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 | | | | 56 Year(s) | F | 23 | Apr | 2025 | ☐ PATIENT DIED |

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [Low Level Term]

itchy throat [Throat irritation] (10043521 v28.0) - Not serious - Unknown - 23-Apr-2025/UNK

burning sensation sensation in her mouth and lips [Oral discomfort] (10030973 v28.0) - Not serious - Unknown - 23-Apr-2025/UNK

cystitis [Cystitis] (10011781 v27.1) - Not serious - Unknown - 26-Apr-2025/UNK

Truxima, Solution for injection (Rituximab) [Incorrect product formulation administered] (10074946 v28.0) - Not serious - Unknown -

☐ 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] Truxima, Solution for injection (Rituximab)

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

| 15. DAILY DOSE(S) | 16. ROUTE(S) OF ADMINISTRATION |
|---|---|
| #1 500 milligram | #1 Intravesical |

17. INDICATION(S) FOR USE

#1 Drug use for unknown indication [Drug use for unknown indication] (10057097 v27.1)

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

| 18. THERAPY DATES (from/to) | 19. THERAPY DURATION |
|---|---|
| #1 23-Apr-2025 | #1 |

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 | |

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.
2025000199

25b. NAME AND ADDRESS OF REPORTER
PRIVACY

24c. DATE RECEIVED BY MANUFACTURER
30-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**

Case description : This initial non-serious spontaneous report was received from a consumer (patient) and non-health professional in Panama on 30 Apr 2025.

This case refers to a 56-year-old female patient who experienced events itchy throat, burning sensation in her mouth and lips, and cystitis following therapy with Truxima (Rituximab).
The patient received Truxima (Rituximab) at 500 milligram with unspecified frequency for unknown indication on 23 Apr 2025.
Batch/lot number was unknown.
The patient experienced events itchy throat and burning sensation in her mouth and lips (coded to Itchy throat, Oral discomfort) on 23 Apr 2025 and cystitis (coded to Cystitis) on 26 Apr 2025. Corrective treatment in response to Itchy throat and Oral discomfort were chlorotrimetron and corticosteroids while unknown for Cystitis. Action taken with Truxima was withdrawn (temporarily). Dechallenge result and outcome of events were unknown.
Relevant medical history and concomitant medication were not reported.
Past drug included Methotrexate at unknown dose via unknown route on unknown therapy start date until 2024 (withdrawn) (reaction: Cystitis).
Additionally, event Inappropriate formulation of drug administered was captured considering Truxima, Solution for injection (Rituximab) was used which is not an established formulation per RSI. The reporter did not describe this event.
The reporter assessed the events as non-serious, whereas causality with Truxima was related.

Case Comment: Case comment: Causality of Oral discomfort (unlisted, non-serious), Throat irritation, Cystitis (both listed, non-serious) is related based on the established temporal relationship between events' occurrence and drug use. Causality of event Incorrect product formulation administered (unlisted, non-serious) is not applicable and dependent on the HCP's prescribing practice.
Duplicate numbers : 2025PA013564 (Celltrion).

**14-19. Drugs**

| # | Name | Dosage Information | Lot/Batch | Route of Admin. | Indication | Therapy dates | Therapy duration |
|---|---|---|---|---|---|---|---|
| 1 | [Suspect] Truxima Solution for injection (Rituximab) | 500 milligram | UNK | Intravesical | Drug use for unknown indication [Drug use for unknown indication] (10057097 v27.1) | 23-Apr-2025 | |

**23. OTHER RELEVANT HISTORY continued**

**Past Drug Therapy**

# 1 methotrexate

Indication : Drug use for unknown indication

Reaction : Cystitis

**23. OTHER RELEVANT HISTORY continued**

Methotrexate (METHOTREXATE); Drug Indication: Drug use for unknown indication (Product used for unknown indication), Drug Reaction: Cystitis (Cystitis)