SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. INITIALS	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6. REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
PRIVACY	PA				33 Year(s)	M	24	Mar	2025	☐ PATIENT DIED

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [Low Level Term]
During the infusion process, the patient presents facial redness and throat itching / During the allergic reaction process, hydrocortisone and chlorpheniramine were administered [Infusion related(Continue on page 2)

☐ LIFE THREATENING
☐ HOSPITALIZATION
☐ DISABILITY OR INCAPACITY
☐ CONGENITAL ANOMALY/BIRTH DEFECT
☐ OTHER MEDICALLY IMPORTANT CONDITION
☐ REQUIRED INTERVENTION (MEDICAL DEVICE)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1 [Suspect] Remsima (Infliximab)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1 300 milligram	#1 Intravenous (not otherwise specified)

17. INDICATION(S) FOR USE
#1 Crohn's disease [Crohn's disease] (10011401 v27.1)

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

18. THERAPY DATES (from/to)	19. THERAPY DURATION
#1 /29-Apr-2025	#1 37 Day(s)

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUGS(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

From / To Dates	Description
# 1	Crohn's disease[Crohn's disease] (10011401 v27.1) - continue : Yes

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
LABORATORIOS STEIN
Escazú, Meridiano Building, 5th floor
10203 San José CR

26. REMARKS

24b. MFR CONTROL NO.
2025000189

25b. NAME AND ADDRESS OF REPORTER
PRIVACY

24c. DATE RECEIVED BY MANUFACTURER
29-Apr-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
■ HEALTH PROFESSIONAL ■ OTHER

DATE OF THIS REPORT
14-May-2025

25a. REPORT TYPE
■ INITIAL ☐ FOLLOW UP :

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

During the infusion process, the patient presents facial redness and throat itching / During the allergic reaction process, hydrocortisone and chlorpheniramine were administered [Infusion related hypersensitivity reaction] (10082742 v28.0) - Not serious - Recovered - 24-Mar-2025/29-Apr-2025(37 Day)

Case description :
Case Description: This initial non-serious spontaneous report was received from a physician in Panama on 29 Apr 2025.
This case refers to a 33-year-old male patient who experienced event described as "During the infusion process, the patient presents facial

redness and throat itching / During the allergic reaction process, hydrocortisone and chlorpheniramine were administered" following therapy with Remsima (infliximab).
The patient received Remsima at 300 mg with unspecified frequency via intravenous route for Crohn's disease on 24 Mar 2025 and 29 Apr 2025. Batch/lot numbers were unknown.
Co-suspect drug was not reported.
On 24 Mar 2025, the patient experienced event described as "During the infusion process, the patient presents facial redness and throat itching / During the allergic reaction process, hydrocortisone and chlorpheniramine were administered". Corrective treatment in response to the event included hydrocortisone and chlorpheniramine. Action taken with Remsima was withdrawn. Dechallenge result was unknown. Outcome of the event was recovered/resolved on 29 Apr 2025 (duration: 37 days).
Relevant medical history included ongoing Crohn's disease (ongoing). Past and concomitant drugs were not reported.
The reporter assessed the event as non-serious, while causality with Remsima was related.
Case Comment: Case Comment: Causality of the event Infusion related hypersensitivity reaction (listed, non-serious) is related based on the established temporal relationship between the event and drug use, and known drug safety profile.

14-19. Drugs

#	Name	Dosage Information	Lot/Batch	Route of Admin.	Indication	Therapy dates	Therapy duration
1	[Suspect] Remsima (Infliximab)	300 milligram	UNK	Intravenous (not otherwise specified)	Crohn's disease [Crohn's disease] (10011401 v27.1)	/29-Apr-2025	37 Day(s)