

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”

17-06-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Apremilast and the Risk of Diverticulitis

The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Diverticulitis** associated with the use of **Apremilast**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.

Introduction

Apremilast is an oral small molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP). PDE4 inhibition results in increased intracellular cAMP levels.^[1] Diverticulitis of the colon, i.e. inflammation of one or more diverticula, is the most common manifestation of diverticulosis, which affects more than 60% of people over the age of 70 in developed countries. Acute diverticulitis includes a range of degrees of inflammatory involvement, from mild diverticulitis to stercoral erythematosis.^[2] The aim of this review is to evaluate the risk of Diverticulitis associated with the use of Apremilast and to suggest regulatory recommendations if required.

Methodology

Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, Vigibase, with literature screening to retrieve all related information to assess the potential link between Diverticulitis and Apremilast use.

Results

Case Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). The WHO database resulted in 156 global case reports while no local cases found. The authors used signal detection tool (Vigilyze) to retrieve global cases.^[3] The author applied Who Causality assessment tool on the 14 extracted cases with completeness score (>0.8).^[3] Among them, two cases were probably linked to Apremilast and one case resulted in possible association, while the remaining eleven cases lacked sufficient information for a proper assessment.

Datamining: The disproportionality of the observed and the expected reporting rate for drug/adverse drug reaction pair is estimated using information component (IC), a tool developed by WHO-UMC to measure the reporting ratio. Positive IC reflects higher statistical association while negative values indicates less statistical association. The IC result is (1.0) for this drug/ADR combination which reflects positive statistical association.^[3]



Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Apremilast. The search identified two published studies suggesting a possible association between the drug and this potential risk. ^{[4][5]}

Conclusion

The weighted cumulative evidence identified from assessed cases, disproportionality analysis and literature are suggestive for causal association between Apremilast and Diverticulitis. Health care professionals and health regulators must be aware of the potential risk in drug recipients.

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

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