

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”

25-3-2020

Saudi Food and Drug Authority (SFDA) – Safety Signal of Baricitinib and the Potential 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 **Baricitinib**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.

Introduction: Baricitinib is antirheumatic drug that belongs to disease-modifying antirheumatic drugs (DMARD) ^[1]. Diverticular disease (diverticulosis, diverticulitis) is a broad term that refer to the presence of diverticula. It is a small pouches in the large intestinal (colonic) wall ^[2]. A signal of Baricitinib and diverticulitis was retrieved from Pharmacovigilance Risk Assessment Committee (PRAC) new signals ^[3]. Saudi Food and Drug authority (SFDA) has conducted this safety review based on that. The purpose of this review is to evaluate the risk of diverticulitis in association with Baricitinib use.

Methodology Signal Detection team at SFDA have retrospectively searched World Health Organization (WHO) database (Vigibase) and the National Pharmacovigilance Center (NPC) database to retrieve all reported cases of Baricitinib and diverticulitis. ^[4] We used the WHO- Uppsala Monitoring Centre (UMC) criteria as standard for assessing the causality of the reported cases.

Results

Case Review: Local Cases: The search in the National Pharmacovigilance Center (NPC) database resulted in zero cases. Global Cases: On March 25th, 2020, a search in the World Health Organization (WHO) database (Vigibase) was conducted to retrieve all reported cases between 2017 and 2020 via signal detection tool (Vigilyze).The search resulted in 23 Individualized Case Safety Reports (ICSRs).One report was excluded due to duplication. The author applied WHO causality assessment on the exported reports, resulted in one case with probable association, nine cases with possible association. Twelve cases were unassessable due to lack of information.

Data Mining: Information Component (IC) value was measured using the method for disproportionality analysis developed by Uppsala Monitoring Center (UMC). A Positive cumulative value (IC = 2.4) for spontaneous reporting suggests that the reported cases of Baricitinib and diverticulitis have been observed more than expected when compared to other medications in the WHO database.

Conclusion

The causality assessments of the reported cases showed a possible association. Moreover, the data mining showed a positive IC value (2.4), that provide a potential statistical association between drug and event. This safety review suggest that the current available evidence point to a possible association between Baricitinib and diverticulitis. Health regulators and health care professionals should be aware for the potential risk of diverticulitis associated with Baricitinib use.

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@sfd.gov.sa

References:

- 1- Dailymed.nlm.nih.gov. 2020. Dailymed - OLUMIANT- Baricitinib Tablet, Film Coated. [online] Available at: <<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=866e9f35-9035-4581-a4b1-75a621ab55cf>> [Accessed 16 November 2020].
- 2- Emedicine.medscape.com. 2020. Diverticulitis: Practice Essentials, Background, Pathophysiology. [online] Available at: <<https://emedicine.medscape.com/article/173388-overview#a2>> [Accessed 29 March 2020].
- 3- Ema.europa.eu. 2020. [online] Available at: <https://www.ema.europa.eu/en/documents/agenda/agenda-prac-draft-agenda-meeting-13-16-january-2020_en.pdf> [Accessed 29 March 2020].
- 4- Uppsala Monitoring Center (UMC) (2020), Vigilyze database; Available at: <https://vigilyze.who-umc.org/#> [Accessed 25/3/2020]