

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 76 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		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)
she felt very bad, with pain [Feeling bad]
she felt very bad, with pain [Pain]

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

A 76-year-old female patient received tofacitinib citrate (XELJANZ), at 5 mg 2x/day (5 mg, 2x/day(at morning and night)); methotrexate sodium (METHOTREXATE). The patient's relevant medical history was not reported. The patient took concomitant medications.

(Continued on Additional Information Page)

☐ 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) Xeljanz (TOFACITINIB CITRATE) Tablet #2) Methotrexate (METHOTREXATE SODIUM) 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) 5 mg, 2x/day(at morning and night) #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. PV202500098105	
24c. DATE RECEIVED BY MANUFACTURER 11-AUG-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 14-AUG-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.

14-Aug-2025 10:49

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

The following information was reported: FEELING ABNORMAL (non-serious), PAIN (non-serious), outcome "unknown" and all described as "she felt very bad, with pain". The action taken for tofacitinib citrate and methotrexate sodium was unknown.

Additional information: The patient indicated that: "They did a blood count, and she felt bad, she was here at the doctor, she felt very bad, with pain." It was confirmed that the patient had already started using the drug. She indicated that she consumed 4 medications, the names were unknown. She only mentioned the name of Methotrexate.