

EROSIVE BALANITIS AS A POSSIBLE ADVERSE EFFECT TO TREATMENT WITH TOFACITINIB. A CASE REPORT.

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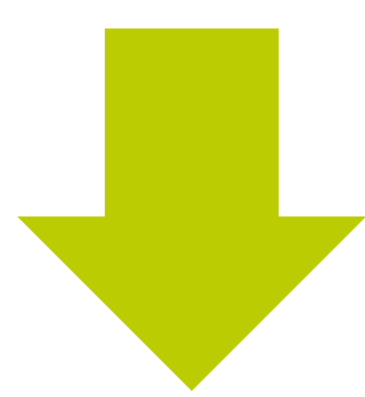
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BACKGROUND AND IMPORTANCE

Tofacitinib → selective **inhibitor** of the **janus kinase** family indicated for the treatment of various **rheumatological pathologies**.

According to technical data sheet (TDS), most frequently reported **adverse effects (AE)** during the first three months of clinical studies were headache, upper respiratory tract infections and viral respiratory tract infections upper.



Pharmacovigilance collects information, and analyses and notifies case of suspected adverse drug reactions to prevent them occurring in the future.

AIM AND OBJECTIVES

Describe the causal relationship in a patient who suffers from erosive balanitis after administration of tofacitinib, besides the multidisciplinary intervention in its management.

MATERIAL AND METHODS

- Retrospective and multidisciplinary study
- Describes case of a **66-year-old patient** with rheumatoid arthritis → after numerous failures with disease-modifying drugs, began treatment with tofacitinib.
- Safety profile of tofacitinib was reviewed in its TDS and the **Naranjo Algorithm** was applied to establish drug-adverse reaction causal relationship.

RESULTS

PATIENT

In January 2022, the patient was referred from primary care to the dermatology clinic due to **erythema in glans area** that had been developing for a month, reporting that he had an outbreak with the same characteristic's previous year.

RHEUMATOLOGY TEAM

The **precautionary suspension** of tofacitinib was agreed upon with rheumatology team. Specialists contact the Hospital Pharmacy Service to confirm whether it is an **AE secondary** to tofacitinib.

PHARMACIST

The pharmacist performs a review of TDS and literature confirming that there is no evidence of **erosive balanitis** as an AE of tofacinib. The suspected AE was reported to the Spanish Pharmacovigilance System and a causal relationship was established between the drug and the AE according to the **Naranjo Algorithm**, obtaining a score of 1 that establishes a possible relationship between the drug of interest and the AE. After topical cures for two months, treatment with tofacitinib **was restarted** in May 2022 without reporting **new incidents**.

CONCLUSION AND RELEVANCE

Multidisciplinary participation in the detection, notification and actions, to establish the causal relationship of AE associated with drugs, contributes to improving patient safety.

