SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	DOMINICAN REPUBLIC		PRIVACY		39 Years	Male	Unk		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
colitis was activating/relapse/few relapses/ suffered from ulcerative colitis [Ulcerative colitis relapse]
fever [Fever]
bleeding [Bleeding]
there was a virus and it has already caught him/activated by parasites such as Entamoeba histolytica [Infection parasitic]

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

(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 {Lot # HR8191; Exp.Dt. SEP-2026}
(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)
#1) 5 mg, 2x/day

16. ROUTE(S) OF ADMINISTRATION
#1) Unknown

17. INDICATION(S) FOR USE
#1) rheumatoid arthritis (Rheumatoid arthritis)
(Continued on Additional Information Page)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)
#1) Ongoing

19. THERAPY DURATION
#1) 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	Inflammation (Inflammation)

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.
PV202500040097

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

24c. DATE RECEIVED BY MANUFACTURER
06-MAY-2025

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

DATE OF THIS REPORT
13-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

Mfr. Control Number: PV202500040097

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 39-year-old male patient received tofacitinib citrate (XELJANZ), (ongoing) (Lot number: HR8191, Expiration Date: Sep2026) at 5 mg 2x/day for rheumatoid arthritis, colitis ulcerative. The patient's relevant medical history included: "inflammatory disease" (unspecified if ongoing). The patient's concomitant medications were not reported.
The following information was reported: COLITIS ULCERATIVE (medically significant), outcome "unknown", described as "colitis was activating/relapse/few relapses/ suffered from ulcerative colitis"; PYREXIA (non-serious), outcome "unknown", described as "fever"; HAEMORRHAGE (non-serious), outcome "unknown", described as "bleeding"; INFECTION PARASITIC (non-serious), outcome "unknown", described as "there was a virus and it has already caught him/activated by parasites such as Entamoeba histolytica".
Patient indicated that he was half sick. He woke up with a fever and with bleeding it seems that colitis was activating. Besides, there was a virus and it has already caught him. As of 01May2025, patient informed that the recent relapse was not due to Xeljanz but rather to his inflammatory disease, which was activated by parasites such as Entamoeba histolytica. After that, the doctor prescribed medication that restored him, and he did not have to suspend or stop Xeljanz, which he was still taking to date and had just renewed for another 6 months to continue its use. Additionally, he mentioned that the bottle he was taking when the relapse occurred was not expired and had no issues. He was taking the medication normally and was stable to date. Patient stated the doctor had even recommended psychology because this disease requires all those things. The colon required tranquility, psychology, zero stress. But she recommended it, even though his colitis was more infectious than anything else, like due to infection and things like that, but they got activated. Because he had a few relapses. He suffered from ulcerative colitis, and that medication was used for two things, both for rheumatoid arthritis and ulcerative colitis. The action taken for tofacitinib citrate was dosage not changed.

The reporter considered "colitis was activating/relapse/few relapses/ suffered from ulcerative colitis" not related to tofacitinib citrate.

Follow-up (01May2025): This is a spontaneous follow-up report received from the same contactable consumer.
Updated information included: new event (relapse, unrelated), medical history (inflammatory disease), action taken (updated from unknown to dose not changed).

Follow-up (06May2025): This is a spontaneous follow-up report received from the same contactable consumer
Updated information: suspect drug indication, even term, and clinical course details.

Case Comment: The event "relapse" is likely due to the natural course of the underlying disease that is unrelated to tofacitinib.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Xeljanz (TOFACITINIB CITRATE) Tablet {Lot # HR8191; Exp.Dt. SEP-2026}; Regimen #1	5 mg, 2x/day; Unknown	rheumatoid arthritis (Rheumatoid arthritis) ulcerative colitis (Colitis ulcerative)	Ongoing; Unknown