



SFDA SAFETY SIGNAL

“A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature”

19-10-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Apremilast and the Risk of Mycobacterium Tuberculosis complex test positive

*The Saudi Food and Drug Authority (SFDA) recommends that all healthcare professionals be aware of the safety signal of **Mycobacterium Tuberculosis complex test positive** associated with the use of **Apremilast**. The signal originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Apremilast is a phosphodiesterase 4 (PDE4) inhibitor. It is indicated for adults with active psoriatic arthritis, plaque psoriasis (candidates for phototherapy or systemic therapy), and oral ulcers associated with Behçet's disease. It is also indicated for pediatric patients aged 6 and older with active psoriatic arthritis or moderate to severe plaque psoriasis.^[1] Mycobacterium tuberculosis is responsible for over a million deaths annually and millions of new tuberculosis diagnoses worldwide. Transmitted from person to person through respiratory droplets, Mycobacterium tuberculosis can develop resistance to some or all currently available antibiotics if antimycobacterial treatment is not initiated promptly.^[2] This review aims to evaluate this potential risk and to suggest regulatory recommendations if required.

Methodology

The Signal Detection Team at SFDA performed a signal review using the National Pharmacovigilance Center (NPC) database and the World Health Organization (WHO) database, Vigibase, along with a literature review to retrieve all relevant information and assess the potential link between mycobacterium tuberculosis complex test positive and Apremilast use.

Results

Cases Review: The Signal Detection Team at SFDA searched the Saudi national database and the WHO database to identify individual case safety reports (ICSRs). The WHO database yielded 46 global case reports, while the NPC database yielded no local cases. The authors used the signal detection tool (VigiLyze) to retrieve global cases.^[3] The authors applied the WHO causality assessment tool to all cases. All cases were unassessable due to lack of important information.

Datamining: The disproportionality between the observed and expected reporting rates for a drug/adverse drug reaction (ADR) pair is estimated using the Information Component (IC), a tool developed by WHO-UMC to measure the reporting ratio. A positive IC reflects a higher statistical association, while negative values indicate a lower statistical association. The IC result for this drug/ADR combination was 2.7, reflecting a positive statistical association.^[3]

Literature: The Signal Detection team reviewed regulatory sources and published literature to identify evidence linking apremilast to the risk of mycobacterium tuberculosis complex test positive. The signal team also conducted a literature search to identify publications linking Mycobacterium tuberculosis complex test positive with apremilast. The search identified two publications suggesting a possible association, including an FAERS-based study and a case report of tuberculosis reactivation following apremilast initiation.^[4,5]

Conclusion

The cumulative weight of evidence identified from global cases, literature and disproportionality analysis suggests a potential causal association between Apremilast and mycobacterium tuberculosis complex test positive. Healthcare professionals and health regulators should be aware of this potential risk in patients receiving apremilast.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (ADRs) resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 northern ring branch rd
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia
Toll free number: 19999
Email: NPC.Drug@sFDA.gov.sa

References

- 1- DailyMed - Otezla- apremilast tablet, film coated Otezla- Apremilast Kit (no date) U.S. National Library of Medicine. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f6b1f516-4972-4d82-bced-113e47b41cc5>
- 2- Testcatalog.org. (2022). Mycobacterium tuberculosis complex, molecular detection, PCR, paraffin, tissue - Mayo Clinic Laboratories | pediatric catalog. [online] Available at: <https://pediatric.testcatalog.org/show/MTBT>
- 3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/>
- 4- Gan, K., Liu, J., Shen, J., Lu, L., Xu, R., Xu, Z., Chen, J. and Lu, Y. (2026). Adverse Event Profile of Apremilast: Pharmacovigilance Study Based on FDA Adverse Event Reporting System (FAERS). Experimental Dermatology, 35(7). doi:[10.1111/exd.70303](https://doi.org/10.1111/exd.70303)
- 5- Adams, L., Smith, E.L., Tilakaratne, D. and Krause, V. (2024). Tuberculosis reactivation following apremilast therapy for psoriasis: Time to consider routine TB screening? Australasian Journal of Dermatology, 65(8). doi:[10.1111/ajd.14364](https://doi.org/10.1111/ajd.14364)