and it cannot be obtained.

Additional information: Patient contacted to request the service of Healthrides and commented that she is in a wheelchair. On 07Jul2025, the patient's caregiver said: "We live in a red zone, sometimes Ubers do not go all the way there, we have to go out to a reference point (the school), and my sister is currently having a crisis (referring to pain), so sometimes she cannot walk. Right now, she is not walking, so it is hard for me to take her to the school. I also use Pfizer, because it is like we inherited it (arthritis). Sometimes she does badly and sometimes well." The caregiver assures that it is not the medication that makes them feel bad, but that the disease is like that, sometimes it causes pain suddenly. Family Medical History: The patient's caregiver says that they inherited arthritis.

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

Amendment: This follow-up report is being submitted to amend previously reported information: reference number updated.

Follow-up (13Mar2025): This is a spontaneous follow-up report received from a contactable consumer. Updated information included: reporter (additional consumer added), events (outcome updated).

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

Follow-up (07Jul2025): This is a spontaneous follow-up report received from a consumer.
Updated information included: dosing details, medical history, reaction data (events: pain and unable to walk), course details and event outcome.

Relevant med history, Dosage Regimens and new event (pain).
Additional information: