



## 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.<sup>[1]</sup> 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.<sup>[2]</sup> 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.<sup>[3]</sup> The author applied Who Causality assessment tool on the 14 extracted cases with completeness score (>0.8).<sup>[3]</sup> 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.<sup>[3]</sup>



**Literature:** The signal team conducted a literature search to identify publications linking this adverse drug reaction to Baricitinib. The search identified two published studies suggesting a possible association between the drug and this potential risk. <sup>[4][5]</sup>

### **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](mailto:NPC.Drug@sFDA.gov.sa)

### **References**

- 1- Nih.gov. (2026). Welcome To Zscaler Directory Authentication. [online] Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f6b1f516-4972-4d82-bced-113e47b41cc5>
- 2- Hoch J. Diverticulitis of the colon. *Rozhl Chir.* 2025;104(2):47-54. English. doi: 10.48095/ccrvch202547. PMID: 40117272.
- 3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/>
- 4- Kang Q, Chen J and Yang H (2022) Efficacy and safety profile of phosphodiesterase 4 inhibitor in the treatment of psoriasis: A systematic review and meta-analysis of randomized controlled trials. *Front. Immunol.* 13:1021537. doi: 10.3389/fimmu.2022.1021537.
- 5- Afra, T. P.; Razmi, T Muhammed; Dogra, Sunil,. Apremilast in Psoriasis and Beyond: Big Hopes on a Small Molecule. *Indian Dermatology Online Journal* 10(1):p 1-12, Jan–Feb 2019. | DOI: 10.4103/idoj.IDOJ\_437\_18